



X-eHealth

Exchanging Electronic Health Records
in a common framework

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WP5 - Definition of EEHRxF Functional Specifications

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Terms and Abbreviations

Term	Description
Laboratory medicine	A clinical science and discipline, devoted to the quantitative measurement, or qualitative assessment, of any substance which can be assayed in any type of biological fluid of any animal species, thus including humans, for either medical or research purposes. The results of these measurements are translated into actionable information for improving the care and/or maintaining the wellness of both a single individual and an entire population. Source: Lippi, G., & Plebani, M. (2020). CCLM, 58(8), 1171-1171.
Medical laboratory, clinical laboratory	Laboratory for the biological, microbiological, immunological, chemical, immunohaematological, haematological, biophysical, cytological, pathological, genetic or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation. Note 1 to entry: These examinations also include procedures for determining, measuring or otherwise describing the presence or absence of various substances or microorganisms. Source: ISO 15189:2012.
Laboratory request	A request or order for a laboratory service, an intent directed from a requesting entity (request author) to a laboratory (service performer).
Laboratory result, measurement result	The final value reported for a measured or computed quantity, after performing a measuring procedure including all sub procedures and evaluations. Source: PAC, 1994, 66, 595.
Laboratory result report	A combination of specimen information and results. The report should contain information about unequivocal identification of the source and type of material analysed and the requesting agency. It may contain such other information that is pertinent to the correct interpretation of a result (e.g., confidence interval, reference data and interpretative information). Source: PAC, 1989, 61, 1657.
Laboratory summary	A summary created from one or more laboratory reports. The summary could include the most recent results and/or historical results for every type of observation.
Observation method, examination technique	Technique used to administer a particular examination or assessment. Source: NCI Thesaurus. It means an adoption of a scientific technique for performing a specific measurement as documented in a laboratory standard operating procedure or as published by a recognised authority.
Specimen	Discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole. Source: ISO 15189:2012. Note: for the purposes of this document, also non-biological specimens, e.g., environment specimens, are included.
Laboratory order	A single order from a Provider for one or more laboratory tests for a single patient that meets the then current transaction specifications and is successfully transmitted to a laboratory
Test profile	Lab profiles are groups of tests that are targeted at a certain organ or disease process. A profile can assess and diagnose a condition.

Term	Description
Study type	Group of tests comprising tests that are usually produced from a certain system (specimen) or by a certain laboratory specialty. Proposed EU standard for study types is provided in this document.

Acronym	Description
API	Application Programming Interface
CEF	Connecting Europe Facility
CIS	Clinical Information System
CPOE	Computerized Provider Order Entry system
EHDS	European Health Data Space
eHDSI	eHealth Digital Service Infrastructure
eHN	eHealth Network
EEHRxF	European Electronic eHealth Record exchange format
EMR	Electronic Medical Record
EQALM	European Organization for External Quality Assurance Providers in Laboratory Medicine
EU	European Union
EU DCC	EU Digital Covid Certificate
FSN	Fully Specified Name
HIS	Hospital Information System
HL7 CDA	Health Level 7 Clinical Document Architecture
ICT	information and communications technology infrastructure
IVDR	In vitro device Regulation
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
IUPAC	International Union of Pure and Applied Chemistry
LAS	Laboratory Automation System
LIS	Laboratory Information System
LIMS	Laboratory Information Management System
LOINC	Logical Observation Identifiers Names and Codes
MS	Member State
MVC	Master Value Catalogue
NPU	Nomenclature for Properties and Units
SI Unit	International Standard of Units
SNOMED CT	Systematized Nomenclature of Medicine – Clinical Terms
SNOMED CT GPS	SNOMED CT Free Global Patient Set
UCUM	The Unified Code for Units of Measure
UDI	Unique Device Identifier
UI	User Interface

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Executive Summary

The document provides a functional specification for cross-border and cross-enterprise exchange of laboratory test results. While mainly focused on semantic interoperability, the document also elaborates some general legal, regulatory and organisational aspects that are important for sharing documents and data within the laboratory domain. The scope of the document is focused on laboratory test results and laboratory test requests as the most common laboratory use cases. LOINC, NPU and SNOMED-CT are identified as baseline standards. A brief comparative analysis of the standards is provided as well as some examples of mapping. Illustrative data models and process diagrams are presented. The document provides a broad overview of the laboratory domain and guidelines for further development of functional building blocks and semantic elements.

Scope and Interdependencies

In scope

Laboratory (requests and) results within the core fields of in vitro diagnostics, for example clinical biochemistry, haematology, immunohematology, microbiology, immunology.

Out of scope

Specialised laboratory domains requiring specialised reporting structure: histopathology and medical genetics.

Interdependencies

This document will be the main input for the WP6 Task 6.1 - Definition of technical specification for the Laboratory Domain but it will be also used by task T5.5 - Hospital Discharge Report and T5.6 – Patient summary. Functional specifications for the laboratory domain are not directly dependent on any other project task, however it considers results of the surveys performed by WP1 about the current status of the laboratory domain in the participating EU member states.

1 Introduction

1.1 Description of the domain

Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. Sharing of laboratory results in cross-border health information exchange is an expected and wanted further extension within the CEF eHDSI.

Furthermore, exchange of laboratory test orders and result reports will support free movement of the services as one of the key principles of the EU (Commission Recommendation of 6.2.2019 on a European Electronic Health Record exchange format - EEHRxF). It can also prevent unnecessary repetition of laboratory testing, thus reducing costs for patients and healthcare systems.

It is important that laboratories produce high quality test results as they often are the basis for clinical decision making. Proper quality management is therefore essential.

It is also important that laboratory requests include all necessary information about specimen to enable laboratory to properly respond to the lab order, thus laboratory requests should always include sufficient medical background information of the subject.

Laboratory area is one of the most standardised areas of the medical industry, thanks to the extended use of automation (produced by global companies), as well as to a long tradition in the organisation of external quality control programs. Medical laboratories have internal quality control procedures and participate in national and/or international external quality assessment (EQA) programs. The European Organization for External Quality Assurance Providers in Laboratory Medicine (EQALM¹) was founded in 1996 and currently has members from 29 European countries and 6 countries from outside the EU. (Network, 2019)

1.2 Challenges and opportunities

According to a survey performed in 2019 during preparation of a Common Semantic Strategy paper (Network, 2019), two main international laboratory terminology systems for test coding are being used: Logical Observation Identifiers Names and Codes (LOINC²) and Nomenclature for Properties and Units (NPU³).

It should be noted that additional code systems are needed for coding of specimen types, anatomic specification, specimen collection, processing and examination techniques, devices, containers, measurement units, and ordinal or nominal-scale test results.

Complementary to the coding of laboratory tests, test results are to be documented in a standardised and coded way too. Regularly, test qualitative results are expressed via SNOMED CT concepts, quantitatively measured results are documented by standardised units, which are expressed preferably via UCUM to allow computer processing. As SNOMED CT is the most extensive terminology in health care, this code system offers solutions for the coded representation of laboratory-related facts in most cases.

¹ <http://www.eqalm.org/>

² <https://loinc.org/>

³ <https://www.npu-terminology.org/>

Terminology-wise, requests are not as well standardised as reports, where requests more often reflect local ordering practices where national standardisation is lacking. Some laboratories use standard terminologies like LOINC and NPU also for ordering while others do not.

Exchange of laboratory orders and results is currently not a supported use case by the eHDSI infrastructure. EU countries with well-established electronic laboratory communication will not change their existing laboratory coding systems, e.g., NPU and LOINC, thus transcoding to the selected pivot terminology or acceptance of two different code systems represents one of the main challenges on the way to the semantic interoperability of the order/result cross-border communication.

Still, while laboratory medicine is highly standardised, comparison of results between different laboratories is a major challenge due to differences in examination techniques, instruments, and lack of international calibrators. Also, the maintenance of coding standards is demanding because new tests are constantly emerging due to dynamical scientific and technological developments.

1.3 Ambition

To develop a common functional specification comprising of business needs, legal and regulatory concerns, technical and application requirements, and logical information models for the entire laboratory domain as well as specific models for selected use cases and propose preferred semantic artefacts in the domain of laboratory orders and result reports.

The aim of the project is to define standards to enable standardised cross-border exchange of laboratory requests and laboratory test results and their transmission in cross-border context.

2 Objectives and principles

Objectives:

- Provide a generic functional specification for laboratory domain, applicable for the most common cross-enterprise and cross-border scenarios
- Provide basic information on legal, policy, technical, operational and infrastructure aspects
- Provide an overview of semantic standards and recommended baseline standards for cross-border interoperability in laboratory domain
- Provide data models and proposed coding standards for laboratory test results and laboratory test orders
- Provide basic examples of mapping between LOINC and NPU
- Provide guidance for application of standards
- Identify areas to be addressed in further projects

Basic principles:

- Re-use of existing specifications and build upon existing standards
- Include specifications for all major types of laboratory services
- Make specifications technology agnostic
- Develop functional specifications not only suitable for cross-border exchange but applicable to national and local use
- Establish a solid ground for state-of-the-art and safe exchange of laboratory related data

3 Laboratory use cases

3.1 Business needs

Laboratory is an essential domain for diagnostics and clinical decision making. Laboratory services are highly demanded by a variety of practice settings and medical specialties. Not all healthcare providers have their internal laboratory resources, and some tests can only be provided by specialised laboratories. Access to diverse external laboratory resources is thus essential for care providers, and this access must be digitalised by means of internationally standardised ordering procedure. Also, care providers must be able to interpret results provided by any qualified laboratory. To assure flawless interpretation, laboratory results should be recorded in a universal manner by means of standard coding systems and data models for examination techniques, specimens, and results. Exchange of laboratory results across departments and organisations will minimise need to repetition of tests and lessen burden on the patient.

Apart from supporting care scenarios, there is an increasing need to enable secondary use of health data. Establishing of European Health Data Space (EHDS) is one of the top priorities of European Commission 2019-2025. Structured and standardised laboratory results are valuable for clinical research, improving quality of health services policy making etc. (European data space, nedatováno).

3.2 Scope

Laboratory use cases cover all types of in-vitro diagnostics performed by clinical laboratories on:

- Human specimens (from human subject)
- Non-human specimens such as non-human material or non-human living subject
- Non-human specimens paired with a human subject

With the exclusions specified for this project, i.e., histopathology, and medical genetics. Tests performed (analysed) by patients themselves are not covered by this document.

3.3 Laboratory use cases for cross-border data exchange

High level use cases identified for cross-border European Electronic Health Record Exchange Format (EEHRxF) are summarised in the Table 1. Use cases were classified from the project scope point of view and working priority was assigned.

Several use cases could be performed on different scale levels: from cross-border, national/regional, to within an organisational or patient level. For the X-eHealth project we will focus on cross-border exchange, but we do acknowledge that the other levels may apply. Please find below the description of each level:

- Cross-border: exchange of laboratory orders and reports between different countries
- National/regional: the use case is applicable nationally or at least in one or more regions.
- Within the healthcare organisation: exchange of orders and reports in one organisation, from department X to department Y.

- Citizens at home and on the move: indicate that use case involves patients both at home and on the move

The detailed use cases and corresponding functional requirements can be found in Chapter 5.

Table 1: List of laboratory use cases for cross-border EEHRxF

Use case number	Use case name	Comments	Project scope
UC5.3.1	Laboratory results report	<p>Laboratory results could be:</p> <ul style="list-style-type: none"> reported to the ordering entity and/or reported to another entity (e.g., in case of referral) reported to patient <p>report should contain machine and human readable content</p>	In-scope Priority 1
UC5.3.2	Laboratory test order from healthcare provider	<p>order could be directed (into a particular lab) or undirected (e.g., patient will select the lab).</p> <p>order could have a list of individual tests and/or test batteries</p> <p>sample collection could be provided by ordering healthcare provider entity (in such case the order is directed), such as by hospital, GP or at-home nurse or by laboratory or a central sample collection unit. In some cases, sample collection could be performed by the patient itself, e.g., urine.</p> <p>national regulation might pose additional constraints on the test that can be ordered (e.g., only for a specific diagnosis or specialty of the ordering physician)</p> <p>Ordering entity might change a report destination (in case of patient referral to another HCP)</p> <p>A copy of the result report to another healthcare professional might be required as part of the order</p> <p>Standard sets (batches) of tests may be predefined to facilitate most frequent test orders, e.g., hemogram</p>	In-scope Priority 1
UC5.3.3	Querying of lab results	<p>Query the lab or EHR system for a laboratory summary and/or result report or for extract of the lab result data based on combination of query parameters.</p>	In-scope Priority 2

Use case number	Use case name	Comments	Project scope
UC5.3.4	Querying of lab orders	Query the lab or EHR system for orders based on combination of query parameters.	In-scope Priority 2
UC5.3.5	Querying for lab services	Query for set of tests or individual test service that could be performed by laboratory. Assuming that laboratories use matching coding standards and maintain an accurate list of available tests.	In-scope Priority 3
UC5.3.6	Laboratory test order from a patient	test order is created by a patient in this case reimbursement of the test might be required prior the lab testing national legislation might limit a range of tests that might be ordered by patient, especially in case of public laboratories	In-scope Priority 3
UC5.3.7	Laboratory test sub-order to another laboratory	Laboratory that received a test order could create a sub-order to another lab for several reasons: lab is not capable to perform a test or have a sub-contracted lab a test result needs to be confirmed by another lab, e.g., referential lab. Sub-orders are always directed in this case.	In-scope Priority 3
UC5.3.8	Laboratory reimbursement	Reimbursement for laboratory services.	Out-of-scope
UC5.3.9	Patient tracking	Ordering entity informs laboratory of change of the result report recipient, such as in case of patient transfer/referred to a different workplace or a different healthcare provider.	Out-of-scope
UC5.3.10	Report to the public health authority for communicable diseases surveillance	Some of the results are sent to the national public health agency for national surveillance of communicable diseases.	Out-of-scope
UC5.3.11	Reporting results for secondary use of data	Laboratory test results could be reported to the healthcare quality registries for selected types of treatments or health problems, e.g., National oncology register, National diabetology register. In general, this use case covers all types of data collection for secondary use, i.e., research, statistics, big data etc.	Out -of-scope

The priority levels are defined as follows:

Priority 1 – X-eHealth partners value the use case as most significant to be implemented within the domain.

Priority 2 – X-eHealth partners value the use case as medium priority to be implemented within the domain. These use cases will be described only if time of this project allows.

Priority 3 – X-eHealth partners value the use case as least urgent to be implemented within the domain. These use cases will be described only if time of this project allows.

Out-of-Scope: indicated as not relevant at this moment within the goals of X-eHealth laboratory domain.

3.3.1 Common Actors

Actors described in this chapter represent an abstraction of users or information systems involved in different laboratory workflows. Use case participants perform their roles in different workflows using the following actors, inspired by documentation of relevant IHE profiles (XDS, XD-LAB).

Order Placer: The Order Placer is the application implemented by the systems used by the clinical practice or a patient to prepare and send the orders to the Laboratory.

Order Filler: The Order Filler is the Laboratory application responsible for splitting any order or order group received from the Order Placer into the appropriate set of work orders for the laboratory work area and sending them to the Automation Manager, and when receiving the test results, it is responsible for consolidating them into the appropriate order or order group, and for sending these results to the Order Result Tracker on the clinical side.

Automation Manager: The Automation Manager is implemented by systems operated by the laboratory and responsible of performing the test analysis of the specimens and generating the test results. The Automation Manager manages the automation in the laboratory or a part of it. Automation involves the integration or interfacing of automated or robotic transport systems, analytical instruments, and pre- or post-analytical process equipment such as automated centrifuges and aliquoters, decappers, recappers, sorters, and specimen storage and retrieval systems. Receives work orders from the Order Filler. It manages the processing of the ordered tests on the appropriate devices and sends technically validated results back to the Order Filler.

Order Result Tracker: The system that stores observations of test results obtained for the patients, registers all state changes in the results notified by Order Fillers. This actor doesn't store standalone observations but ordered observations. The observations are always stored within the context of the order that generated them, with all the information related to that order. The Order Result Tracker is the application implemented by the systems used by the clinical practice to consume the results report received from Laboratory. It could be also a central/regional or local result repository (EHR) system for later retrieval by the ordering entity or by any other entity involved in the healthcare episode of a patient.

The results can also be received and seen by the patient.

Document source: The Document Source is the producer and publisher of documents. It is responsible for sending documents to a Document Repository Actor. It also supplies metadata to the Document Repository for subsequent registration of the documents with the Document Registry Actor.

Document consumer: The Document Consumer queries a Document Registry for documents meeting certain criteria and retrieves selected documents from one or more Document Repository Actors.

Document registry: The Document Registry maintains metadata about each registered document in a document entry. This includes a link to the Document in the Repository where it is stored. The Document Registry responds to queries from Document Consumer Actors about documents meeting specific criteria. It also enforces some healthcare specific technical policies at the time of document registration.

Document repository: The Document Repository is responsible for both the persistent storage of these documents as well as for their registration with the appropriate Document Registry. It assigns a unique Id to documents for subsequent retrieval by a Document Consumer.

4 Methodology

The guidelines have been developed in line with the process agreed by the X-eHealth project coordination.

To ensure monitoring and evaluation of cross-border services and related interoperability provisions and systems, Member States should consider setting up a facility as well as relevant policy, legal, organisational, and technical mechanisms to enable progress on organisational, technical and semantic aspects for their successful implementation.

4.1 Analysis of existing materials

4.1.1 National Implementation Guides for electronic health records, laboratory orders and result reports

This document considers results of previous international projects as well as various national implementation guides related to laboratory result reports and orders. These sources served as a resource of inspiration for the work on these functional specifications, namely Trillium II - Deliverable 3.3: Laboratory results library data sets, information structures, value sets and tools, the laboratory result report guidelines from Austria⁴, Czech Republic⁵, France⁶, Germany⁷, Italy⁸, Sweden as well as different laboratory test result report examples from Czech Republic, France, Spain, and Austria.

Also, existing laboratory order specifications and implementation guides were consulted, e.g., Switzerland⁹.

4.1.2 Existing standards and standardisation initiatives for electronic health resources and laboratory result reports

Additionally, different standards and healthcare standardisation initiatives were used to support the logical modelling and value set definitions of the EU laboratory test result report, namely: IHE XD-LAB Profile¹⁰, HL7 FHIR¹¹, Health and Care Information Models (HCIM)¹².

⁴ https://wiki.hl7.at/index.php?title=ILF:Labor-_und_Mikrobiologiebefund_Guide

⁵ <https://www.dastacr.cz/>

⁶ https://esante.gouv.fr/sites/default/files/media_entity/documents/ci-sis_contenus_cr-biologie_v2.0_20180928.pdf

⁷ https://www.medizininformatik-initiative.de/Kerndatensatz/Modul_Laborbefund/DiagnosticReport.html

⁸ http://www.hl7italia.it/hl7italia_D7/Implementation%20Guide%20CDA%202%20-%20Referto%20di%20Medicina%20di%20Laboratorio

⁹ <https://fhir.ch/>

¹⁰ https://wiki.ihe.net/index.php/Sharing_Laboratory_Reports

¹¹ <http://hl7.org/fhir/>

¹² https://zibs.nl/wiki/HCIM_Mainpage

5 Functional specifications

5.1 Common aspects of laboratory use cases

5.1.1 Legal and regulatory

5.1.1.1 Legal and regulatory pre-conditions

Being an essential domain for diagnostics, laboratory medicine must comply to highest standards of quality and accuracy. The standards are enforced by means of regulative framework and clinical laboratories are obliged to follow certain rules and conditions.

Laboratory products fall in within the scope of in vitro diagnostic medical devices and are subject of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, 2017). The Regulation is in force from 26 May 2020. The harmonisation of national regulations with IVDR is the responsibility of member states.

The upcoming Regulation on the European Health Data Space (EHDS regulation) aims to foster interoperability through harmonisation rules concerning EHR systems, such as obligation to follow standards and common specifications. The EHDS Regulation introduces, inter alia, conformance assessment of EHR systems (certification) and obligation to provide secure access to EHR for patients and healthcare professionals.

National healthcare systems may apply different conditions, depending on their healthcare organisation and payment models. The following aspect are typically subject of national regulation:

Laboratories as healthcare providers: Laboratories may be considered as healthcare providers and subject of common regulations, such as obligation to register in national registry of healthcare providers and engage licensed healthcare professionals.

Accreditation, licensing, and auditing: Laboratories are only allowed to operate with a valid license or certificate. Appointed national authorities grant licenses upon an exhaustive auditing procedure. The laboratory licenses are typically of limited duration (e.g., 5 years) and need to be renewed periodically. Country specific regulations should apply in order to achieve mutual trust of the quality of lab services.

Payments: Laboratory Services may be paid directly by insurance or out-of-pocket, or indirectly. In case of indirect payments, the price of laboratory test is embedded in the healthcare services and reimbursed to the ordering healthcare provider.

Ordering of laboratory services may be subject of public procurement

Patient's direct access to laboratories: Patients may order laboratory services directly (as self-payers)

Laboratory market: Public and private laboratories may coexist, and distinct regulations may apply according to their legal status

Obligation of laboratories to report to public health authorities: Results of specific tests may need to be reported to public health authorities, e.g., for surveillance of communicable diseases

Regulations may define minimal dataset for laboratory results

Regulations may define communication procedures regarding workflow (e.g., admission, intermediate results, final results)

Market regulation may apply to laboratory services: Authorised bodies may be appointed to regulate specific segments of laboratory market, e.g., approval of tests for hospital use, certification of laboratory products).

External quality control schemes may be required by law and enforced by authorized accreditation entities. Field specific schemes may apply, e.g., microbiology diagnostics of specific diseases

5.1.1.2 Definition of sampling area

Any physical space where health professionals perform specific tasks of obtaining, receiving, and identifying human biological samples, to be processed by the laboratory.

Patient rooms, emergency rooms, operating rooms and consultations are also considered to be sampling areas (near-patient tests/point of care tests).

5.1.1.3 Professional staff requirements

Sampling area must be under the responsibility of a university graduate from the laboratory or other authorised health care provider.

The personnel assigned to obtain and prepare the samples must be qualified and in possession of the corresponding degree, according to current regulations. A distinction must be made between:

- Authorised personnel for obtaining samples.
- Authorised personnel for sample preparation.

The staff of the sampling area must have defined their professional connection with healthcare provider where the area is located.

Staffing must, at all times, be sufficient to ensure the quality of the sampling process. Alternate staff must have the knowledge and skills to obtain samples.

5.1.1.4 Samples' collection equipment and material requirements

The necessary equipment for the storage and preparation of the samples must be provided and labelled correctly.

5.1.1.5 Requirements for patient identification, requests, and samples

The procedure for identifying patients, requests, and samples should be designed to avoid errors. The identification must be unique and unambiguous. The ordering party and the laboratory must assure a consistent end-to-end use of patient identifier aligned with eHDSI requirements, Alphanumeric encoding, barcode, or a computerised process can be used.

The verification of the identification of patients, requests and samples must be done at the time of obtaining and by the person who performs it and must be registered.

5.1.1.6 Documentation requirements

5.1.1.6.1 Sampling procedure

There must be an up-to-date sample collection and handling procedure manual in each sampling area.

5.1.1.6.2 Information sheets with instructions for patients

They must be prepared by the laboratory and written in a brief, clear manner and using comprehensible language.

In those cases where the collaboration of the patient at home is necessary for the taking of the sample, the area for obtaining samples must provide the relevant instructions in writing.

5.1.1.6.3 Sanitary waste disposal protocol

Every sampling area must have an explanatory protocol on the methodology of classification and storage of the sanitary waste that generates.

5.1.1.6.4 Action protocol in case of health emergency

In the areas of sampling there must be an action protocol to address the following health emergencies:

Accidental puncture of the personnel involved or patients

Alteration of the patient's consciousness

Other adverse reactions.

5.1.1.7 Technical requirements for sampling

The technical requirements for sample acquisition must be described in a sample collection and handling procedure manual, which must be updated periodically. A copy must be available, in the areas of the sampling points, for consultation by the staff obtaining samples.

The manual has an important function to assist in the correct acquisition of the samples collected in the appropriate containers for each component, and to provide information on the time required for their realisation.

5.1.1.8 Technical requirements for sample preparation, conservation, and transport

There must be a protocol on the correct conservation of the samples to guarantee stability of the biological quantities to be determined.

The following must be specified: the system implemented to prevent deterioration and contamination of the primary samples; the adoption of safety rules during centrifugation, if applicable; the proper preparation of the samples, before their transport; and the recommendations adopted in handling and storage, depending on the type of sample and the constituents to be analysed.

In general, samples must be delivered to the laboratory as quickly as possible, Transport of samples of biological material between different locations must be managed by an authorised health service

provider or transport agency. The transportation of infectious samples may be subject of specific regulations on transport of dangerous goods.

5.1.1.9 Confidentiality of data

The staff of the clinical laboratory must comply with applicable law and regulation on Protection of Personal Data.

5.1.1.10 Chain of custody

Both the information received and that generated by the laboratory and the biological material obtained in the production area must be handled and stored in an organised manner to prevent unauthorised use; likewise, the traceability of the custody, both of the information and of the samples obtained and sent from the sampling area, must be ensured. (Taskinen, Beck, Bosh, & al, 2017)

The realisation of the chain of custody is essential to maintain the confidentiality of the information, as well as the validity of the sample, and is mandatory in the analysis of components, the determination of which may have a legal impact (alcohol in the blood, drugs of abuse in the urine, toxic substances, etc.).

5.1.2 Risks

All information sharing in healthcare introduce risks, for example for information integrity, privacy, misinterpretation, or reliance on information that may be missing. Sharing of information cross-border may increase the likelihood of adverse events, due to language differences, cultural differences or different coding systems and practices in use at national or regional levels.

In addition to generic risks present in sharing of information cross-border, transmitting laboratory orders and/or reports from one context to another poses specific challenges, including lack of consensus regarding code systems for laboratory use cases in the EU.

Specific risks are identified per use case (e.g., transcoding, unit transformation, interpretation of ranges, relative “unfamiliarity” with examination techniques and results, mutual recognition of test results, etc.)

Misinterpretations of laboratory test results due to coding errors to a certain limited degree might be acceptable when data are collected and used for research purposes. In the case of transfer of individual patient test results no errors should in principle be allowed.

5.1.3 Policy

The laboratory must be committed to maintaining and improving the security of information within the current legislative framework as a clinical analysis laboratory. Following this commitment, it must have an Information Security Policy aimed at guaranteeing the protection of all information assets and the technology used for their processing and establishes through its management the following fundamental principles of information security:

- **Principle of regulatory compliance:** adjust information systems to the applicable regulations that affect the security of information, including regulations relating to the security of systems, communication, services, and the protection of personal data.

- **Risk management principle:** minimise risks to acceptable levels and seek a balance between security controls and the nature of the information.
- **Principles of confidentiality, integrity and availability:** Guarantee the confidentiality of information and limited access to authorized persons only. Ensure the integrity of the data managed by the laboratory information system (LIS), so that these are precise, concise, and accurate, both in content and in the processes involved. Ensure the availability of information, ensuring the continuity of the laboratory supported by the information services through the development of a contingency plan.
- **Proportionality principle:** find the balance between the measures of security, the nature of the information and the risk.
- **Principle of awareness and training:** articulate training and awareness actions for all professionals in the laboratory, in matters of information security and protection of personal data.
- **Principle of continuous improvement:** periodically review the degree of effectiveness of the security controls implemented to increase the ability to adapt to the constantly evolving risk and the technological environment.

Member states shall undertake policy measures for facilitating cross-border exchange in laboratory domain, such as:

- ensuring national legal base for cross-border sharing in laboratory domain
- formal authorisation of National Contact Point for exchanging of laboratory results and/or orders
- active promotion and/or incentives for participating laboratories
- provide funding for national EHR exchange infrastructure
- adoption of common European EEHRxF standards
- provide dissemination and implementation support to health ICT vendors and laboratories
- provide assistance to vendors, healthcare providers and laboratories applying for EU funds.

5.1.4 Semantic

Healthcare industry is knowledge-based and clinical information derived from clinical data is a key enabler. Implementation of an electronic health record expands the capacity of information systems to capture, use and exchange sensitive personal health data.

Semantic interoperability is the ability of computer systems to exchange data with unambiguous, shared meaning. It is a requirement to enable machine computable logic, inferencing, knowledge discovery, and data federation between information systems. This is accomplished by adding data about the data (metadata), linking each data element to a controlled, shared vocabulary. It is this shared vocabulary, and its associated links to an ontology, which provides the foundation and capability of machine interpretation, inference, and logic.

While the journey of semantic interoperability varies across Member States, the chapters below discuss the most common elements in the laboratory domain.

5.1.4.1 Main coding systems for laboratory test ordering and result reporting

As the laboratory work is one of the first areas in healthcare that have been supported by information systems, several coding systems for structured information recording and exchange have been developed over the years – like Logical Observation Identifiers Names and Codes (LOINC), Nomenclature for Properties and Units (NPU), or SNOMED Clinical Terms (SNOMED CT), to name the main ones. Many other national code systems exist across Europe.

Sharing of laboratory test results between different healthcare providers requires standardised terminology used to clearly identify what is examined by use of laboratory tests, including information about types of specimens (arterial blood, 24 hours urine collection, cerebrospinal fluid), anatomical location of sample, (e.g. sample from skin of left knee), investigated system (blood, plasma, urine), the target analytes (components or elements such as Sodium, Alanine transaminase, Brucella antibody), examined properties (kind of properties such as mass concentration, volume, numeric fraction, frequency, mass etc.), specific procedure or observation technique, and the units by which the value is presented (for values with units).

5.1.4.1.1 LOINC (Logical Observation Identifier Names and Codes)

Many laboratories use electronic message standards to transmit results to their clients. If all laboratories used the same "universal" set of test identifiers, electronic transmission of results would be greatly simplified. The Logical Observation Identifier Names and Codes (LOINC) database aims to be a universal and comprehensive coding system for laboratory tests. It is the world's most widely used coding system, covering at least 98% of the average laboratory's tests. (A W Forrey, 1996)

International initiatives for EHR interoperability and standardisation bodies are commonly referring to LOINC as a reference coding system for laboratory test. As an example, IHE has published a Laboratory Technical Framework document (LAB TF-4)¹³ providing a subset of LOINC test codes to facilitate implementation.

There are six axes or major elements, called **LOINC Parts**, that comprise the **LOINC Terms** semantic structure: component, property, timing, system, scale, and examination technique (method). Table 2 provides a summary of the elements of the LOINC semantic structure and their extended definitions with examples relevant to survey research.

Table 2: LOINC semantic structure

No.	Axis	Definition
1	Component	The analyte or attribute being measured or observed. E.g., potassium, haemoglobin
2	Property (Kind of)	Distinguishes among different kinds of quantities relating to the same substance. E.g., mass concentration, catalytic activity
3	Time (Aspect)	Identifies whether the measurement is made at a point in time or a time interval. E.g., 24H for a urine sodium concentration

¹³ https://www.ihe.net/Technical_Framework/upload/ihe_lab_TF_rel2_1-Vol-4_FT_2008-08-08.pdf

No.	Axis	Definition
4	System	The sample, specimen, body system, patient, or other object of the observation. E.g., serum, urine, radial artery
5	Scale (Type of)	The scale or precision that distinguishes among observations that are quantitative, ordinal (ranked choices), nominal (unranked choices), or narrative.
6	Method (Type of)	An optional axis that identifies the way the observation was produced. It is only used to distinguish observations that have clinically significant differences in interpretation when made by different examination technique.

LOINC Parts are coded representations of the attribute values that combine to create a LOINC term. LOINC Parts support the translation of LOINC terms into other languages, easy linking of synonyms across many terms, the creation of hierarchies to group related LOINC terms, and several other functions¹⁴.

The LOINC Parts and Part hierarchies are only intended to be constituents of and/or organise LOINC terms. As described in the LOINC license¹⁵, they are not intended for use as a “standalone” terminology apart from LOINC terms.

Furthermore, LOINC Parts and Part hierarchies are not strictly managed under the same policies (e.g., concept orientation, concept permanence) as are LOINC terms.

The LOINC system is maintained and developed by Regenstrief Institute, Minneapolis, US and funded by National Library of Medicine, among others. To help guide the overall LOINC development, Regenstrief organised the LOINC Committees. The terms are translated and available in several European languages, and the system is implemented in several countries according to our initial survey.

More information about LOINC terminology could be found at <https://loinc.org> website. LOINC codes could be searched online at <https://loinc.org/search> (free after registration).

5.1.4.1.2 NPU (Nomenclature for Properties and Units)

The NPU terminology is a patient-centred clinical laboratory terminology used for clinical laboratory sciences. The joint committee for nomenclature, C-NPU, under the two international organisations IFCC (International Federation of Clinical Chemistry and Laboratory Medicine) and IUPAC (International Union of Pure and Applied Chemistry) is responsible for the scientific development of the NPU terminology according to strict metrological principles and international scientific recommendations in terminology.

The NPU coding system is freely available for use. It is fully implemented in the three Scandinavian countries Denmark, Norway, and Sweden. Czech Republic is using its own national lab test coding system which is derived from NPU and maintains mapping to it. National Release Centres in the

¹⁴ <https://loinc.org/part-file/>

¹⁵ <https://loinc.org/license/>

three Scandinavian countries are responsible for translations of terms into local languages and for the distribution of a controlled national subset of NPU codes, and for the addition of national codes for concepts necessary within the national health care systems. The National Release Centres have also agreed to cover some of the costs for maintenance of the international NPU system, in lack of other major funding sources.

NPU is used to communicate patient examination results safely between laboratory information systems, hospital patient records, GPs, and local and national data repositories. Data can be recognised, compared, reused in calculations, extracted for research or statistics, and stored for documentation, without loss of meaning.

The NPU concept model identifies examined properties of a patient, independent of the technology or procedure used to obtain the information. The NPU definition encompasses essential information about an examination result or a measurement in a formal structure, identifying:

- the system (or “part of the universe”) that is studied
- the component examined in that system
- the estimated kind-of-property of the component in that system
- the measurement unit is added where relevant, preferable an SI unit
- the scale type

With the NPU Terminology examination results from clinical laboratories can be communicated between different systems across technology, time, and geography. The formal syntax and the use of international nomenclatures, classifications and recommendations for all terms ensures that the NPU definitions can be translated easily and safely into other languages. The system does not include information about the observation technique or assay used for the measurement, as long as the intended measurand does not depend on the measurement technique.

The International Release Centre, at the Danish Health Data Authority in Copenhagen, Denmark, is responsible for maintenance and publication of the English version of the terminology. New codes and concepts are created after suggestions by users under the condition that the descriptions of the concept fulfil the metrological principles.

More information about NPU terminology principles and concept model could be found at <https://labterminology.com>, terminology homepage at <https://www.npu-terminology.org/> and searchable database of NPU terminology terms at <https://www.ifcc.org/ifcc-scientific-division/sd-committees/c-npu/npusearch>.

5.1.4.1.3 SNOMED CT

SNOMED CT is an international standard of multilingual clinical healthcare terminology, encompassing clinical findings, symptoms, diagnoses, procedures, body structures, organisms and other aetiologies, substances, pharmaceuticals, devices, and specimens in computer processable format used in clinical documentation and reporting.

The primary purpose of SNOMED CT is to encode the meanings that are used in health information by providing a consistent means to index, store, retrieve, and aggregate clinical data across specialties and sites of care.

SNOMED CT is maintained and distributed by SNOMED International to support the effective clinical recording of data with the aim of improving patient care and provides the core general terminology for electronic health records by reducing the variability in the way data are captured, encoded and used for clinical care of patients and research.

The SNOMED CT semantic structure consists of the following core components as shown in Figure 1.

Concept Codes – numerical codes that identify clinical terms, primitive or defined, organised in hierarchies

Descriptions – textual descriptions of Concept Codes

Relationships – relationships between Concept Codes that have a related meaning, and are continually evolving, for example

Reference Sets – used to group Concepts or Descriptions into sets, including reference sets and cross-maps to other classifications and standards

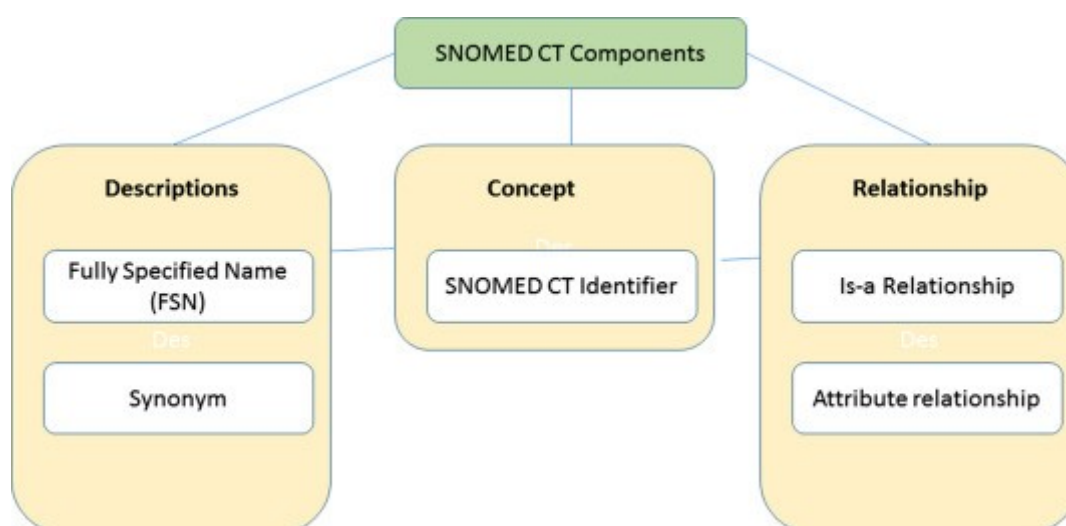


Figure 1: SNOMED CT core components

Every concept represents a unique clinical meaning, which is referenced using a unique, numeric and machine-readable SNOMED CT identifier. All concepts are organised into acyclic taxonomic (is-a) hierarchies; for example, *Viral pneumonia* IS-A *Infectious pneumonia* IS-A *Pneumonia* IS-A *Lung disease*. Concepts may have multiple parents, for example *Infectious pneumonia* is also a child of *Infectious disease*. The taxonomic structure allows data to be recorded and later accessed at different levels of aggregation.

SNOMED CT assigns each concept a semantic tag and there can be multiple semantic tags used within each SNOMED CT top level hierarchy. There are three types of description are used to represent every concept – Fully Specified Name (FSN), Synonym and (Text) Definition.

The FSN represents a unique, unambiguous description of a concept's meaning. This is particularly useful when different concepts are referred to by the same commonly used word or phrase. Each concept can have only one FSN in each language or dialect.

A synonym represents a term that can be used to display or select a concept. A concept may have several synonyms. This allows users of SNOMED CT to use the terms they prefer to refer to a specific clinical meaning.

A Definition is described as a narrative text explanation of the meaning of a concept.

A Relationship represents an association between two concepts and is used logically to define the meaning of a concept in a way that can be processed by a computer. Furthermore, attributes (relationship types) are used to represent the meaning of association between the source and destination concepts. There are different types of relationships available within SNOMED CT.

SNOMED CT is maintained and distributed by SNOMED International. These releases contain new concepts and important changes to existing ones as a result of the latest medical knowledge.

Currently, releases are issued every 6 months with plans to move to monthly in Jan 2022.

5.1.4.1.4 UCUM

UCUM stands for “Unified Code for Units of Measure”. UCUM was developed by Regenstrief Institute¹⁶. According to the UCUM website "the Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. A typical application of The Unified Code for Units of Measure are electronic data interchange (EDI) protocols, but there is nothing that prevents it from being used in other types of machine communication." UCUM has been adopted internationally by many organisations such as IEEE¹⁷, DICOM¹⁸, LOINC¹⁹, and HL7²⁰."

UCUM is basis for application and modelling in the ISO 11240:2012²¹ standard for representing units of measure in healthcare context. UCUM assigns to each defined unit code a concise meaning and definition in terms of SI units or other references where units cannot be converted to SI units. The codes are publicly available, and their use is royalty free. All SI units and their prefixed derivatives are expressible using this coding system. In addition, UCUM provides unambiguous machine-processable rules for converting quantity values between SI base units and other units in practical use, where applicable. The unit codes provided by UCUM for units of measurement are constructed by algebraic rules that reflect the underlying system of units and quantities. Each code expression for a unit of measurement represents a particular unit quantity and refers to the underlying definitions, i.e., the SI base units. UCUM codes are designed to enhance human readability. Therefore, the codes closely resemble commonly used symbols for units of measurement.

The symbols conventionally used to display or print units of measurement may differ from the UCUM codes for the same concepts. Usage of HL7 V3 based standards, such as HL7 CDA R2, requires UCUM as the code system for units of measurement for physical quantities (see the HL7 V3

¹⁶ <http://www.regenstrief.org/>

¹⁷ <https://www.ieee.org/>

¹⁸ <https://www.dicomstandard.org/>

¹⁹ <https://loinc.org/>

²⁰ <http://www.hl7.org/>

²¹ <https://www.iso.org/standard/55033.html>

definition of datatype PQ). Data type PQ (as well as its FHIR equivalent) allows the addition of an alternative representation of the same physical quantity expressed in a different unit from a different unit code system and possibly with a different value.

Some units commonly used in laboratory medicine are not based on the SI system (typical example: biological activities), but in terms of a measurement related to an arbitrarily defined reference quantity. The definition of a particular arbitrary reference quantity generally is not included in the definition of the arbitrary unit code (e.g., "IU" is used for a multitude of WHO reference quantities). Therefore, conformant structures and vocabularies for communication should be used to provide the required reference information explicitly or implicitly in the context of the quantity value. This can be seen as a requirement for structures and vocabularies for lab tests and examination techniques and is outside the scope for UCUM. WHO IUs are a prominent case of such arbitrary units. UCUM provides codes for "international units" and for a number of other commonly used arbitrary units.

For cross-border exchange (eHDSI) a publicly available sample set for UCUM notation²² is in use and maintained in the Master Value Catalogue (MVC). This sample set contains commonly used units from different areas. The data set contains SI units as well as arbitrary units. Informal parts of units are expressed by curly brackets {}. Eventually a subset in relation to measurements in the laboratory and healthcare context may be defined. However, this example list is not an extensive and complete "collection" of possible combinations of units. When designing data models, it should be considered whether the complexity on the side of the data model is thought through the provision of individual data fields for a free combination of units or whether this complexity should be created through the provision of all possible combinations of units in a catalogue of units of measurement.

Due to unambiguous machine-processable rules for converting quantity values via algebraic rules UCUM offers the possibility to compile data from different sources and "normalise" them. This will support to use data for secondary evaluations and scientific research.

5.1.4.1.5 Licensing conditions

5.1.4.1.5.1 LOINC

LOINC is maintained by the Regenstrief Institute. LOINC codes are available for free and without the requirements to sign a contract. However, copyright rules²³ on the website must be observed. Among others for "group 1 artifacts", no changes or modifications or developments of other standards are allowed. In electronic systems the Copyright Notice and License or a reference thereto has to be included in the message "This material contains content from LOINC (<http://loinc.org>). LOINC is copyright © 1995-2021, Regenstrief Institute, Inc. and the Logical Observation Identifiers Names and Codes (LOINC) Committee and is available at no cost under the license at <http://loinc.org/license>. LOINC® is a registered United States trademark of Regenstrief Institute, Inc".

LOINC codes should not be expressed alone but in combination with either the 6 axes fully specified name, short name, long common name or display name. Translations have to be announced and are incorporated into accessory linguistic variants file, assigning also the property rights to

²² <https://ucum.nlm.nih.gov/example-UCUM-Codes-v1.4.pdf>

²³ <https://loinc.org/kb/license/>

Regenstrief Institute. Special conditions apply to parts of LOINC (i.e., surveys, list of answers) which contain third party content, translations for this third-party content are regularly not accepted by Regenstrief.

5.1.4.1.5.2 NPU

NPU terminology license terms grant perpetual permission to use and copy the NPU Terminology content in all formats in which it is distributed by The Danish Health Data Authority or supplied by a licensed NPU National Release Centre for any commercial or non-commercial purpose without payment of license fees or royalties. License terms further specify conditions and terms under which use of the terminology is granted.

The publications of NPU terminology content consist of three main sets of data: NPU definitions and codes, terms and terminological references, and NPU group structures (lists). Users may download, access or receive the publications of NPU Terminology content in English, as available from www.labterm.dk, www.npu-terminology.org or www.ifcc.org, or as original or translated versions published by a licensed NPU National Release Centre.

NPU code values and other content in part or full may be incorporated in programs, instruments, and devices for the purpose of identifying clinical patient observations.

Users may incorporate portions of the NPU content into another document (e.g., an implementation guide or other technical specification) for distribution outside of the user's corporation or organisation, subject to these terms:

- Every copy of the document that contains portions of the NPU content must contain a reference to the NPU Terminology as the property of IFCC and IUPAC, and to the publication website www.npu-terminology.org
- Any information in the document that is extracted from the NPU definition publications must always be associated with the corresponding NPU code.

A user may use all or a subset of NPU definitions and codes to deal with the user's local requirements. A user may add local or national extensions, provided that the codes and content cannot be confused with NPU codes and content.

License to translate NPU terminology content is granted by the NPU Steering Committee only to National (or organisational) Release Centres.

5.1.4.1.5.3 SNOMED CT

The use of SNOMED CT in production systems requires a license²⁴. There are two types of licenses:

Country/territory membership in SNOMED International (charged according to gross national product).

Affiliate license (dependent on the number of end users). LDCs (least developed countries) can use SNOMED CT without charges.

²⁴https://www.snomed.org/SNOMED/media/SNOMED/documents/IHTSDO-Affiliate-License-Agreement_UK_20190101_v0-1.pdf

Those wishing to obtain a license for its use and to download SNOMED CT should contact their country's National Release Centre for further instruction. Approval of the license is associated with obligations such as the annual specification of end users or the type of use.

Since SNOMED CT is a multilingual clinical healthcare terminology, publicly available translations are announced at the SNOMED International General Assembly and are promoted by SNOMED International and the Member States National Release Centre.

More recently, SNOMED International has introduced the Global Patient Set (GPS) to support the sharing of patient health information coded with SNOMED CT without the need for a SNOMED International license. This is a licence free subset of unique identifiers, fully specified names (FSN) preferred terms in international English, and status flags. The GPS supports health information interoperability across care settings, systems, organisations, and national borders at no cost to users.

Furthermore, the European Commission supports Member States by providing partial payment for the SNOMED licence for those wishing to implement SNOMED CT in their healthcare systems.

5.1.4.1.5.4 UCUM

UCUM is maintained by the Regenstrief Institute. The use of the UCUM notation rules and example data sets are free of charge. According to the copyright conditions²⁵ the example extensions to the UCUM table are to be requested²⁶ (which is not practical as the table is not extensive in regard of possible combination of units). In electronic system the copyright notice "This product includes all or a portion of the UCUM table, UCUM codes, and UCUM definitions or is derived from it, subject to a license from Regenstrief Institute, Inc. and The UCUM Organization. Your use of the UCUM table, UCUM codes, UCUM definitions also is subject to this license, a copy of which is available at <http://unitsofmeasure.org>. The current complete UCUM table, UCUM Specification are available for download at <http://unitsofmeasure.org>. The UCUM table and UCUM codes are copyright © 1995-2009, Regenstrief Institute, Inc. and the Unified Codes for Units of Measures (UCUM) Organization. All rights reserved. THE UCUM TABLE (IN ALL FORMATS), UCUM DEFINITIONS, AND SPECIFICATION ARE PROVIDED "AS IS." ANY EXPRESS OR IMPLIED WARRANTIES ARE DISCLAIMED, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE" has to be incorporated. Copyright conditions are currently under revision. Translation of display names of unit lists are encouraged²⁷.

UCUM specification and roadmap are publicly available on their web site (<https://ucum.org/ucum.html>).

5.1.4.1.6 Release management

5.1.4.1.6.1 LOINC

Regenstrief Institute, a non-profit medical research organisation associated with Indiana University, is the owner and overall steward of the LOINC vocabulary standard. Led by Clem McDonald, MD, Regenstrief's informaticians initiated the LOINC effort in 1994. The LOINC team at Regenstrief maintains the LOINC databases and supporting documentation, processes submissions and edits to

²⁵ <https://ucum.org/trac/wiki/TermsOfUse>

²⁶ <https://ucum.org/trac/newticket>

²⁷ <https://ucum.org/trac/wiki/MultiLingual>

the contents, develops and curates accessory content (descriptions, hierarchies, other attributes, etc), develops the RELMA mapping program and co-ordinates LOINC releases, twice yearly.

Since release 2.71 (and RELMA 7.4) the release cycles have switched to mid-August and mid-February. Until release 2.70 (and RELMA 7.3) they were at mid-June and mid-December. Translations (Linguistic Variants) can be submitted until end of July and mid of January to be released as accessory files²⁸.

LOINC is an open standard and actively encourage their community to propose enhancements and revisions to existing content like synonyms, terms descriptions, new kinds of measurements or use of LOINC codes in ways not previously agreed upon by the LOINC Committee. Change requests are handled through a Procedure for Submitting Additions or Changes to LOINC²⁹. LOINC currently has 1,622 requested LOINC's with a median turnaround of agreed new terms of 148 days duration to release.

5.1.4.1.6.2 NPU

The NPU-terminology encompasses 25 000 codes and definitions of clinical laboratory results, covering almost 10 different clinical laboratory fields (e.g., chemistry, immunology and blood banking, microbiology and allergology). The terminology is freely accessible to search from the international website (<https://www.npu-terminology.org/npu-database/>) or download from the Danish LabTerm website (<https://www.labterm.dk/download/Index1>).

The NPU terminology has a frequent release schedule with monthly updates. The updates include addition of new codes and definitions to the terminology, updates of existing codes and definitions, as well as inactivation of codes that are no longer required. The addition of new codes originates in most cases from requests from the national release centres in Sweden, Norway and Denmark. Since the content is based on international recommendations and standards, new and existing codes need to be added and updated accordingly.

The NPU terminology provides a comprehensive code system to enable safe communication of laboratory results between different laboratory- and health information systems. To this end, the codes are examination technique independent and complementary terminologies e.g., SNOMED CT would be needed to cover this aspect, as well as information on e.g., specimen type, localisation, and test tube.

5.1.4.1.6.3 SNOMED CT

While SNOMED CT is an extensive terminology not every concept for sharing of laboratory data is in SNOMED CT today. The current content of SNOMED CT is accumulated from use cases of all SNOMED CT users to date and while it is expected that the terminology will grow and evolve with the inclusion of additional use cases, some gaps may still exist.

Different options, listed below, which are based on the X-eHealth and MyHealth@EU use cases, should be also considered.

- There are today 19 EU members which are also SNOMED International members which could make or request changes or additions to SNOMED CT to meet needs raised in EU projects, either directly to SNOMED International or through an existing extension in an EU member country.

²⁸ <https://loinc.org/news/loinc-version-2-71-is-now-available-for-free-download/>

²⁹ <https://loinc.org/kb/users-guide/procedure-for-submitting-additions-or-changes-to-loinc/>

The 19 EU + SNOMED members currently have the knowledge, skills, and tools to do SNOMED CT content development.

- SNOMED International manages multi-national (as opposed to international) collaboration through a mechanism named “community content”. One or more community content areas for EU content might be set up by the request from EU and SNOMED International member countries. The scope of these areas, e.g., limited by application domains such as laboratory medicine, is to be discussed.
- This likely requires discussions between EU and SNOMED International about managing use of SNOMED content for non-SNOMED International members for example through SNOMED GPS extensions

SNOMED International maintains a rigorous product release schedule. Releases are issued every 6 months with plans to move to monthly in January 2022 and includes new content and/or inactivation of content no longer required.

The ability to incorporate changes from International and National editions of SNOMED CT is key to the delivery of high-quality products and services.

5.1.4.1.6.4 UCUM

UCUM releases are not frequent. The current version of specification 2.1 was released in 2017. The history and timeline of the releases is available at <https://ucum.org/trac/roadmap>. The content of the upcoming release is accessible at <https://ucum.org/trac/timeline>.

Typically, there is around 10 requests for new unit code per year. The maintenance activity is less in numbers and requires more in-depth discussions. Change requests could be submitted using change management procedure³⁰ and further described by Organization and Procedures document³¹.

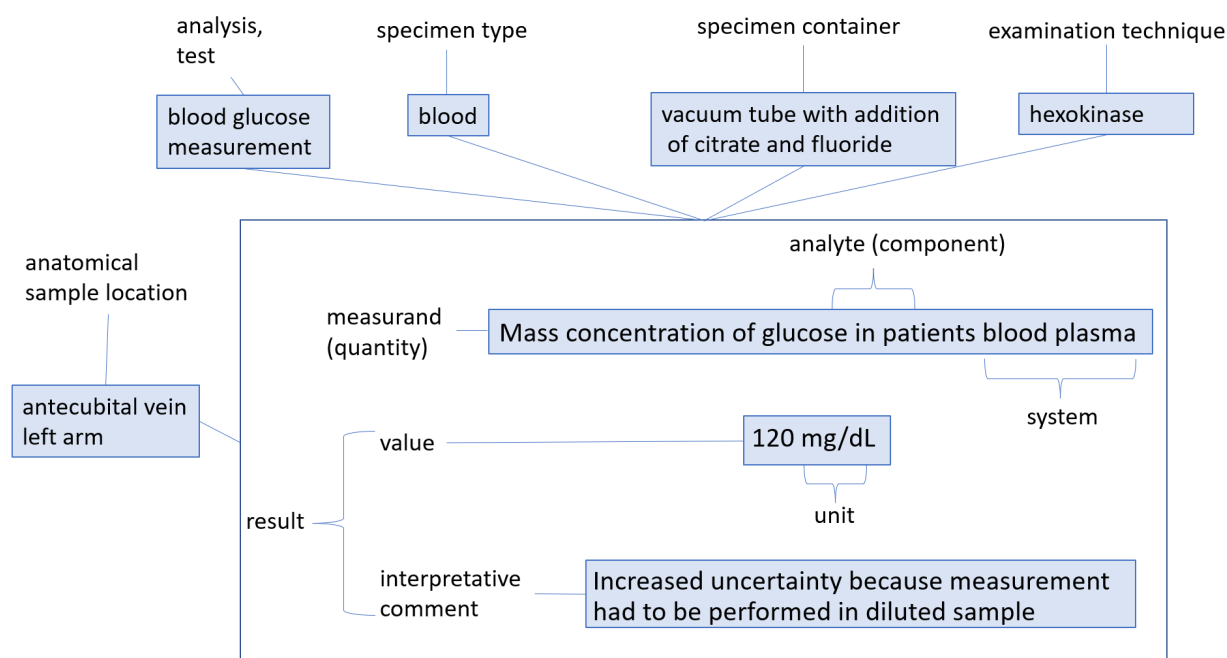
5.1.4.2 Laboratory tests

To evaluate the usefulness of a terminology for laboratory test results, the different constituents of a laboratory result must be recognised, see Figure 2.

³⁰ <https://ucum.org/trac/wiki/RequestsForUnit>

³¹ <https://ucum.org/trac/wiki/CharterAndBylaws>

Figure 2: Basic constituents of laboratory test result



5.1.4.2.1 LOINC

Each record in the LOINC database contains a fully specified description composed of 6 major axes (also referred to as parts) that combine to uniquely identify each individual observation or measurement. Of note, only the examination technique (method) axis is optional. Although each LOINC item is inclusive of this specific information it is not sufficient on its own. It lacks other relevant information required by end users for the pragmatic use of the standard. For example, LOINC does not include details regarding the type of instrument used, testing priority, performing site, interpretation criteria, the individual responsible for the interpretation, or related diagnoses.

LOINC creates several different text labels (names) to represent each concept. The six-part formal name, as described above, is the Fully Specified Name (FSN). LOINC also create a more clinician-friendly display called the Long Common Name (LCN) and a Short Name that can be handy when you need a column header in a report. Here are the names for LOINC code 806-0:

Name	Value
Fully Specified Name (FSN)	Leukocytes: NCnc: Pt: CSF: Qn: Manual count
Long Common Name (LCN)	Leukocytes [# /volume] in Cerebral spinal fluid by Manual count
Short Name	WBC # CSF Manual

5.1.4.2.2 NPU

NPU nomenclature includes a fully specified name and short name of each concept which is composed from following semantic elements, as depicted in Table 3.

Table 3: NPU concept model

Axis	Extended Definition
System	System represents the biologic system for which the measurement result is expressed (e.g., blood plasma, even though the sample can be blood).
Specification to system	<p>The system may form the operative part of a supersystem or a subsystem may form the operative part of the system. Specifications about the supersystem or subsystem are conventionally placed (without space) in parenthesis after the name of the system in reports from the clinical laboratory: System (Specifications about the system)</p> <p>Specification to the system may have one of two purposes: to circumscribe the term or to indicate sampling conditions. The two types of specification are separated by a semicolon, and the ones on sampling conditions are mentioned last.</p>
Component	The component examined in the system. Names used for components are the official names according to rules of nomenclature for inorganic, organic and biological chemistry.
Specification to component	Specification of a set of elements (chemical entities) examined in the component of a system.
Kind-of-property	State- or process-descriptive feature of a system including any pertinent components
Specification to property	Distinguish different types of property according to the algebraic characteristics of the types of properties, e.g., nominal, ordinal, linear differential, logarithmic differential or rational.
Unit	Measurement units based on SI units (preferred) and supplemented with non-SI units from various biological fields.
Scale type	Results belongs either to the ratio (quantitative), ordinal, or nominal scale type, or are narrative

NPU system includes syntax rules to compose fully specified name and short name of the test out of the 4 basic semantic axes.

- System(specification)–Component(specification); Kind-of-property(procedure) = ? Unit.

Unlike LOINC, timing aspect is not a separate entity but given by the kind-of-property element. For example, the property “mass rate” (g/d) is assumed to reflect a defined period.

As fully specified name is precise but too long and complex in some cases, and short NPU names might be difficult to read by nonlaboratory professionals, several implementing countries have created national extensions to the NPU terminology and specified shorter standard test names, called synonyms, trivial names, or patient friendly names. Such extensions exist in the Danish, Norwegian, Swedish, and Czech languages.

The NPU terminology allows expression of the test examination technique (method) when the technique affects what is measured, for example antithrombin can be measured with enzymatic, coagulation, or immunologic techniques.

A specific feature with the NPU terminology is that each term in the fully specified name is not only an English term, but includes also, when possible, a reference to a formal definition. If this is not possible an internal definition is given within the NPU system.

Here are the names for NPU code NPU02594:

Name	Value
Systematic name (SN)	Cerebrospinal fluid–Leukocytes; number concentration = ? × 10 ⁶ /L
Short definition (SD)	Csf—Leukocytes; num.c. = ? × 10 ⁶ /L
Primitive Name (Denmark)	Leukocytes; Csv
Report name (Sweden)	Csv—Leukocytes
Report name (Norway)	Csv-Leukocytes

5.1.4.2.3 SNOMED CT

The SNOMED CT could be also used for the laboratory test coding, however not frequently used between EU Member states. SNOMED CT concepts from the 15220000 |Laboratory test| or 363787002 |Observable entity| hierarchy may be used.

5.1.4.2.3.1 Synergy between SNOMED CT and LOINC coding systems

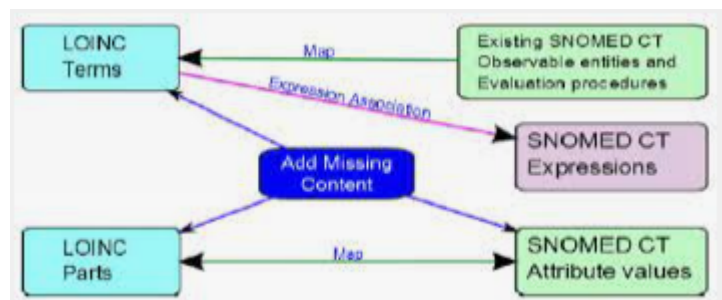
LOINC and SNOMED CT are medical terminologies, each with a growing international user base. There is a synergy between the two terminologies, LOINC has traditionally represented questions and SNOMED CT represented answers to those questions.

The collaborative efforts of the “LOINC - SNOMED CT Cooperation Project” provided new content to the SNOMED CT International Release which provides supporting content for mapping, specifically to the LOINC Parts. Tenets of this agreement include minimising further duplication between SNOMED and LOINC, however, this work has been suspended in 2017. The package has not been updated since July 2017 and SNOMED International and Regenstrief Institute confirm that there are no current plans to do so. Nonetheless, this collaborative approach offers significant improvements in the future delivery of healthcare, providing linkages between LOINC and SNOMED, enabling the two to work better together, and providing additional value for their use. In January 2014 work commenced on the project.

Besides the LOINC – SNOMED mapping co-operation there are agreements in place between Regenstrief Institute and SNOMED International regarding handling new concepts in the branches “observation entity” and “evaluation procedures”. Applications for new terms will be handled jointly^{32,33}.

³²https://www.snomed.org/SNOMED/media/SNOMED/documents/IHTSDO_and_RII_20130817.pdf

³³https://www.snomed.org/SNOMED/media/SNOMED/documents/IHTSDO_Regenstrief_2013_agreement_announcement_20130724.pdf



5.1.4.2.4 Comparison between LOINC and NPU coding systems

Both LOINC and NPU represent international laboratory test coding systems used by several EU member states, both systems are multiaxial with similar axis but also with slight conceptual differences. The similarities between the systems are many. Both systems describe measurable and observable properties in a multiaxial system of definitions, where some of the axes are identical. There are also some conceptual differences.

The major similarities and dissimilarities between the two coding systems are summarised in the following table:

Axes	LOINC	NPU
System	Designates often the “sample material” used for the measurement. For example, “blood” or “serum/plasma” can be the system for measurement of the glucose concentration in blood plasma.	Designates the biological system for which a measurement result is expressed. If the concentration of glucose is expressed per volume of blood plasma (and thus not per volume of whole blood), then “blood plasma” is the system, although the sample material is blood.
Component	The component, or analyte, are often identical, and always comparable with corresponding NPU-term	The NPU terms are often identical with LOINC terms. Sometimes the spelling differs, as the NPU terms strictly follows preferred spelling of terms from the international databases source to which it refers.
Kind-of-property	Basically, comparable with kind-of-property in the NPU system	Basically, comparable with kind-of-property in the LOINC system
Specification to property	-	When results are given with International Units (IU) as unit the defining standard for the unit is specified for the code. Other types of procedure specification according to international agreements

Axes	LOINC	NPU
		may also be given as specifications. Each new specification results in a new unique NPU-code.
Unit	The measurement unit is not specified in the LOINC system. The same LOINC code can be used to express result with different units.	For quantitative results, the NPU code is defined for each unit. For local procedures, with procedure defined units, a NPU code is defined for an unspecified unit. All units for concentrations are expressed per litre, for example “mg/L” or “mmol/L”, and not as “mg/dL” according to conventions of the SI.
Timing aspect	Measurement concerning a sample from a specified time point, “Pt”, is distinguished from a sample collected during a period of time, such as “24H”.	Timing aspect is covered by information in kind of property and unit for the measurement. For example, the kind of property “mass rate”, expressed with the unit “g/d” indicate that a sample has been collected during a period.
Method (examination technique)	The LOINC system provides unique codes which specify method types that can have impact on the quality of the measurement, such as “manual cell count” vs “automated cell count” or category of detection limits, e.g., for albuminuria “<= 20 mg/L”, “<= 3 mg/L” or “<= 1 mg/L”.	NPU terminology specifies the measurement principle if this has an impact on what is measured. For example, immunoassays which measure the antigen of an analyte, and enzymatic assay which detect the activity of the same analyte, have different NPU codes. Generally, the NPU code gives no information on the used examination technique. The quality, or uncertainty, of the measurement result, is intended be presented by other means.
Measurement standard	Not included in the LOINC code	When the unit is not an SI unit (which in fact is a kind of measurement standard), the measurement standard is specified within the NPU code, for example WHO “IS 01/608” for measurement of low molecular heparin.

Information about assay type system is not mandatory, but more often included in a LOINC code than in a NPU code (Such as “Electrophoresis” with LOINC 6941-9 and “detection limit < 3,0 mg/L” with LOINC 90000-1). Information about the calibrator, or higher order metrological standard, to which measurement results are traceable, is not mandatory, but is often included in a NPU code. As

the measurement unit is not a part of the definition for a given LOINC code, the calibrator information cannot be included in the LOINC code.

All terms used in the NPU system contains references to international databases, facilitating correct translation of terms to local languages.

NPU is very strict in relation to metrological principles and the measurement unit is included in the code. If implemented correctly it allows comparability of the laboratory test results.

LOINC system is more pragmatic as it allows inclusion of information about examination technique constructed, is used by more EU countries but does normally not include standard measurement unit used for the result (some countries, e.g. Netherlands, however overcame this problem by specifying standard measurement unit for each LOINC test code in their national LOINC implementation standard). This aspect could be improved by use of agreed EU wide standard units, assigned to the agreed LOINC codes, and transfer of additional standardised coded information about test observation technique (method) and used measurement standards.

Neither LOINC nor NPU have coded result values. For this reason, users of both LOINC and NPU have adopted SNOMED CT for the coding of non-numerical results.

5.1.4.2.4.1 NPU and LOINC Comparison statistics

A data comparison between the two laboratory catalogues content has been performed. To perform this comparison both catalogues have been filtered using following filter parameters.

NPU (v210923)	LOINC (v2.71)
Active = 1 AND Proc. Not Contain "list"	Active = 1 AND ClassType = 1 AND ORDER_OBS IN ('Both','Observation')

The result is:

LAB Terminology system	Count	Components	System	Units
NPU (v210923)	22 656	7698	183	145
LOINC (v2.71)	56 209	26 279	398	679

Table 4 : Lab Catalogues Statistics

5.1.4.2.4.2 Conclusion

Both laboratory test coding systems could be used (in combination with additional coding systems for examination technique, specimen, test result value, device type and other coded parts of the test/observation result) for safe cross-border exchange of laboratory test orders and results and their qualities sufficiently address present needs. However, safe interoperable cross-border exchange will require establishment and use of European (pivot) value sets as we mentioned already in the chapter 1.2 Challenges and opportunities.

5.1.4.3 Test result value (observation value)

Laboratory test result values might be expressed using various result types – quantitative, ordinal, or nominal scales or using narrative text, depending on kind of measured property or other circumstances of measurement (e.g., broken tube). In many cases the results are being reported

using a designated terminology system. Measures and measured values are closely related. The type of measure is related to the scales which can be allocated to the measured value. Scale can be nominal or ordinal for qualitative results or quantitative e.g., for physical quantities (PQ).

5.1.4.3.1 Coding of quantitative results

The value of a quantity is expressed as a numeric value and a unit of measurement that defines this reference quantity. For HL7 CDA, physical quantities have to be presented with numerical values and UCUM units.

Units of measurements can be expressed by SI (International System of) Units, which are internationally agreed, scalable and convertible, or by so-called “arbitrary units” which can be internationally agreed (for example WHO units for substances with biological activity such as protein hormones and antibodies towards infectious diseases) or follow a local or internal calibration process or a specific measurement procedure.

The SI is based on a system of well-defined quantities including a set of equations defining the relations between those quantities. The relations between the quantities determine the equations relating the units. Quantities that describe biological effects are often difficult to relate to units of the SI. For example, the biological activity of certain substances used in medical diagnosis and therapy cannot yet be defined in terms of the SI based quantities.

For data quality purposes the measurand may be transported together with the test to be measured.

5.1.4.3.2 Coding of qualitative results

The set of potential result values is likely very large, ranging from smaller sets of ordinal scale values such as positive/negative, for example as in the EU DCC, to large sets of nominal scale values, for example all bacteria or (legal or illegal) drug substances. As SNOMED CT is the most extensive terminology in health care, this code system offers solutions for the coded representation of qualitative laboratory-related result values in most cases. The full set of required concepts will likely not be in the current SNOMED CT GPS.

The majority of coded results for reportable laboratory results fall into one of the following SNOMED CT hierarchies:

- Organism (410607006)
- Substance (105590001)
- Evaluation finding (441742003)
- Presence findings (260411009)
- Absence findings (272519000)

Also, the LOINC associated “answer lists” and dedicated HL7 vocabulary lists offer answers to measurable items in dedicated cases.

5.1.4.4 Specimen

Laboratory test names typically include the specimen (e.g., the LOINC "System") upon which the observation was made, but some attributes about the specimen can be carried in other parts of the

information or messaging model. Where such other specimen attributes are reported as coded values, they can use SNOMED CT concepts.

- Specimen type terms can be drawn from the 123038009 |Specimen| hierarchy in SNOMED CT
- Specimen source site terms can be drawn from the 123037004 |Body structure| hierarchy
- Specimen collection method terms can be drawn from the 71388002 |Procedure| hierarchy

5.1.4.5 Examination technique

Examination technique, sometimes also called laboratory test method, is a technique used to administer a particular examination or assessment. It means an adoption of a scientific technique for performing a specific measurement as documented in a laboratory standard operating procedure or as published by a recognised authority.

Information about the laboratory examination techniques is sometimes necessary for the correct interpretation of a laboratory result and for comparison of results from other laboratories. An examination technique, such as “immunoassay” or “mass spectrometry” indicates the accuracy and quality of the result and might in addition serve as a background information to the price charged by the laboratory for the service. To some extent, but not systematically, information about the examination technique (test method) is included in the LOINC code. Examination technique information is included in the NPU code only when necessary to define what is measured. The examination technique might be identified in a systematic way by a SNOMED CT code. For use in Sweden a ref-set has been created for structured information on measurement methods (examination techniques).

5.1.4.6 Laboratory specialty

Laboratory specialty is a meta-attribute of any laboratory setting representing professional qualification of the laboratory to execute certain kind of laboratory tests. Specialty could be used as parameter for searching/querying of laboratory test result and as such should be harmonised across Europe. As member states might have many different types of professional qualifications, specialties, and sub-specialties, we decided to propose a basic value set of common and core specialty types to which all member states could easily map. A SNOMED CT Clinical specialty (qualifier value)/Pathology hierarchy was taken as a source. We propose to add two additional laboratory specialties to SNOMED CT International (marked yellow).

Code (SNOMED CT)	Concept name (specialty)
394596001	Chemical pathology
394916005	Hematopathology
421661004	Blood banking and transfusion medicine
394915009	General pathology
394598000	Immunopathology
408454008	Clinical microbiology
New concept proposed to SNOMED CT	Genetic pathology
New concept proposed to SNOMED CT	Histocompatibility and Immunogenetics

5.1.4.7 Laboratory study/service types

Apart of laboratory specialty, which is an attribute of the laboratory, laboratory services, i.e., results of tests performed, could be characterised using typology of services, commonly called study types. Study type could be seen as a meta-attribute or grouping mechanism that assigns a common clinical sense to certain types of laboratory test results. Each laboratory or clinical practice has usually its own convention of grouping test results for easier navigation through a result report, however if a common standard display tool is to be prepared, like in case of MyHealth@EU project, a common set of study types should be agreed. Each laboratory test then could be assigned to one or more study types and/or sub-types in a hierarchical view.

Standard study types have been specified in the IHE XD-LAB profile³⁴ using LOINC code system.

Code	Name	X-eHealth*
18717-9	BLOOD BANK STUDIES	X
18718-7	CELL MARKER STUDIES	X
18719-5	CHEMISTRY STUDIES	X
18720-3	COAGULATION STUDIES	X
18721-1	THERAPEUTIC DRUG MONITORING STUDIES	X
18722-9	FERTILITY STUDIES	X
18723-7	HEMATOLOGY STUDIES	X
18724-5	HLA STUDIES	X
18725-2	MICROBIOLOGY STUDIES	X
18727-8	SEROLOGY STUDIES	X
18728-6	TOXICOLOGY STUDIES	X
18729-4	URINALYSIS STUDIES	
18767-4	BLOOD GAS STUDIES	X
18768-2	CELL COUNTS+DIFFERENTIAL STUDIES	
18769-0	MICROBIAL SUSCEPTIBILITY TESTS	X
26435-8	MOLECULAR PATHOLOGY STUDIES	
26436-6	LABORATORY STUDIES	X
26437-4	CHEMISTRY CHALLENGE STUDIES	
26438-2	CYTOLOGY STUDIES	
18716-1	ALLERGY STUDIES	X

*Study types recommended by the X-eHealth project

We collected examples from several countries that could serve as a basis for future agreement. SNOMED CT Procedure hierarchy or LOINC seems to be a potential candidate for a coding system.

Table 5: Standard study types used in the Czech Republic

Study type
Electrolytes
Enzymes
Proteins
Carbohydrates, aminosaccharides
Lipids

³⁴<https://art-decor.ihe-europe.net/art-decor/decor-valuesets--XDLAB-?id=1.3.6.1.4.1.19376.1.3.11.1&effectiveDate=2008-08-08T00:00:00&language=en-US>

Study type
Lipoproteins
Inorganic substances
Trace elements, metals
Organic (carboxylic) acid and their derivatives
Carbonyl compounds
Acid-base parameters, pH and blood gases
Hormones, mediators
Steroids
Purins and Pyrimidins
Tumor markers
Medications
Xenobiotics (except drugs)
Alcohol
Vitamins
Hepatal markers, AG and AB viral liver diseases
Antibodies
Antibodies of infectious diseases
Specific IgE
Specific IgE - only molecular allergens
Specific IgE - only other allergens
Specific IGG4
Auto-antibodies
Antibodies against antigens of external environment
Antigens
Antigens of infectious diseases
Amino acids
Nucleic acids, nucleosides and nucleotides
Receptors
Cyclic derivatives of hemoproteins
Blood Group Systems
Blood cells, their altered forms and characteristics
Blood cells and their forms
Aggregation
Coagulation
Leukocytes, their modified forms and characteristics
Erythrocytes, their modified forms and characteristics
Platelets, their altered forms and characteristics
Tissue cells
Gamete (sex) cells

Study type
Viruses
Bacteria
Mushrooms and molds
Parasites
Stones
Non-cellular organisms
Functional tests
Functional stress tests (Observation over an interval of time)
Tracking at a time interval
Anthropometric variables
Calculated results
Calculations for metabolic balance
Other components
Signals and auxiliary values of the meters, intra-laboratory

Table 6: Standard study types used in Sweden

Study type
general (body weight, height)
haematology and inflammation
coagulation (hemostasis)
metabolism and heart disease
electrolyte and renal disorders
gastrointestinal disorders
endocrinology
microbiology
tests in cerebrospinal fluid
therapeutic drug monitoring
tumor markers
tests in other fluids
blood gas measurements
immunology
allergology
antibiotics (susceptibility tests)

Table 7: Standard study types used in Ireland

Study type
General Haematology
Coagulation
Haemoglobinopathies
Immunophenotyping
Haematology Bone Marrows
Biochemistry
Endocrinology
Toxicology
Therapeutic Drug Monitoring
Specialist Biochemistry
Dynamic Function Tests
Haematinics
Autoimmune Serology
Immunodeficiency
Cellular Immunology
Protein Electrophoresis/Immunofixation
Allergy
Blood Gasses
General Bacteriology
Molecular Microbiology
Mycology
Mycobacteriology
Serology
Parasitology
Serological Virology
Molecular Virology
Surgical Pathology
Gynae Cytology
Non-Gynae Cytology
Non-Gynae Pathology
Pathology Bone Marrows
Autopsy Report
Autopsy Neuropathology
Non Coroner's Autopsy
Renal Pathology
Renal Light Microscopy
Renal Electron Microscopy
Neuropathology
Immunofluorescence

Study type
Molecular Anatomic Pathology
Molecular Haematology
Molecular Coagulation
Molecular Biochemistry
Cancer Molecular Genetics
Molecular Immunology
Histocompatibility
HLA studies
Near Patient testing

A draft proposal for test grouping based on XD-LAB study types and synthesis of grouping from several European countries (three examples are displayed in tables above) has been prepared by the X-eHealth project team. Elaboration of European set of study types might need further elaboration as well as selection of a coding system.

Table 8: X-eHealth proposal for hierarchical study types

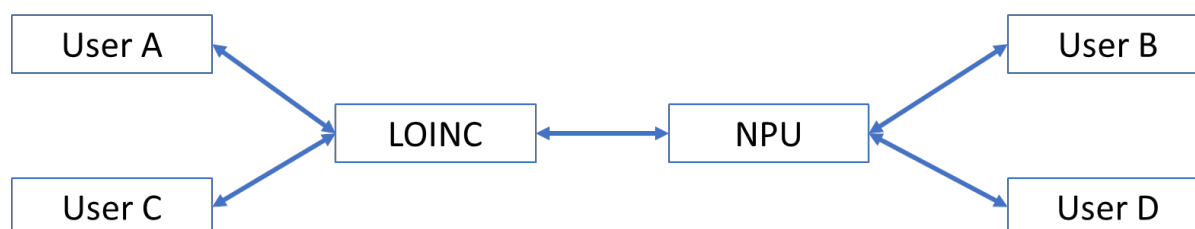
Code	Study type	Study sub-type	SCT Name
18716-1	ALLERGY STUDIES	Allergology	In vivo test of hypersensitivity (procedure)
18717-9	BLOOD BANK STUDIES	Autoimmunity	Autoantibody measurement (procedure)
		Immunohaematology	Laboratory test related to immunohematology (procedure)
18719-5	CHEMISTRY STUDIES	Autoimmunity	Autoantibody measurement (procedure)
		Blood gas measurements	Blood gas analysis (procedure)
		Cardiac markers	Cardiac markers (procedure)
		Cerebrospinal fluid	Evaluation of cerebrospinal fluid (procedure)
		Electrolytes	Electrolytes measurement (procedure)
		Endocrinology	Endocrine studies (procedure)
		Enzymes	Enzyme measurement (procedure)
		Lipids	Lipids measurement (procedure)
		Proteins	Protein measurement (procedure)
		Serology	Serologic test (procedure)
		Tumor markers	Tumor marker measurement (procedure)
		Vitamins	Vitamin measurement (procedure)
		Urinanalysis	Evaluation of urine specimen (procedure)
		Functional tests	Functional assessment (procedure)
		Trace elements	Essential elements screen (procedure)
18722-9	FERTILITY STUDIES	Sperm analysis	Sperm measurement (procedure)

Code	Study type	Study sub-type	SCT Name
18723-7	HEMATOLOGY STUDIES	Coagulation (haemostasis)	Laboratory test related to hemostasis (procedure)
		Haematology	Hematology procedure (procedure)
18725-2	MICROBIOLOGY STUDIES	Bacteriology	Bacteriology - general (procedure)
		Parasites	Detection of parasite (procedure)
		Viruses	Detection of virus
		Microbial susceptibility tests	Culture and susceptibility (procedure)
18728-6	TOXICOLOGY STUDIES	Drugs of abuse	Drug of abuse screen (procedure)
		Therapeutic drug monitoring	Medication monitoring (regime/therapy)
		Heavy metals	Heavy metals measurement (procedure)
		Trace elements	Essential elements screen (procedure)

5.1.4.8 Mapping between different test coding systems

Only few attempts have been made to map a concept from one terminology system used by User A to a concept in another terminology system used by User B, including pilot investigation on the possibility to map NPU codes to SNOMED CT in parallel to what has been done for LOINC³⁵.

Figure 2: The same concept, e.g., a specific laboratory test, must be understood in the same way by all users, independent of the coding system used.



To ensure an unambiguous data exchange across the EU, a mapping between both coding systems on an EU level is recommended. Different national mapping initiatives could result in mismatches that might be difficult to detect and to dissolve.

A mapping between NPU and LOINC codes must by necessity include some presumptions regarding, at least specimen type, measurement principles, measurement unit and traceability of results. Although this is not a trivial task, it is probably doable as shown in the LOINC-SNOMED CT collaboration project. However, for User A to correctly understand User C in the figure above, and vice versa, both users must have implemented LOINC laboratory test coding system or mapping to it in their local systems (LIS or EHR) in the same way. Likewise, User B and D must have implemented the NPU coding system in the same way.

³⁵ <https://loinc.org/collaboration/snomed-international/>

It remains to be investigated how strict LOINC and NPU codes really are implemented in the different countries to evaluate the feasibility to use the coding systems as identifiers for cross-border exchange of laboratory data.

Specification of the laboratory examination technique (test method) is in some cases critical, e.g., to understand the detection limits (test sensitivity) and specificity. Compare the difference between the different techniques used to measure SARS-Cov-2 RNA and antibody tests respectively:

- SARS-Cov-2 RNA detection, whether based on sequencing, Nucleic acid amplification with or without probe-based detection
- SARS-Cov-2 antibody detection whether based on rapid immunoassay, immunoassay or pseudovirus neutralisation test

SARS-Cov-2 RNA quantitative tests results can now be traceable to the first WHO International Standard for SARS-CoV-2 RNA (NIBSC code: 20/146) which makes measurement results comparable if traceable to the same calibrator.

1. **Conclusion:** To facilitate data exchange across EU member states, a mapping between NPU and LOINC developed on an EU level is recommended and feasible but complex. This mapping should consider also test examination techniques and metrological traceability of results. Such mapping is outside scope of this project, but examples will be provided.
2. Despite the complexity of a potential mapping system between the LOINC and NPU codes, it will not represent a bottleneck for cross-border laboratory data exchange. Major problem will instead represent their proper local implementation of the coding system and their use by national infrastructures.

Here we present an example of mapping from LOINC to NPU. More details on mapping will be provided in a separate document.

Table 9: Example of LOINC - NPU laboratory test mapping

LOINC Long common name	LOINC system	LOINC property	LOINC example unit	LOINC code	NPU definition	NPU system	NPU property	NPU Unit	NPU code	Comment
Hemoglobin [Mass/volume] in Blood	Blood	mass concentration	g/dL	718-7	Blood—Haemoglobin; mass concentration.	Blood	Mass concentration	g/L	NPU28309	Equivalent meaning. American versus English spelling. Values must be recalculated according to units.
Valproate Free/Valproate.total in Serum or Plasma	Serum or plasma	Mass fraction	%	32283-4	Valproate(P)—Valproate(free); substance fraction	Valproate	Mass fraction	1	NPU60421	Equivalent meaning, but different syntax. Values must be recalculated according to units.
EPINEPHrine [Moles/volume] in Plasma	Plasma	Substance concentration	nmol/L	14711-6	Plasma—Adrenalinium; substance.concentration	Plasma	Substance concentration	μmol/L	NPU14042	Equivalent meaning. American versus English spelling. Values must be recalculated according to units.
C reactive protein [Mass/volume] in Serum or Plasma	Serum or Plasma	Mass concentration	mg/L	1988-5	Plasma—C-reactive protein; mass concentration.	Plasma	Mass concentration	mg/L	NPU19748	Equivalent meaning
C reactive protein [Mass/volume] in Serum or Plasma by High sensitivity method	Serum or Plasma	Mass concentration	mg/L	30522-7						LOINC concept is narrower, as it is reserved for “high sensitivity” methods
C reactive protein [Mass/volume] in Capillary blood	Capillary blood	Mass concentration	mg/L	48421-2						LOINC concept is narrower, as it is reserved for capillary specimen
C reactive protein [Mass/volume] in Blood by High sensitivity method	Blood	Mass concentration	mg/L	71426-1						LOINC concept is narrower as it is reserved for whole blood specimen
Thyrotropin [Units/volume] in Serum or Plasma	Serum or Plasma	Arbitrary concentration	mIU/L	3016-3						
					Plasma—Thyrotropin; arb.subst.c.(IRP 81/565; proc.)	Plasma	Arbitrary substance concentration	10 ⁻³ IU/L	NPU27547	NPU concept is narrower as it is reserved for traceability of results to a specific standard (the definition of “IU”)
					Plasma—Thyrotropin; arb.subst.c.(IRP 68/38; proc.)	Plasma	Arbitrary substance concentration	10 ⁻³ IU/L	NPU04026	NPU concept is narrower as it is reserved for traceability of results to a specific standard (the definition of “IU”)
					Plasma—Thyrotropin; arb.subst.c.(IRP 80/558; proc.)	Plasma	Arbitrary substance concentration	10 ⁻³ IU/L	NPU03577	NPU concept is narrower as it is reserved for traceability of results to a specific standard (the definition of “IU”)
Thyrotropin [Units/volume] in Serum or Plasma by Detection limit <= 0.05 mIU/L	Serum or Plasma	Arbitrary concentration	mIU/L	11579-0						LOINC concept is narrower and restricted to methods with a spec detection limit
Thyrotropin [Units/volume] in Serum or Plasma by Detection limit <= 0.005 mIU/L	Serum or Plasma	Arbitrary concentration	mIU/L	11580-8						LOINC concept is narrower and restricted to methods with a spec detection limit

5.1.4.9 Generic requirements for interoperable laboratory test ordering and result sharing

- Laboratory tests must be precisely and unambiguously specified.
- Laboratory test specification should include information about specimen type or the investigated system, analyte (component), the test examination technique (method), the property of measurement, the timing (e.g., point in time, period of sample collection, if relevant), and measurement unit.
- A display name compiling main information of the different axes of the lab test terminology (e.g., long common name in LOINC or short definition in NPU) must be available, at least in English, preferably in recipients' native language.
- The units must be scalable – use of derived units which can always be represented as products of powers of the base units must be possible.
- It should be possible to group and aggregate codes on a higher granularity level (for example the same items regardless of the examination technique) or for comparable measurements.
- The lab result must be interpreted.

5.1.5 Information

Modelling approach in this document is based on the clinical information modelling standards as described by ISO/TS 13972:2015. Logical laboratory information model was divided in several parts (partial models) due to its complexity. Some of the partial models are specific for laboratory domain while other models are more general. All models could be reused also outside laboratory domain, e.g., to model hospital discharge reports or imaging reports. Common part of logical model comprises of the following parts:

-
- Address Information Model
- Anatomical Location Information Model
- Contact Information Model
- Contact Person Information Model
- Container Information Model
- Condition Information Model
- Condition Stage Information Model
- Encounter Information Model
- Group Information Model
- Healthcare Professional Information Model
- Healthcare Provider Information Model
- Laboratory Test Specification
- Location Information Model

- Organisation Part Information Model
- Patient Information Model
- Payer Information Model
- Person Name Information Model
- Specimen Information Model
- Test Panel
- Time Interval Information Model

Laboratory specific information models can be found in chapter 5.2.1.7.1 and 5.2.2.7.1.

The entire information model for all X-eHealth domains can be found in browsable form at <https://x-ehealth.min-saude.pt>.

5.1.5.1 Address Information Model

Address information model describes partial information model of address information. Address information, if not null, must include at least a StreetAddressLine sub element.

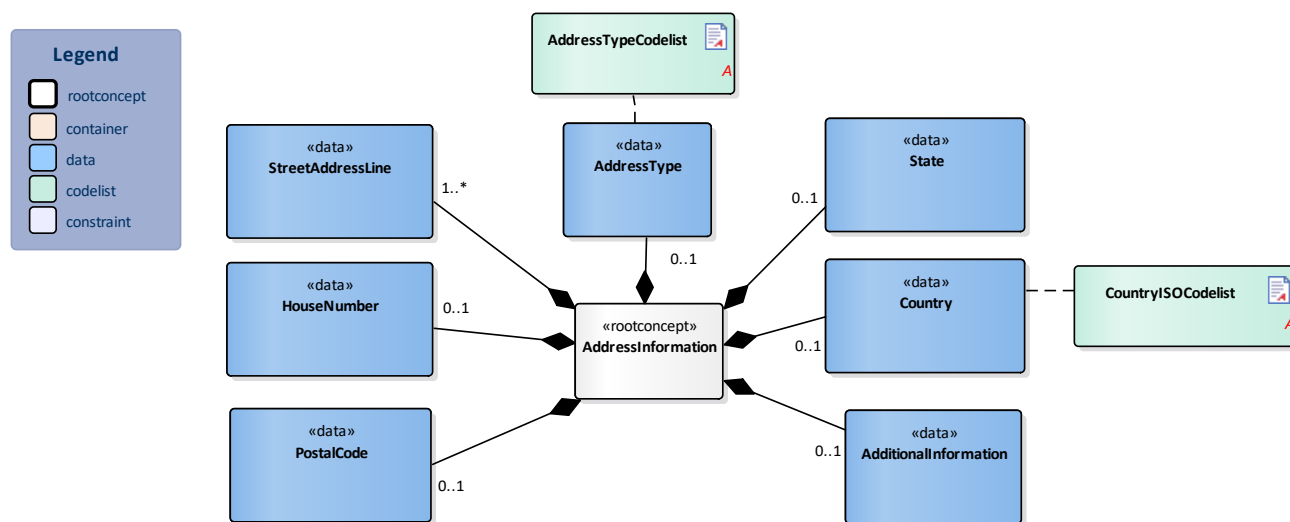


Figure 3: Address Information Model

Type	Concept	Card	Description
«rootconcept»	AddressInformation		Root concept of the AddressInformation partial information model. This root concept contains all data elements of the AddressInformation partial information model.
«data»	StreetAddressLine	1..*	Street Address line.
«data»	HouseNumber	0..1	House number of the address.
«data»	PostalCode	0..1	PostalCode of the address, also known as a ZIP code.
«data»	State	0..1	State or province.

Type	Concept	Card	Description
«data»	Country	0..1	Country in which the address is located.
«data»	Additional Information	0..1	Extra information such as the building name, building number, entrance, route number.
«data»	AddressType	0..1	The type of address in question, such as a home address or mailing address.

CountryISOCodeList		OID:
Codes	Coding Syst. Name	Coding System OID
All values	ISO 3166-1 (alpha-2)	1.0.3166.1.2.2

AdresTypeCodeList			OID:	
ConceptName	Code	Code System	Code System OID	Description
Postal Address	PST	hl7:AddressUse	2.16.840.1.113883.5.1119	Used to send mail.
Primary Home	HP	hl7:AddressUse	2.16.840.1.113883.5.1119	The primary home, to reach a person.
Visit Address	PHYS	hl7:AddressUse	2.16.840.1.113883.5.1119	Used primarily to visit an address.
Temporary Address	TMP	hl7:AddressUse	2.16.840.1.113883.5.1119	A temporary address.
Work Place	WP	hl7:AddressUse	2.16.840.1.113883.5.1119	An office address.
Vacation Home	HV	hl7:AddressUse	2.16.840.1.113883.5.1119	A vacation home, to reach a person while on vacation.

5.1.5.2 Anatomical Location Information Model

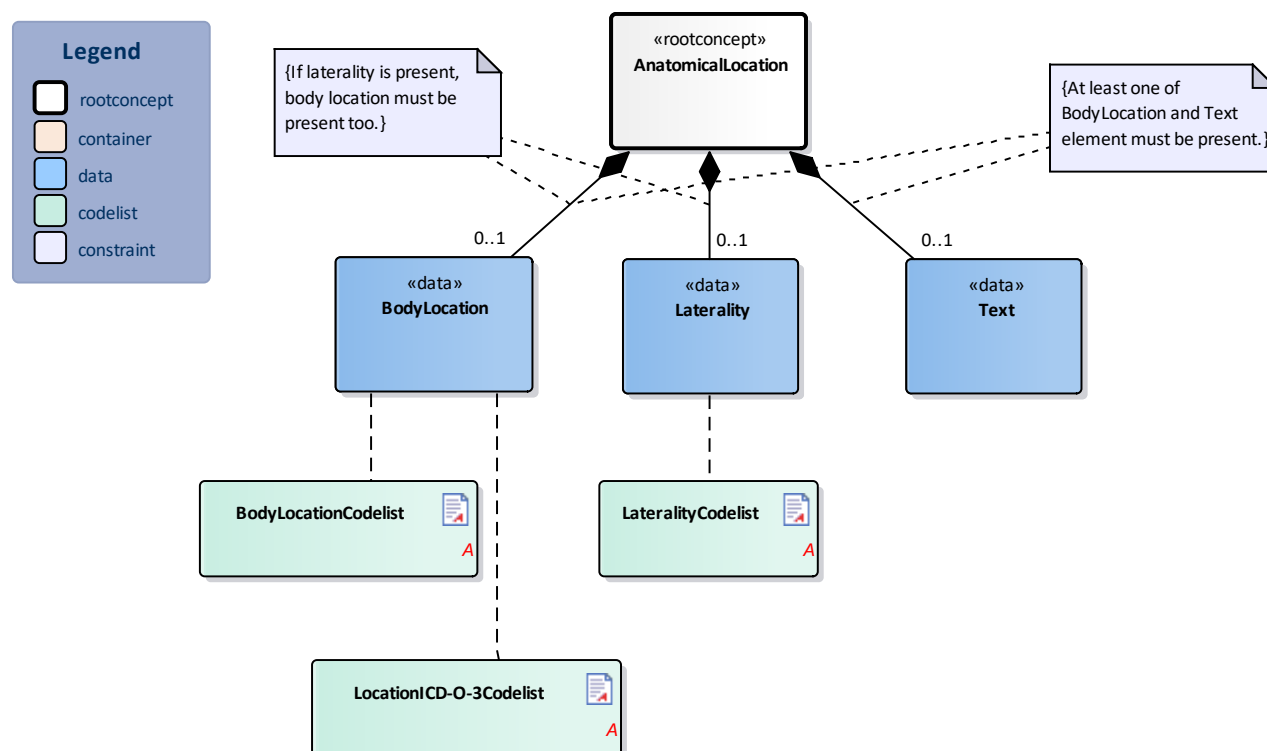


Figure 4: Anatomical Location Information Model

Type	Concept	Card	Description
«rootconcept»	AnatomicalLocation		Root concept of the AnatomicalLocation partial information model. This root concept contains all data elements of the AnatomicalLocation partial information model.
«data»	Text	0..1	Human readable specification of the body side location.
«data»	BodyLocation	0..1	Localization on/in the body.
«data»	Laterality	0..1	Body side of the body location, if needed to distinguish from a similar location on the other side of the body.

BodyLocationCodelist		OID:	
Codes		Coding Syst. Name	Coding System OID
SNOMED CT < 123037004 Body structure		SNOMED CT	2.16.840.1.113883.6.96

LocationICD-O-3Codelist		OID:
Codes	Coding Syst. Name	Coding System OID
International Classification of Diseases for Oncology, version 3 (Topography codes)	ICD-O-3	2.16.840.1.113883.6.43.1

LateralityCodelist			OID:	
Concept Name	Concept Code	Coding System Name	Coding System OID	Description
left	7771000	SNOMED CT	2.16.840.1.113883.6.96	Left
right	24028007	SNOMED CT	2.16.840.1.113883.6.96	Right
bilateral	51440002	SNOMED CT	2.16.840.1.113883.6.96	Bilateral

5.1.5.3 Contact Information Model

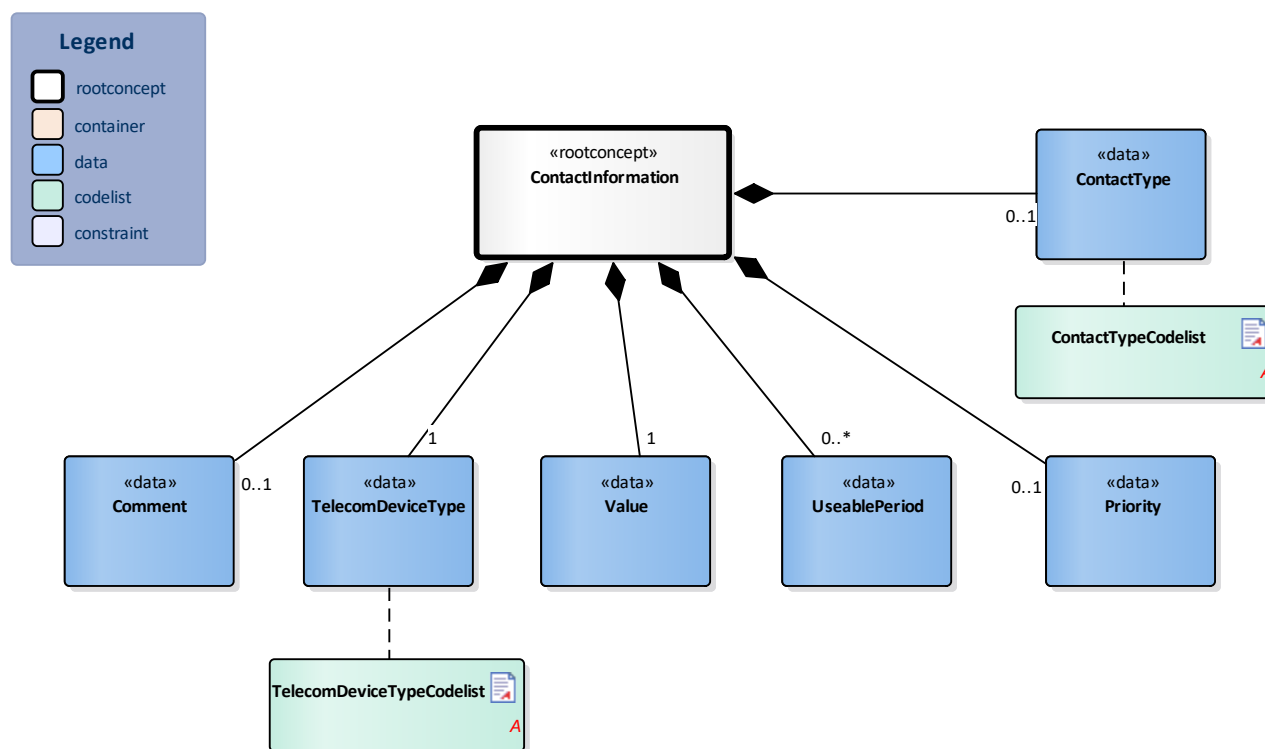


Figure 5: Contact Information Model

Type	Concept	Card	Description
«rootconcept»	ContactInformation		Root concept of the ContactInformation partial information model. This root concept contains all data elements of the ContactInformation partial information model.
«data»	Priority	0..1	Preferred order of use (1 = highest)
«data»	Value	1	Contact details, e.g. telephone number, e-mail, URL.

Type	Concept	Card	Description
«data»	TelecomDeviceType	1	The telecom or device type that the telephone number is connected to.
«data»	ContactType	0..1	ContactType indicates type of the contact, e.g. home, work, mobile etc..
«data»	Comment	0..1	Explanation about contact point and how to use it. It can be indicated, for example, that it is a department telephone number (for healthcare professionals) or that availability by phone is only possible during a specified part of the day.
«data»	UseablePeriod	0..*	Specifies the periods of time during which the telecommunication address can be used.

TelecomDeviceTypeCodelist			OID:	
ConceptName	Code	Code System	Code System OID	Description
Phone	phone	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
Fax	fax	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
Email	email	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
URL	url	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
Pager	pager	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
SMS	sms	ContactPointSystem	2.16.840.1.113883.4.642.4.72	
Other	other	ContactPointSystem	2.16.840.1.113883.4.642.4.72	

ContactTypeCodelist			OID:	
ConceptName	Code	Code System	Code System OID	Description
Home	home	ContactPointUse	2.16.840.1.113883.4.642.4.74	
Temp	temp	ContactPointUse	2.16.840.1.113883.4.642.4.74	Temporary contact point. The period can provide more detailed information.
Work	work	ContactPointUse	2.16.840.1.113883.4.642.4.74	
Old	old	ContactPointUse	2.16.840.1.113883.4.642.4.74	Old or not valid address
Mobile	mobile	ContactPointUse	2.16.840.1.113883.4.642.4.74	A telecommunication device that moves and stays with its owner.

5.1.5.4 Contact Person Information Model

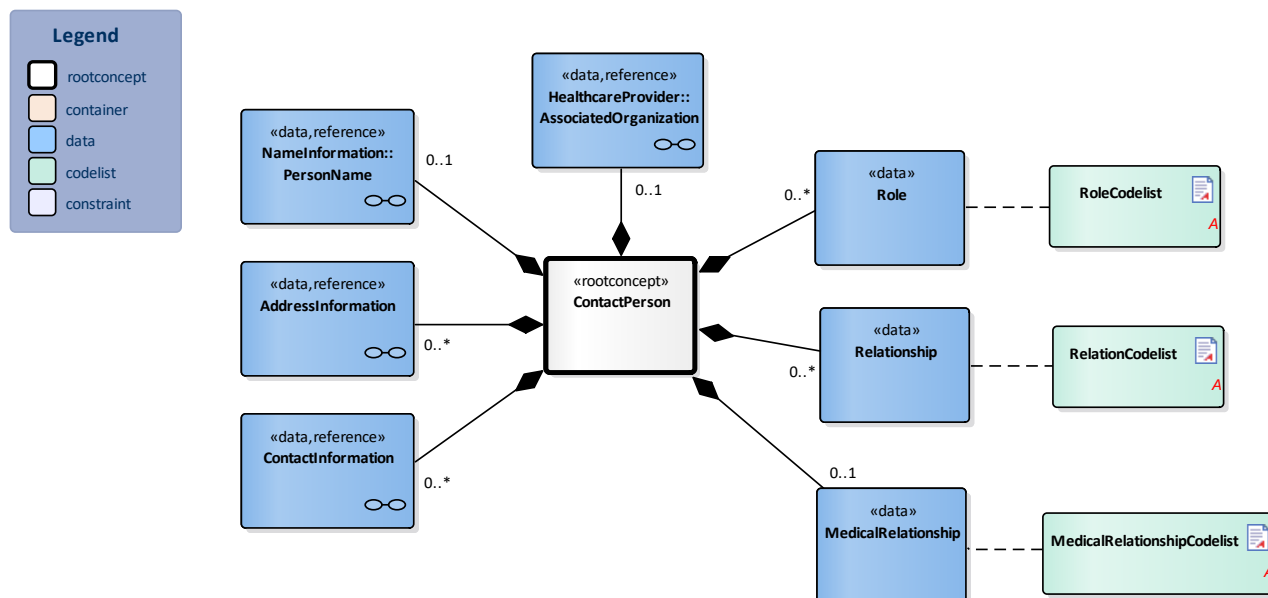


Figure 6: Contact Person Information Model

Type	Concept	Card	Description
«rootconcept»	ContactPerson		Root concept of the ContactPerson information model. This root concept contains all data elements of the Contact information model.
«data»	HealthcareProvider::AssociatedOrganization	0..1	Organisation associated with the contact person.
«data»	MedicalRelationship	0..1	Defines the contact medical relationship to the patient.
«data»	NameInformation::PersonName	0..1	Full name of the contact.
«data»	ContactInformation	0..*	The contact's telephone number and/or e-mail address.
«data»	AddressInformation	0..*	Contact's address information.
«data»	Role	0..*	Defines the role of the contact in relation to the patient.
«data»	Relationship	0..*	Defines the contact's familial relationship to the patient.

MedicalRelationCodeList			OID:	
ConceptName	Code	CodeSystem	CodeSystemOID	Description
RD centre				Rare disease centre
GP				General practitioner

TSP				Treating specialist
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RelationCodelist			OID:	
ConceptName	Code	CodeSystem	CodeSystemOID	Description
Adoptive father	ADOPTF	RoleCode	2.16.840.1.113883.5.111	
Adoptive mother	ADOPTM	RoleCode	2.16.840.1.113883.5.111	
Aunt	AUNT	RoleCode	2.16.840.1.113883.5.111	
Brother	BRO	RoleCode	2.16.840.1.113883.5.111	
Brother-in-law	BROINLAW	RoleCode	2.16.840.1.113883.5.111	
Cousin	COUSN	RoleCode	2.16.840.1.113883.5.111	
Daughter	DAUC	RoleCode	2.16.840.1.113883.5.111	
Daughter in-law	DAUINLAW	RoleCode	2.16.840.1.113883.5.111	
Domestic partner	DOMPART	RoleCode	2.16.840.1.113883.5.111	
Father	FTH	RoleCode	2.16.840.1.113883.5.111	
Father-in-law	FTHINLAW	RoleCode	2.16.840.1.113883.5.111	
Foster daughter	DAUFOST	RoleCode	2.16.840.1.113883.5.111	
Foster father	FTHFOST	RoleCode	2.16.840.1.113883.5.111	
Foster mother	MTHFOST	RoleCode	2.16.840.1.113883.5.111	
Foster son	SONFOST	RoleCode	2.16.840.1.113883.5.111	
Granddaughter	GRNDDAU	RoleCode	2.16.840.1.113883.5.111	
Grandfather	GRFTH	RoleCode	2.16.840.1.113883.5.111	
Grandmother	GRMTH	RoleCode	2.16.840.1.113883.5.111	
Grandson	GRNDSON	RoleCode	2.16.840.1.113883.5.111	
Great grandfather	GGRFTH	RoleCode	2.16.840.1.113883.5.111	
Great grandmother	GGRMTH	RoleCode	2.16.840.1.113883.5.111	
Husband	HUSB	RoleCode	2.16.840.1.113883.5.111	
Mother	MTH	RoleCode	2.16.840.1.113883.5.111	
Mother-in-law	MTHINLAW	RoleCode	2.16.840.1.113883.5.111	
Nephew	NEPHEW	RoleCode	2.16.840.1.113883.5.111	
Niece	NIECE	RoleCode	2.16.840.1.113883.5.111	
Sister	SIS	RoleCode	2.16.840.1.113883.5.111	
Sister-in-law	SISINLAW	RoleCode	2.16.840.1.113883.5.111	

RelationCodelist			OID:	
ConceptName	Code	CodeSystem	CodeSystemOID	Description
Son	SONC	RoleCode	2.16.840.1.113883.5.111	
Son in-law	SONINLAW	RoleCode	2.16.840.1.113883.5.111	
Stepfather	STPFTH	RoleCode	2.16.840.1.113883.5.111	
Stepmother	STPMTH	RoleCode	2.16.840.1.113883.5.111	
Uncle	UNCLE	RoleCode	2.16.840.1.113883.5.111	
Wife	WIFE	RoleCode	2.16.840.1.113883.5.111	
Other	OTH	NullFlavor	2.16.840.1.113883.5.1008	

RoleCodelist			OID:	
ConceptName	Code	Code System	Code System OID	Description
All elements		ParticipationFunction	2.16.840.1.113883.5.88	

5.1.5.5 Container Information Model

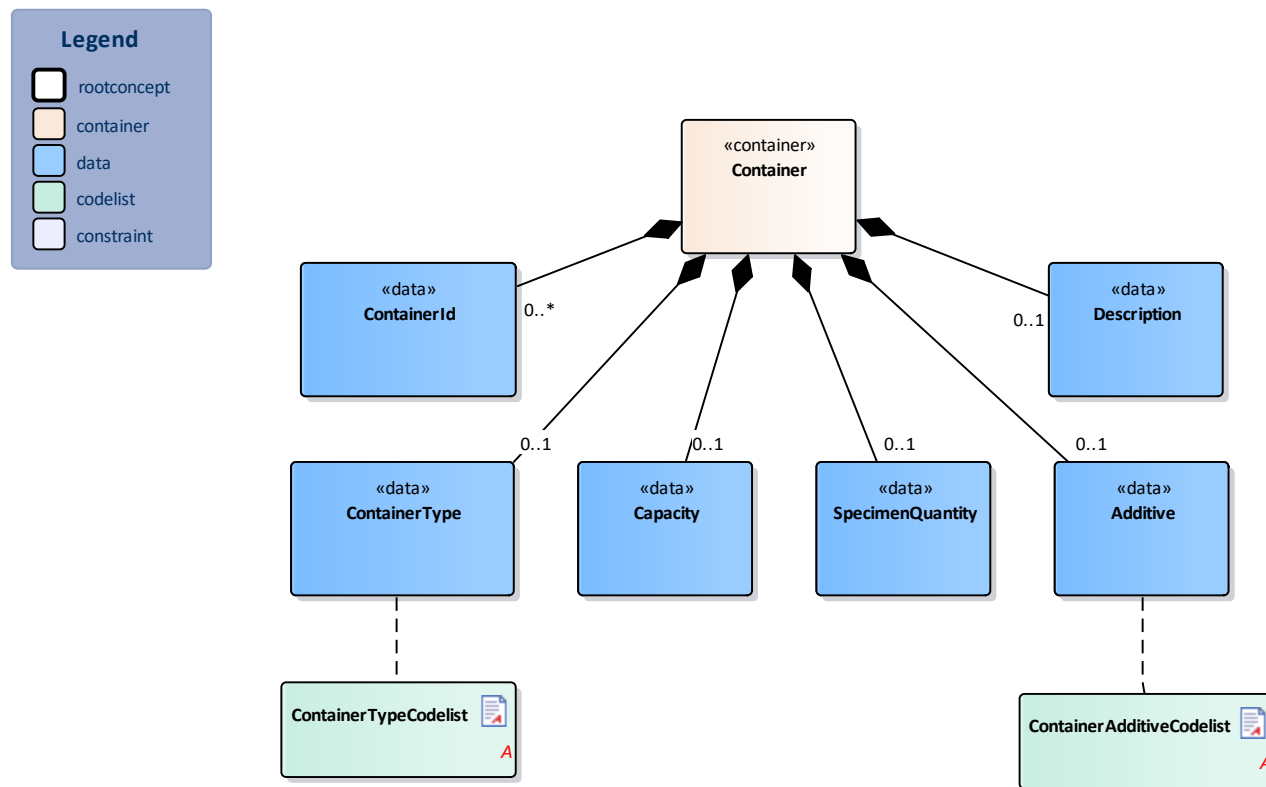


Figure 7: Container Information Model

Type	Concept	Card	Description
«container»	Container		The container holding the specimen. The recursive nature of containers; i.e. blood in tube in tray in rack is not addressed here.
«data»	ContainerId	0..*	Id for container. There may be multiple; a manufacturer's bar code, lab assigned identifier, etc. The container ID may differ from the specimen id in some circumstances.
«data»	ContainerType	0..1	Container type describes the envelope in which the material is collected or sent. Examples include blood tubes, transport container, possibly including culture medium.
«data»	Capacity	0..1	The capacity (volume or other measure) the container may contain.
«data»	SpecimenQuantity	0..1	The quantity of specimen in the container; may be volume, dimensions, or other appropriate measurements, depending on the specimen type.
«data»	Additive	0..1	Introduced substance to preserve, maintain or enhance the specimen. Examples: Formalin, Citrate, EDTA.
«data»	Description	0..1	Textual description of the container.

ContainerAdditiveCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All codes of hl7:AdditivePreservative code system	http://terminology.hl7.org/CodeSystem/v2-0371	

ContainerTypeCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 706046003 Specimen receptacle (physical object)	SNOMED CT	2.16.840.1.113883.6.96

5.1.5.6 Condition Information Model

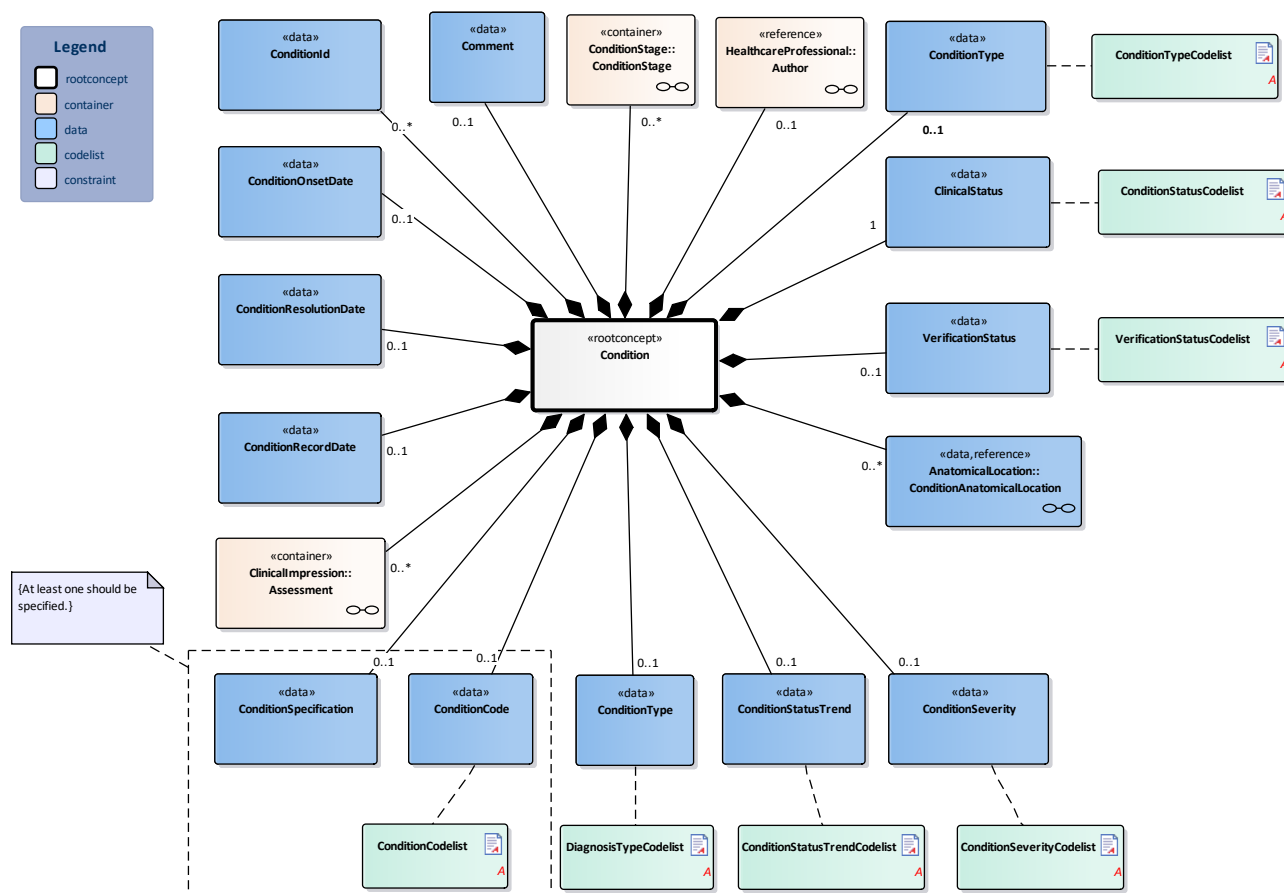


Figure 8: Condition Information Model

Type	Concept	Card	Description
«rootconcept»	Condition		Root concept of the Condition (problem) information model. A clinical condition, problem, diagnosis, or other event, situation, issue, or clinical concept that has risen to a level of concern. A condition describes a situation with regard to an individual's health and/or welfare. This situation can be described by the patient themselves (in the form of a complaint) or by their health professional (in the form of a diagnosis, for example).
«container»	ConditionStage	0..*	A clinical condition, problem, diagnosis, or other event, situation, issue, or clinical concept that has risen to a level of concern, expressed as a stage/grade, usually assessed formally.
«container»	HealthcareProfessional::Author	0..1	A healthcare professional who authored information about the problem.
«data»	ConditionType	0..1	Type of the diagnosis is used to distinguish between the primary reason of the encounter, comorbidity, and complication.
«data»	ClinicalStatus	1	Clinical status describes the condition of the problem: Active problems are problems of which the patient experiences symptoms or for which evidence exists. If condition is abated, then clinicalStatus must be either inactive, resolved, or remission

Type	Concept	Card	Description
			Condition with the status 'Inactive' refer to conditions that don't affect the patient anymore or that of which there is no evidence of existence anymore.
«data»	VerificationStatus	0..1	The verification status to support the clinical status of the condition.
«data»	AnatomicalLocation::ConditionAnatomicalLocation	0..*	Anatomical location which is the focus of the problem.
«data»	ConditionSeverity	0..1	A subjective assessment of the severity of the condition as evaluated by the clinician.
«data»	ConditionStatusTrend	0..1	How patient's given disease, condition, or ability is trending.
«data»	ConditionType	0..1	The type of problem; see the concept description.
«data»	ConditionCode	0..1	The problem code specifies the problem. Depending on the setting, different code systems can be used. The ProblemCodeList provides an overview of the possible code systems.
«data»	ConditionSpecification	0..1	Human readable specification of the problem. This is a general notes/comments entry for description of the problem, its diagnosis and prognosis.
«container»	ClinicalImpression::Assessment	0..*	Assessment and prognosis of future development of the condition.
«data»	ConditionRecordDate	0..1	Date (and time) when this problem was recorded into information system.
«data»	ConditionResolutionDate	0..1	The date or estimated date that the condition resolved or went into remission. A 'vague' date, such as only the year or the month and the year, is permitted
«data»	ConditionOnsetDate	0..1	Onset of the symptom, complaint, functional limitation, complication or date of diagnosis. A 'vague' date, such as only the year or the month and the year, is permitted.
«data»	ConditionId	0..*	Globally unique identifier of this problem which remain constant as the resource is updated and propagates from server to server.
«data»	Comment	0..1	Comment by the one who determined or updated the Problem.

ConditionSeverityCodeList			OID:
Concept Name	Concept Code	Codesystem	Codesystem OID
Severe	24484000	SNOMED CT	2.16.840.1.113883.6.96
Life threatening severity	442452003		
Mild	255604002		
Mild to moderate	371923003		
Moderate	6736007		
Moderate to severe	371924009		

ConditionstatusTrendCodeList		OID:	
Name	Code	Coding Syst. Name	Coding System OID
Not detected (qualifier)	260415000	SNOMED CT	2.16.840.1.113883.6.96
Patient condition improved (finding)	268910001	SNOMED CT	2.16.840.1.113883.6.96

ConditionstatusTrendCodelist		OID:	
Name	Code	Coding Syst. Name	Coding System OID
Patient's condition stable (finding)	359746009	SNOMED CT	2.16.840.1.113883.6.96
Patient's condition worsened (finding)	271299001	SNOMED CT	2.16.840.1.113883.6.96
Patient condition undetermined (finding)	709137006	SNOMED CT	2.16.840.1.113883.6.96

DiagnosisTypeCodelist		OID:	
Name	Code	Coding Syst. Name	Coding System OID
Primary diagnosis			
Comorbidity (present at admission)			
Complication (acquired during the inpatient stay)			

ConditionCodelist		OID:	
Codes	Coding Syst. Name	Coding System OID	
All codes	ICD-10 WHO		
SNOMED CT: ^11721000146100 RefSet Patientproblemen V&VN	SNOMED CT	2.16.840.1.113883.6.96	
no-known-problems	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	
no-problem-info	IPS Absent and Unknown Data	2.16.840.1.113883.5.1150.1	
All codes	ORPHACode		
CORE Problem list	SNOMED CT		
All concepts where concept is-a 404684003 (Clinical finding)	SNOMED CT		
All codes	ICD-11 WHO		

VerificationStatusCodelist			OID:	
Concept Name	Concept Code	Codesystem	Codesystem OID	Description
Suspected	415684004	SNOMED CT	2.16.840.1.113883.6.96	Work
Known possible	410590009	SNOMED CT	2.16.840.1.113883.6.96	Differential
Confirmed present	410605003	SNOMED CT	2.16.840.1.113883.6.96	Confirmed
Known absent	410516002	SNOMED CT	2.16.840.1.113883.6.96	
Unknown	UNK	NullFlavor	2.16.840.1.113883.5.1008	Unknown
Unconfirmed	unconfirmed	hl7:ConditionVerificationStatus	2.16.840.1.113883.4.642.4.1075	There is not sufficient diagnostic and/or clinical evidence to treat this as a confirmed condition.
Provisional	provisional			This is a tentative diagnosis - still a candidate that is under consideration.
Differential	differential			One of a set of potential (and

VerificationStatusCodelist			OID:	
Concept Name	Concept Code	Codesystem	Codesystem OID	Description
				typically mutually exclusive) diagnoses asserted to further guide the diagnostic process and preliminary treatment.
Confirmed	confirmed			There is sufficient diagnostic and/or clinical evidence to treat this as a confirmed condition.
Refuted	refuted			This condition has been ruled out by diagnostic and clinical evidence.
Entered in error	entered-in-error			

ConditionTypeCodelist			OID:	
Concept Name	Concept Code	Codesystem	Codesystem OID	Description
Diagnosis	282291009	SNOMED CT	2.16.840.1.113883.6.96	
Symptom	418799008	SNOMED CT	2.16.840.1.113883.6.96	
Finding	404684003	SNOMED CT	2.16.840.1.113883.6.96	
Complaint	409586006	SNOMED CT	2.16.840.1.113883.6.96	
Functional Limitation	248536006	SNOMED CT	2.16.840.1.113883.6.96	
Complication	116223007	SNOMED CT	2.16.840.1.113883.6.96	

ConditionStatusCodelist			OID:	
Concept Name	Concept Code	Codesystem	Codesystem OID	Description
Active	active	hl7:ConditionClinicalStatusCodes	2.16.840.1.113883.4.642.4.1074	The subject is currently experiencing the symptoms of the condition or there is evidence of the condition.
Recurrence	recurrence			The subject is experiencing a re-occurrence or repeating of a previously resolved condition, e.g. urinary tract infection, pancreatitis, cholangitis, conjunctivitis.
Relapse	relapse			The subject is experiencing a return of a condition, or signs and symptoms after a period of improvement or remission, e.g. relapse of cancer, multiple sclerosis, rheumatoid arthritis, systemic lupus erythematosus, bipolar disorder, [psychotic relapse of] schizophrenia, etc.
Inactive	inactive			The subject is no longer experiencing the symptoms of the condition or there is no longer evidence of the condition.
Remission	remission			The subject is no longer experiencing the symptoms of the condition, but there is a risk of the symptoms returning.
Resolved	resolved			The subject is no longer experiencing the symptoms of the condition and there is a negligible perceived risk of the symptoms returning.

5.1.5.7 Condition Stage Information Model

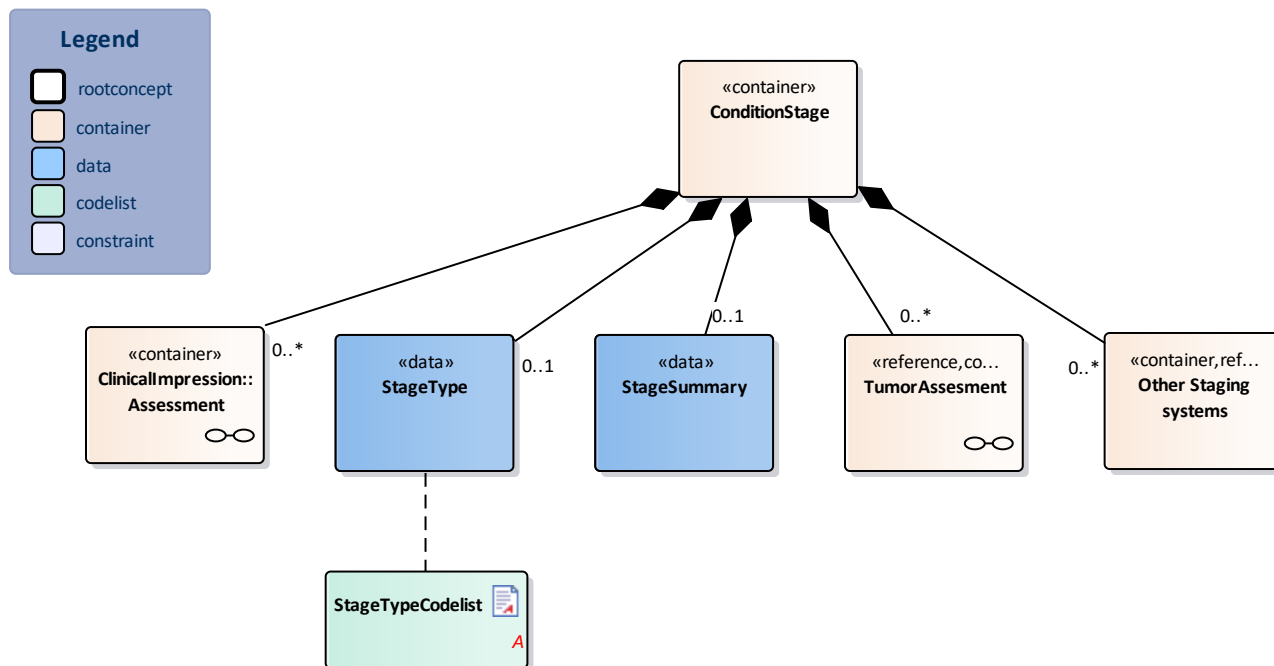


Figure 9: Condition Stage information Model

Type	Concept	Card	Description
«container»	ConditionStage	0..*	Clinical stage or grade of a condition. May include formal severity assessments.
«container»	Other Staging systems	0..*	BI-RADS, PI-RADS, LI-RADS, etc.
«data»	StageSummary	0..1	A simple summary of the stage such as "Stage 3". The determination of the stage is disease-specific.
«data»	StageType	0..1	The kind of staging, such as pathological or clinical staging.
«reference»	TumorAssesment	0..*	TNM Tumour classification
«container»	ClinicalImpression::Assessment	0..*	Reference to a formal record of the evidence on which the staging assessment is based.

StageTypeCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT where concept is a 254291000 (Staging and scales)	SNOMED CT	2.16.840.1.113883.6.96

5.1.5.8 Device Information Model

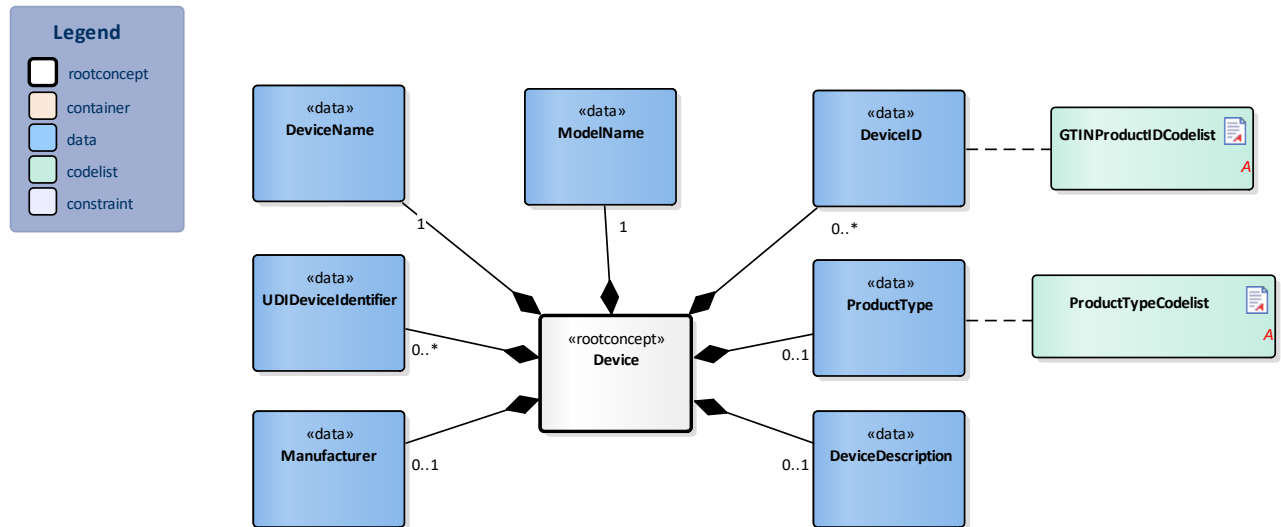


Figure 10: Device Information Model

Type	Concept	Card	Description
«rootconcept»	Device	1	Root concept of the Device information model. This root concept contains all data elements of the Device information model.
«data»	DeviceName	1	Name of the device.
«data»	Identifier	0..*	Unique instance identifiers assigned to a device by manufacturers, other organizations, or owners.
«data»	Manufacturer	0..1	Name of device manufacturer
«data»	ModelName	1	Model of the device.
«data»	UDIDeviceIdentifier	0..*	Unique device identifier (UDI) assigned to device label or package.
«data»	DeviceDescription	0..1	Additional free text description/specification of the device.

5.1.5.9 Encounter Information Model

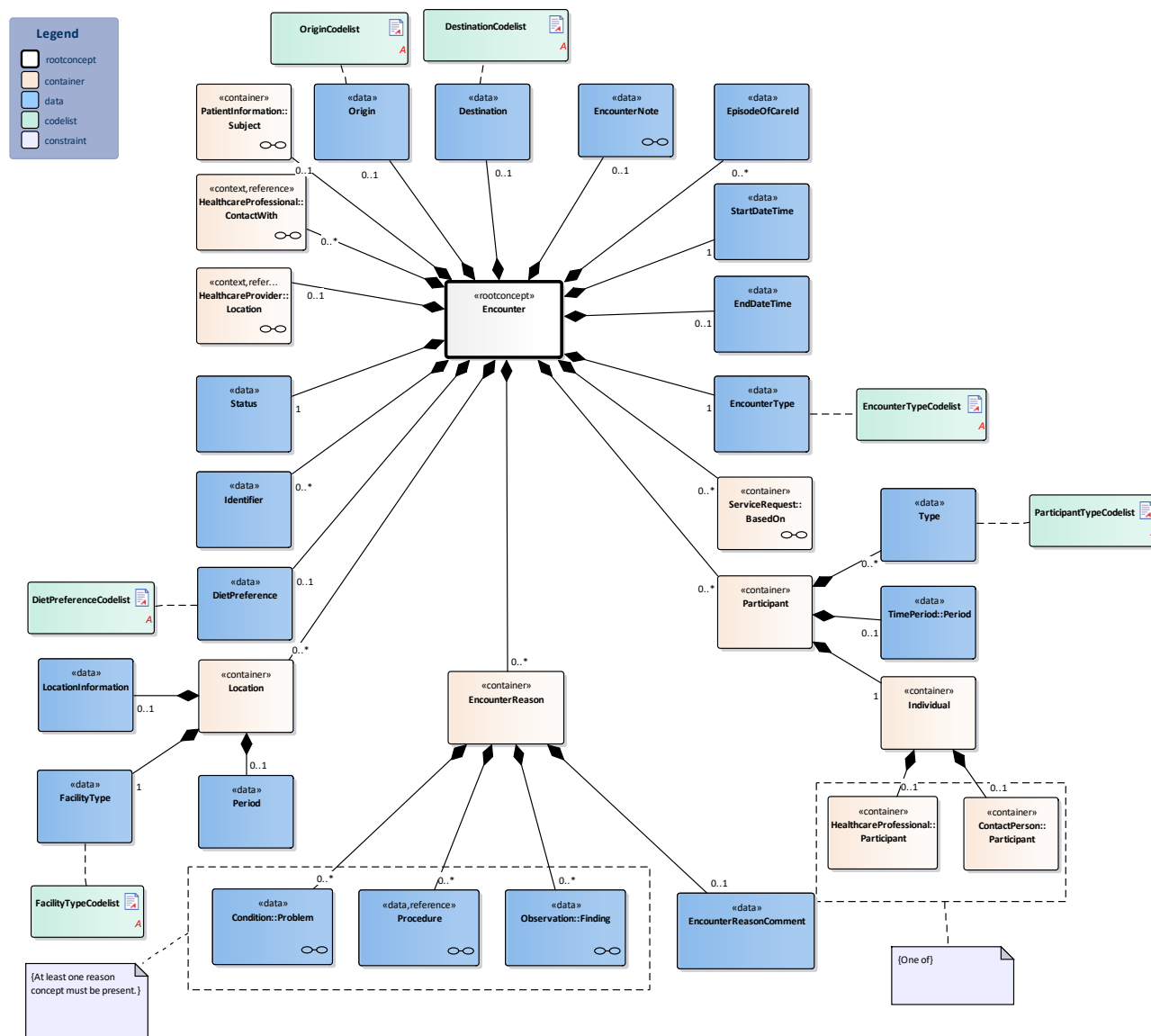


Figure 11: Encounter Information Model

Type	Concept	Card	Description
«rootconcept»	Encounter		Root concept of the Encounter information model. This concept contains all data elements of the Encounter information model.
«container»	PatientInformation::Subject	0..1	The patient present at the encounter.
«data»	Origin	0..1	Location from which the patient comes before the encounter. In most cases this will only be used when the patient is admitted.
«data»	Destination	0..1	Location to which the patient will go after the encounter. In most cases this will only be used when the patient is discharged.
«data»	EncounterNote	0..1	A narrative description of the encounter course.
«data»	EpisodeOfCareId	0..*	Episode(s) of care that this encounter should be recorded against.

Type	Concept	Card	Description
«data»	StartDateTime	1	The date and time at which the encounter took or will take place.
«data»	EndDateTime	0..1	The date and time at which the encounter ended or will end. If the contact takes place over a period of time, this indicates the end of the period, in the case of an admission, for example.
«data»	EncounterType	1	The type of the encounter.
«container»	ServiceRequest::BasedOn	0..*	The request this encounter satisfies (e.g. incoming referral or procedure request).
«container»	Participant	0..*	Participant involved in the encounter
«data»	Type	0..*	Role of the participant in an encounter. The participant type indicates how an individual participates in an encounter. It includes non-practitioner participants, and for practitioners this is to describe the action type in the context of this encounter (e.g., Admitting physician, Attending physician, Translator, Consulting physician etc.). This is different to the practitioner roles which are functional roles, derived from terms of employment, education, licensing, etc.
«data»	TimePeriod::Period	0..1	The period of time that the specified participant participated in the encounter. These can overlap or be sub-sets of the overall encounter's period.
«container»	Individual	1	Persons involved in the encounter other than the patient.
«container»	HealthcareProfessional::Participant	0..1	A healthcare professional participating in a given role during the encounter.
«container»	ContactPerson::Participant	0..1	Person that is involved in the care for the patient and should be contacted on behalf of the patient, but who is not the target of healthcare, nor has a formal responsibility in the care process.
«container»	EncounterReason	0..*	Container of the EncounterReason concept. This container contains all data elements of the EncounterReason concept.
«data»	EncounterReasonComment	0..1	Explanation of the reason for the encounter.
«data»	Observation::Finding	0..*	A deviating result which serves as the reason for the contact. Finding needs to be further modelled, perhaps as observation.
«data»	Procedure	0..*	The procedure carried out or will be carried out during the encounter.
«data»	Condition::Problem	0..*	The problem that is the reason for the contact.
«container»	Location	0..*	List of locations where the patient has been during the encounter
«data»	Period	0..1	Time period during which the patient was present at the location
«data»	FacilityType	1	Type of organizational setting where the clinical encounter, service, interaction, or treatment occurred.
«data»	LocationInformation	0..1	Name of the department/clinic, possibly with room number etc.
«data»	DietPreference	0..1	Diet preferences reported by the patient.

Type	Concept	Card	Description
«data»	Identifier	0..*	Identifier(s) by which this encounter is known.
«data»	Status	1	Status of the encounter, as being planned, in-progress, finished etc. Internal business rules will determine the appropriate transitions that may occur between statuses.
«context»	HealthcareProvider::Location	0..1	The physical location at which the contact took or will take place.
«context»	HealthcareProfessional::Contact With	0..*	The health professional with whom the contact took or will take place, e.g. admitting physician or caring physician at the ambulance. The specialty and role of the health professional can be entered in the HealthcareProfessional information model.

DietPreferenceTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Vegetarian	vegetarian	http://terminology.hl7.org/CodeSystem/diet	2.16.840.1.113883.4.642.4.1091	Food without meat, poultry or seafood.
Dairy Free	dairy-free			Excludes dairy products.
Nut Free	nut-free			Excludes ingredients containing nuts.
Gluten Free	gluten-free			Excludes ingredients containing gluten.
Vegan	vegan			Food without meat, poultry, seafood, eggs, dairy products and other animal-derived substances.
Halal	halal			Foods that conform to Islamic law.
Kosher	kosher			Foods that conform to Jewish dietary law.
Minced food	441761000124103	SNOMED CT		

FacilityTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
All code from the valueset http://hl7.org/fhir/ValueSet/c80-facilitycodes		SNOMED CT		

ParticipantTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
admitter	ADM	http://terminology.hl7.org/CodeSystem/v3-ParticipationType	2.16.840.1.113883.5.90	The practitioner who is responsible for admitting a patient to a patient encounter.

ParticipantTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
attender	ATND			The practitioner that has responsibility for overseeing a patient's care during a patient encounter.
callback contact	CALLBCK			A person or organization who should be contacted for follow-up questions about the act in place of the author.
consultant	CON			An advisor participating in the service by performing evaluations and making recommendations.
discharger	DIS			The practitioner who is responsible for the discharge of a patient from a patient encounter.
escort	ESC			Only with Transportation services. A person who escorts the patient.
referror	REF			A person having referred the subject of the service to the performer (referring physician). Typically, a referring physician will receive a report.
secondary performer	SPRF			A person assisting in an act through his substantial presence and involvement This includes: assistants, technicians, associates, or whatever the job titles may be.
primary performer	PPRF			The principal or primary performer of the act.
Participation	PART			Indicates that the target of the participation is involved in some manner in the act, but does not qualify how.
Translator	translator			A translator who is facilitating communication with the patient during the encounter.
Emergency	emergency			A person to be contacted in case of an emergency during the encounter.

OriginCodelist		OID:		
Concept Name	Concept Code	Code Syst. Name	Code System OID	Description
Home	264362003	SNOMED CT	2.16.840.1.113883.6.96	
Rehabilitation hospital	80522000	SNOMED CT	2.16.840.1.113883.6.96	
Nursing home	42665001	SNOMED CT	2.16.840.1.113883.6.96	

OriginCodelist		OID:		
Concept Name	Concept Code	Code Syst. Name	Code System OID	Description
Psychiatric hospital	62480006	SNOMED CT	2.16.840.1.113883.6.96	
Hospital	22232009	SNOMED CT	2.16.840.1.113883.6.96	
(Liveborn) Born in hospital	442311008	SNOMED CT	2.16.840.1.113883.6.96	
Hospice	284546000	SNOMED CT	2.16.840.1.113883.6.96	

DestinationCodelist		OID:		
Concept Name	Concept Code	Code Syst. Name	Code System OID	Description
Home	264362003	SNOMED CT	2.16.840.1.113883.6.96	
Left against medical advice	445060000	SNOMED CT	2.16.840.1.113883.6.96	
Rehabilitation hospital	80522000	SNOMED CT	2.16.840.1.113883.6.96	
Nursing home	42665001	SNOMED CT	2.16.840.1.113883.6.96	
Psychiatric hospital	62480006	SNOMED CT	2.16.840.1.113883.6.96	
Hospital	22232009	SNOMED CT	2.16.840.1.113883.6.96	
Died in hospital	183676005	SNOMED CT	2.16.840.1.113883.6.96	
Hospice	284546000	SNOMED CT	2.16.840.1.113883.6.96	
Other	OTH	NullFlavor	2.16.840.1.113883.5.1008	

EncounterTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Includes all elements of v3.ActEncounterCode valueset, http://terminology.hl7.org/ValueSet/v3-ActEncounterCode				
ambulatory	AMB	hl7:ActCode	2.16.840.1.113883.5.4	A comprehensive term for health care provided in a healthcare facility (e.g. a practitioner's office, clinic setting, or hospital) on a nonresident basis. The term ambulatory usually implies that the patient has come to the location and is not assigned to a bed. Sometimes referred to as an outpatient encounter.
emergency	EMER	hl7:ActCode	2.16.840.1.113883.5.4	A patient encounter that takes place at a dedicated healthcare service delivery location where the patient receives immediate evaluation and treatment, provided until the patient can be discharged or responsibility for the patient's care is transferred

EncounterTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
				elsewhere (for example, the patient could be admitted as an inpatient or transferred to another facility.)
field	FLD	hl7:ActCode	2.16.840.1.113883.5.4	A patient encounter that takes place both outside a dedicated service delivery location and outside a patient's residence. Example locations might include an accident site and at a supermarket.
home health	HH	hl7:ActCode	2.16.840.1.113883.5.4	Healthcare encounter that takes place in the residence of the patient or a designee
inpatient encounter	IMP	hl7:ActCode	2.16.840.1.113883.5.4	A patient encounter where a patient is admitted by a hospital or equivalent facility, assigned to a location where patients generally stay at least overnight and provided with room, board, and continuous nursing service.
inpatient acute	ACUTE	hl7:ActCode	2.16.840.1.113883.5.4	An acute inpatient encounter.
inpatient non-acute	NONAC	hl7:ActCode	2.16.840.1.113883.5.4	Any category of inpatient encounter except 'acute'
observation encounter	OBSENC	hl7:ActCode	2.16.840.1.113883.5.4	An encounter where the patient usually will start in different encounter, such as one in the emergency department (EMER) but then transition to this type of encounter because they require a significant period of treatment and monitoring to determine whether or not their condition warrants an inpatient admission or discharge. In the majority of cases the decision about admission or discharge will occur within a time period determined by local, regional or national regulation, often between 24 and 48 hours.
pre-admission	PRENC	hl7:ActCode	2.16.840.1.113883.5.4	A patient encounter where patient is scheduled or planned to receive service delivery in the future, and the patient is given a pre-admission account number. When the patient comes back for subsequent service, the pre-admission encounter is selected and is encapsulated into the service registration, and a new account number is generated.

EncounterTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
				Usage Note: This is intended to be used in advance of encounter types such as ambulatory, inpatient encounter, virtual, etc.
short Stay	SS	hl7:ActCode	2.16.840.1.113883.5.4	An encounter where the patient is admitted to a health care facility for a predetermined length of time, usually less than 24 hours.
virtual	VR	hl7:ActCode	2.16.840.1.113883.5.4	A patient encounter where the patient and the practitioner(s) are not in the same physical location. Examples include telephone conference, email exchange, robotic surgery, and televideo conference.

5.1.5.10 Group Information Model

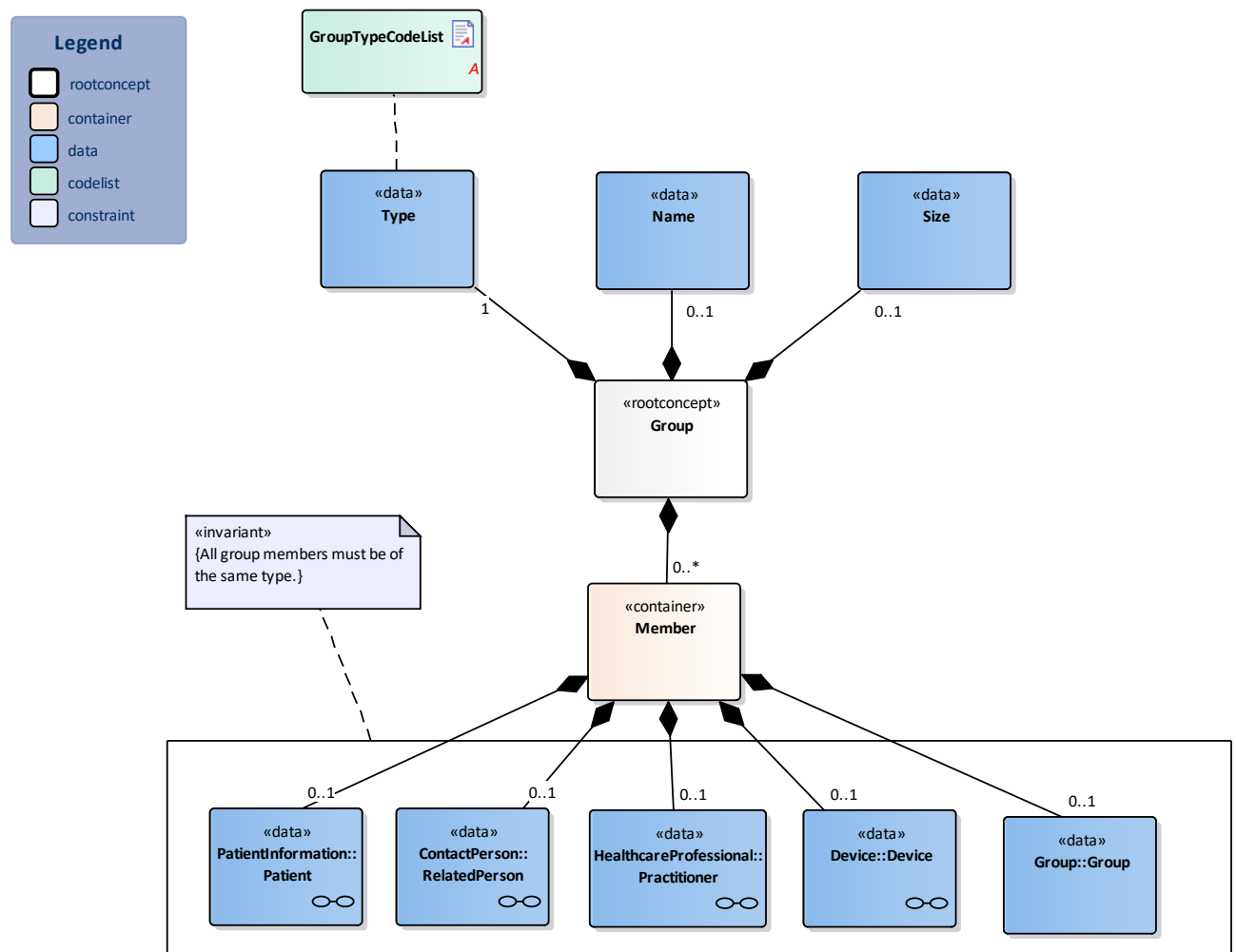


Figure 12: Group Information Model

Type	Concept	Card	Description
«rootconcept»	Group		<p>Root concept for the Group information model.</p> <p>The Group model is used in one of two ways:</p> <p>To define a group of specific people, animals, devices, etc. that is being tracked, examined or otherwise referenced as part of healthcare-related activities</p> <p>To define a set of possible people, animals, devices, etc. that are of interest for some intended future healthcare-related activities</p> <p>Examples of the former could include group therapy or treatment sessions, exposed entities tracked as part of public health, etc. The latter might be used to define expected subjects for a clinical study.</p>
«data»	Name	0..1	Group name - a label assigned to the group for human identification and communication.
«data»	Size	0..1	A count of members of the group.
«data»	Type	1	Identifies the broad classification of the kind of resources the group includes. E.g. person, animal, practitioner, device, medication, substance.
«container»	Member	0..*	Identifies members of the group. Must be consistent with Group type. If the entity is another group, then the type must be the same.
«data»	ContactPerson::RelatedPerson	0..1	Related person member.
«data»	Device::Device	0..1	Device member.
«data»	Group::Group	0..1	Group member. Group must be of the same type.
«data»	HealthcareProfessional::Practitioner	0..1	Practitioner member.
«data»	PatientInformation::Patient	0..1	Patient member.

GroupTypeCodeList			OID:	
Concept Name	Concept Code	CodeSystem	CodeSystem OID	Description
Person	person	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains "person" Patient resources.
Animal	animal	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains "animal" Patient resources.
Practitioner	practitioner	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains healthcare practitioner resources (Practitioner or PractitionerRole).
Device	device	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains Device resources.
Medication	medication	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains Medication resources.
Substance	substance	http://hl7.org/fhir/group-type	2.16.840.1.113883.4.642.4.285	Group contains Substance resources.

5.1.5.11 Healthcare Professional Information Model

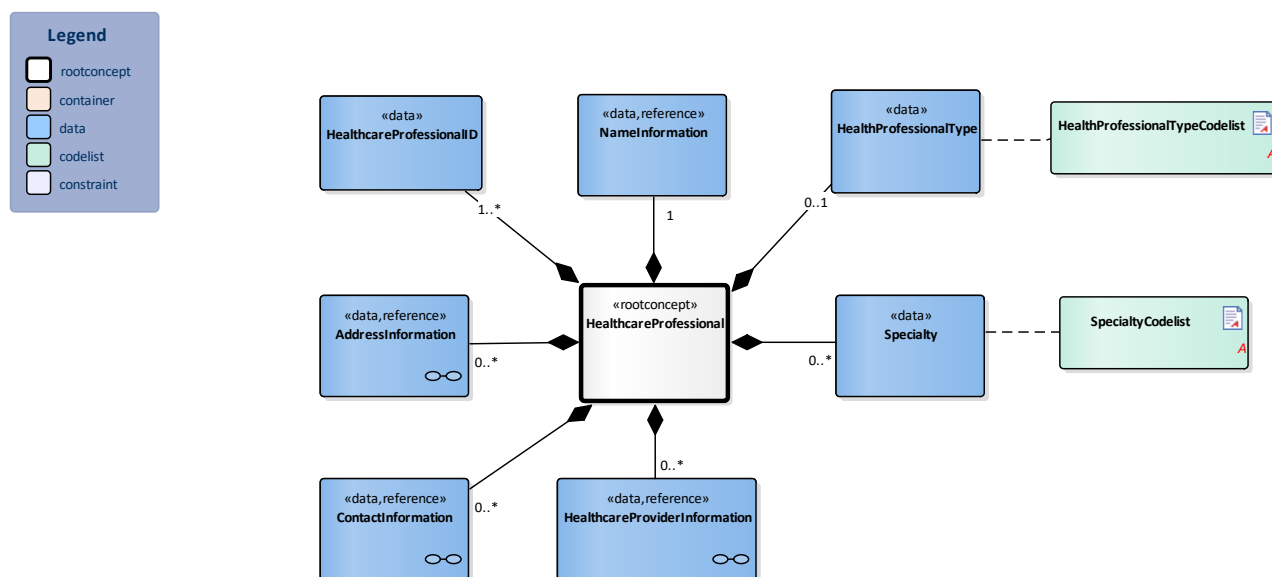


Figure 13: Healthcare Professional Information Model

Type	Concept	Card	Description
«rootconcept»	HealthcareProfessional		Root concept of the HealthcareProfessional information model. This root concept contains all data elements of the HealthcareProfessional information model. When referring to this information model the role the health professional fulfils in the healthcare process can be addressed additionally. For health professionals, this could be for example main practitioner or referrer.
«data»	HealthcareProfessionalID	1..*	The healthcare professional identification number. Either an internal identifier assigned by an healthcare provider institution or (preferably) a national healthcare professional ID such as assigned by a national registry of healthcare professionals. Healthcare professional ID must be globally unique.
«data»	NameInformation	1	Health professional's full name.
«data»	Specialty	0..*	Healthcare professional's medical specialty. For example, general practitioner, or cardiologist.
«data»	AddressInformation	0..*	Health professional's address information.
«data»	ContactInformation	0..*	Health professional's telephone number(s) or e-mail address(es).
«data»	HealthcareProviderInformation	0..*	The healthcare provider organisation information.
«data»	HealthProfessionalType	0..1	The role the health professional in the healthcare process. This could be for example medical doctor, pharmacist, nursing specialist etc.

SpecialtyCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
<< 394658006 Clinical specialty (qualifier value)	SNOMED CT	

HealthProfessionalTypeCodelist		OID:		
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
		ISCO		

5.1.5.12 Healthcare Provider Information Model

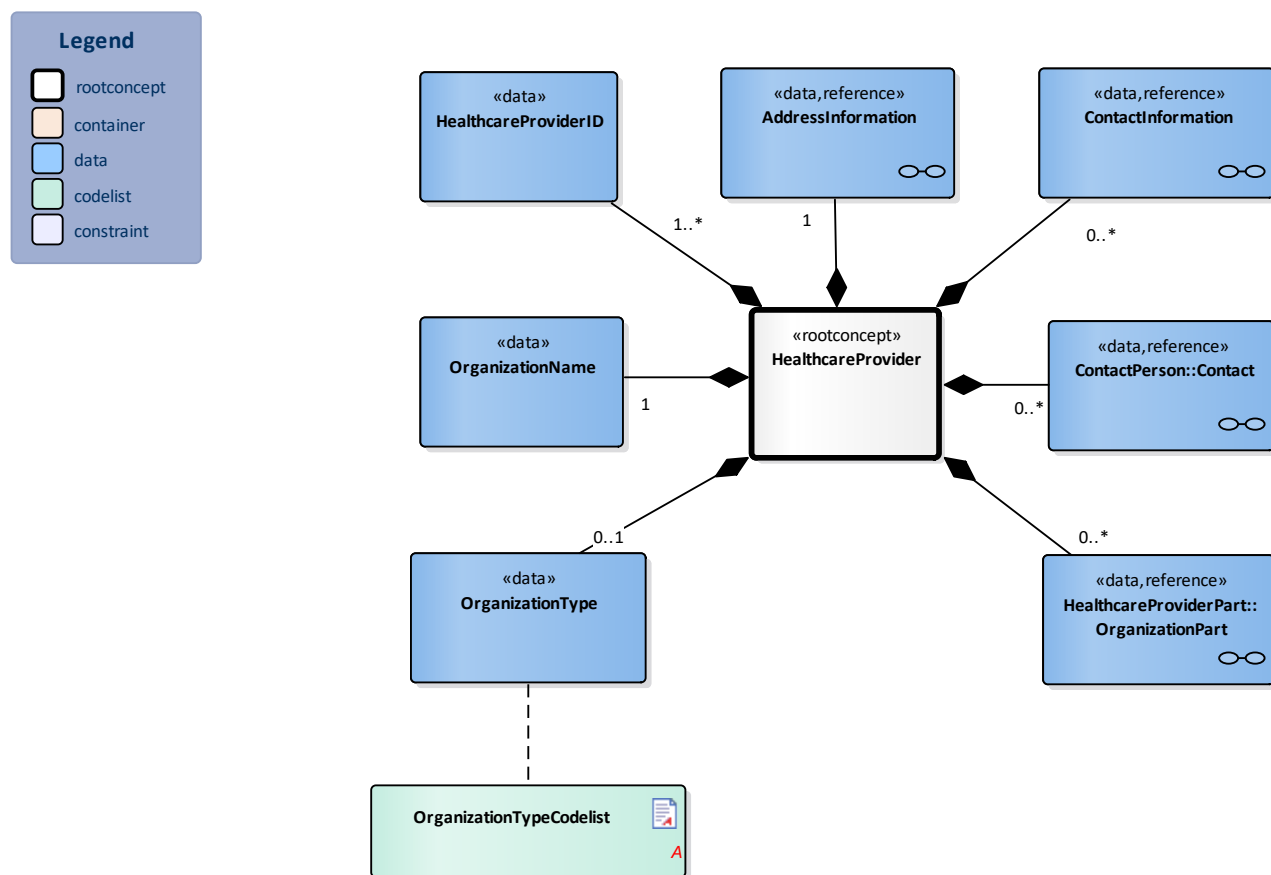


Figure 14: Healthcare Provider Information Model

Type	Concept	Card	Description
«rootconcept»	HealthcareProvider	1	Root concept of the Healthcare Provider information model. This root concept contains all data elements of the Healthcare Provider information model.
«data»	ContactPerson::Contact	0..*	Contact person for the organisation.

Type	Concept	Card	Description
«data»	HealthcareProviderPart::OrganizationPart	0..*	Organizational part of the healthcare provider, such as clinic, department, ward, or ambulance.
«data»	HealthcareProviderID	1..*	The organization's identifier. Legal person's/organization identifier. Should a regulatory (national) coding system exist, such as HCP Registry, a corresponding ID code is applied. Optionally (e.g., for private sector), the ID can be obtained from business registry (registration code, VAT code).
«data»	OrganizationName	1	Name of the organization.
«data»	ContactInformation	0..*	The information needed to contact the healthcare provider via telephone and/or e-mail.
«data»	AddressInformation	1	The physical address of the healthcare provider's location.
«data»	OrganizationType	0..1	The type of healthcare provider, such as general hospital, nursing home, laboratory.

OrganizationTypeCodeList			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
A subset of << 43741000 Site of care (environment)		SNOMED CT		

5.1.5.13 Laboratory Test Specification

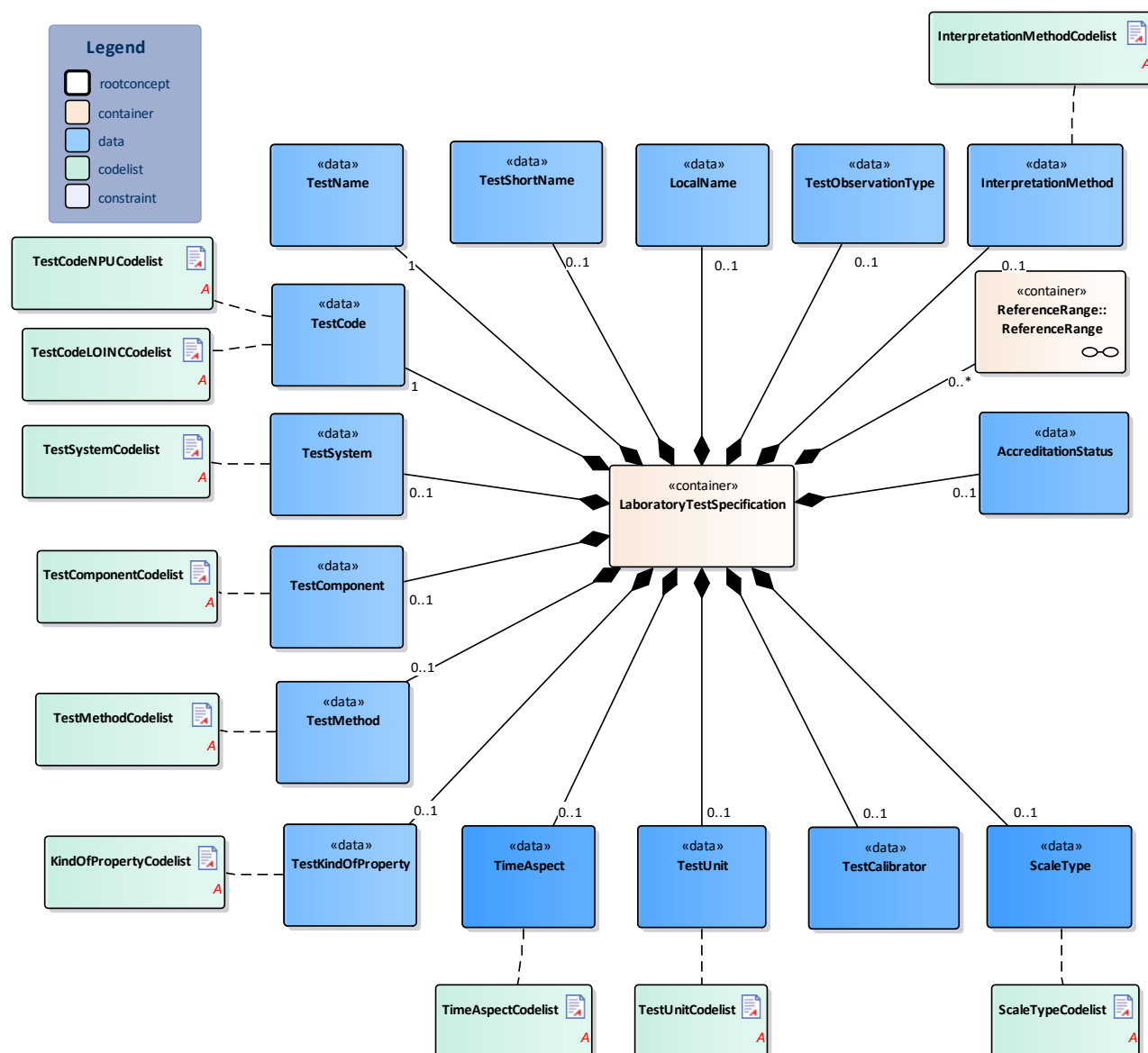


Figure 15: Laboratory Test Specification Information Model

Type	Concept	Card	Description
«container»	LaboratoryTestSpecification		Container of the LaboratoryTestSpecification concept. This container contains all data elements of the LaboratoryTestSpecification concept.
«data»	AccreditationStatus	0..1	Accreditation status holds information about status of the test, i.e., whether laboratory has been accredited for provisioning of the test or not.
«data»	LocalName	0..1	A conventional test name or synonym used by laboratory. for display purposes.
«data»	ScaleType	0..1	How the observation value is quantified or expressed: quantitative, ordinal, nominal.
«data»	TestCalibrator	0..1	All laboratory test results are traceable to either SI units or to some higher or lower order reference material through a series of comparisons. Information

Type	Concept	Card	Description
			<p>about which end-user calibrator the laboratory has been used for the measurement is way to indicate the metrological traceability chain.</p> <p>Further information is given in ISO 17511:2020 In vitro diagnostic medical devices — Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples.</p>
«data»	TestComponent	0..1	Component to be tested, e.g., Natrium, Alanine transaminase, Brucella antibody.
«data»	TestKindOfProperty	0..1	Kind of property, e.g., numeric fraction, concentration, mass concentration, frequency, etc.
«data»	TestName	1	A full name of the test according to the used test coding standard (Long common name or NPU short definition).
«data»	TestObservationType	0..1	<p>This element informs about type of observation:</p> <ul style="list-style-type: none"> - measured, derived, or observed - calculated
«data»	TestShortName	0..1	<p>Short name of the test for reporting:</p> <ul style="list-style-type: none"> - In case of NPU a "short definition" element which is a combination of "System-Component; kind-of-property=unit" should be used. - In case of LOINC a SHORTNAME attribute should be used.
«data»	TestSystem	0..1	<p>System examined (e.g., blood, cerebrospinal fluid, Erythrocytes, etc.). Specimen is sometimes same as the examined System however it could be a different entity derived or contained in the specimen. System represents the part of the universe which is examined.</p> <p>The concept slightly vary between different code systems (LOINC and NPU) which might create a problem for mapping. Mapping could use information about specimen type in such case.</p> <p>E.g., for the examination of Reticulocytes numeric fraction, the primary specimen type is blood (B), the examined system is erythrocytes in blood (ErCs(B)) and the examined component is Reticulocytes.</p>
«data»	TestUnit	0..1	A measurement unit of the (numerical) test result value according to the kind of measured property.
«data»	TimeAspect	0..1	Time Aspect of the measurement (e.g., is it over time or momentary). The interval of time over which an observation was made.
«data»	TestCode	1	Code system and code of the test.
«data»	ExaminationTechnique	0..1	Examination technique (test method) to obtain the result. Examination technique is an important element for comparability of the test results in some cases.
«data»	InterpretationMethod	0..1	The method used to determine interpretation flags. An example of this is EUCAST, for determining clinical breakpoints in microbiological susceptibility tests.

KindOfPropertyCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
NPU kind of property	NPU	

KindOfPropertyCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
LOINC kind of property	LOINC	

ScaleTypeCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
NPU ScaleType	NPU	
LOINC ScaleType	LOINC	

TestCodeNPUCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All NPU Codes	NPU	

TestComponentCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All component codes	NPU	
All component codes	LOINC	

TestSystemCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All system codes	NPU	
All system codes	LOINC	

TestUnitCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All units must follow UCUM syntax rules	UCUM	

TimeAspectCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
LOINC time aspect	LOINC	

TestCodeLOINCCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All values	LOINC	

ExaminationTechniqueCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 272394005 Technique (qualifier value)	SNOMED CT	2.16.840.1.113883.6.96

InterpretatieMethodCodelist		OID:		
Concept Name	Concept Code	CodeSystem Name	CodeSystem OID	Description
EUCAST	tbd	SNOMED CT	2.16.840.1.113883.6.96	EUCAST

A coded entry with information on standard method used to evaluate and interpret result value, e.g., using EUCAST standardised disk diffusion method based on MH agar with an inoculum density equivalent to a McFarland 0.5 standard.

5.1.5.14 Location Information Model

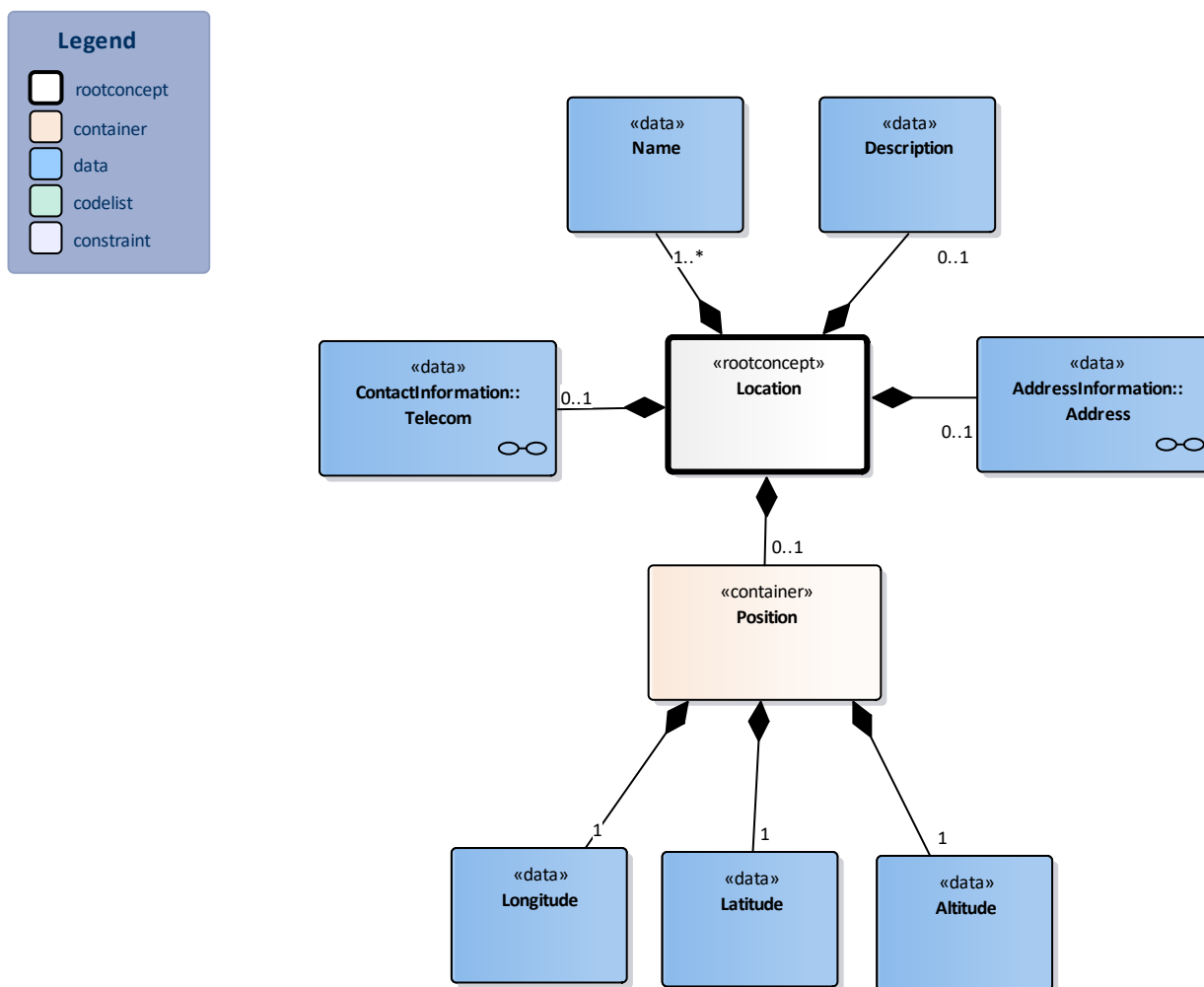


Figure 16: Location Information Model

Type	Concept	Card	Description
«rootconcept»	Location		Root concept of the Location information model. This root concept contains all data elements of the Location information model. A Location includes both incidental locations (a place which is used for healthcare without prior designation or authorization) and dedicated, formally appointed locations.
«data»	Name	1..*	Name of the location as used by humans.
«data»	Description	0..1	Description of the Location, which helps in finding or referencing the place.

Type	Concept	Card	Description
«data»	ContactInformation::Telecom	0..1	The contact details of communication devices available at the location. This can include phone numbers, fax numbers, mobile numbers, email addresses and web sites.
«data»	AddressInformation::Address	0..1	Physical location address.
«container»	Position	0..1	The absolute geographic location of the Location. Location position is expressed using the same syntax, datum and reference system as used in Google Earth's KML files
«data»	Altitude	1	Altitude (KML).
«data»	Latitude	1	Latitude (KML).
«data»	Longitude	1	Longitude.

5.1.5.15 Organisation Part Information Model

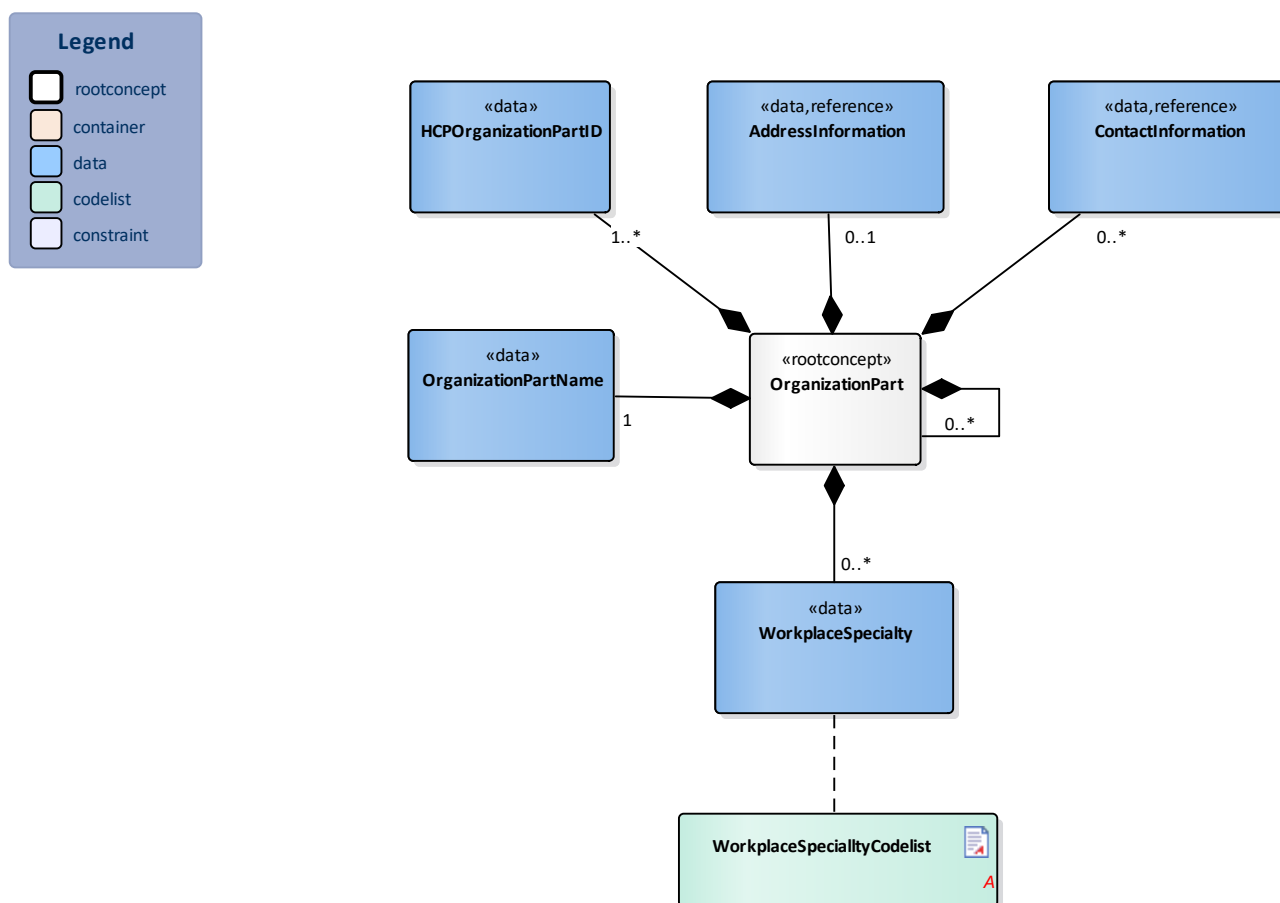


Figure 17: Organisation Part Information Model

Type	Concept	Card	Description
«rootconcept»	OrganizationPart		Root concept of the OrganizationPart Information Model.
«data»	HCPOrganizationPartID	1..*	The organization's identifier.
«data»	OrganizationPartName	1	Name of the organization.
«data»	WorkplaceSpecialty	0..*	The specialty of the healthcare provider's department (organization part).
«data»	ContactInformation	0..*	The information needed to contact the healthcare organization via telephone and/or e-mail.
«data»	AddressInformation	0..1	The physical address of the healthcare provider's location.

WorkplaceSpecialtyCodeList		OID:
Codes	Coding Syst. Name	Coding System OID
All http://hl7.org/fhir/ValueSet/c80-practice-codes , value set needs to be reviewed.	SNOMED CT	2.16.840.1.113883.6.96

5.1.5.16 Patient Information Model

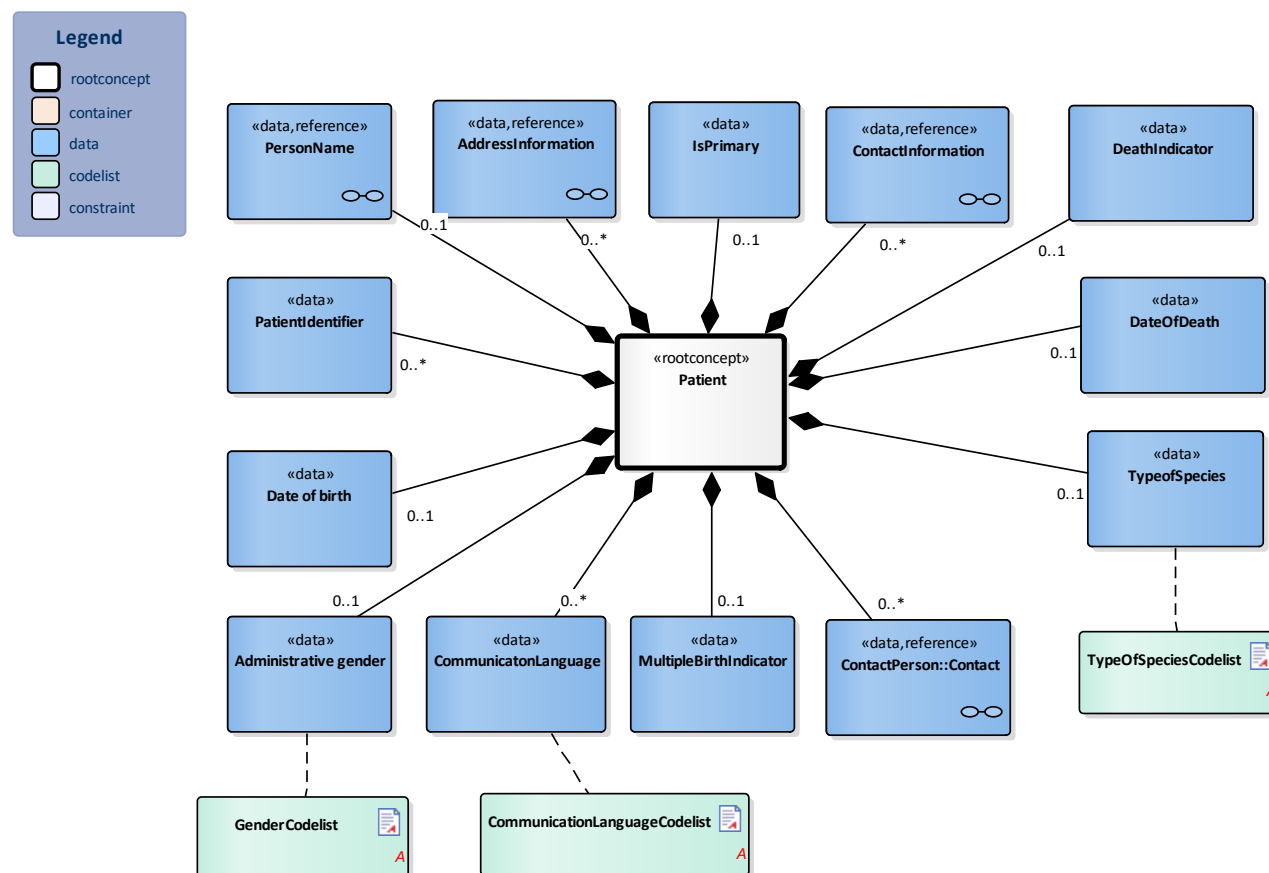


Figure 18: Patient Information Model

Type	Concept	Card	Description
«rootconcept»	Patient		Root concept of the Patient information model. This root concept contains all data elements of the Patient information model.
«data»	CommunicationLanguage	0..*	A language which may be used to communicate with the patient about his or her health.
«data»	ContactPerson::Contact	0..*	Patient contact persons, e.g., emergency contact, relatives, general practitioner/family physician, other specialists etc.
«data»	IsPrimary	0..1	Element indicates if the subject is a primary subject of care. True (default), false in case of subjects associated to the primary subject (e.g., newborn).
«data»	PersonName	0..1	Patient's name.
«data»	AddressInformation	0..*	Patient's address information.
«data»	ContactInformation	0..*	Patient's telephone number(s) or e-mail address(es).
«data»	PatientIdentifier	0..*	The patient's Primary Identifier (Regional/National Health Id) or Secondary Identifier (Social/Insurance Number, etc.).
«data»	Dateofbirth	0..1	Patient's date of birth.
«data»	Administrative gender	0..1	Patient's administrative gender.
«data»	MultipleBirthIndicator	0..1	An indication stating whether the patient is of a multiple birth.
«data»	DeathIndicator	0..1	An indication stating whether the patient has died.
«data»	DateOfDeath	0..1	The date on which the patient died. A 'vague' date, such as only the year, is permitted.

CommunicationLanguageCodelist			OID:	
Concept Name	Concept Code	CodeSystem	CodeSystem OID	Description
All concepts		eHDSILanguage	?	

GenderCodelist			OID:	
Concept Name	Concept Code	CodeSystem	CodeSystem OID	Description
Undifferentiated	UN	AdministrativeGender	2.16.840.1.113883.5.1	Undifferentiated
Male	M	AdministrativeGender	2.16.840.1.113883.5.1	Male
Female	F	AdministrativeGender	2.16.840.1.113883.5.1	Female
Unknown	UNK	NullFlavors	2.16.840.1.113883.5.1008	Unknown

SpeciesCodelist			OID:	
Concept Name	Concept Code	CodeSystem	CodeSystem OID	Description
Homo sapiens	337915000	SNOMED CT		Default for most cases
Domestic dog	448771007	SNOMED CT		

Domestic cat	448169003	SNOMED CT		
Horse	35354009	SNOMED CT		
Sheep	125099002	SNOMED CT		
Cow	34618005	SNOMED CT		
Domestic goat	125097000	SNOMED CT		
etc.				

This is an example value set.

5.1.5.17 Payer Information Model

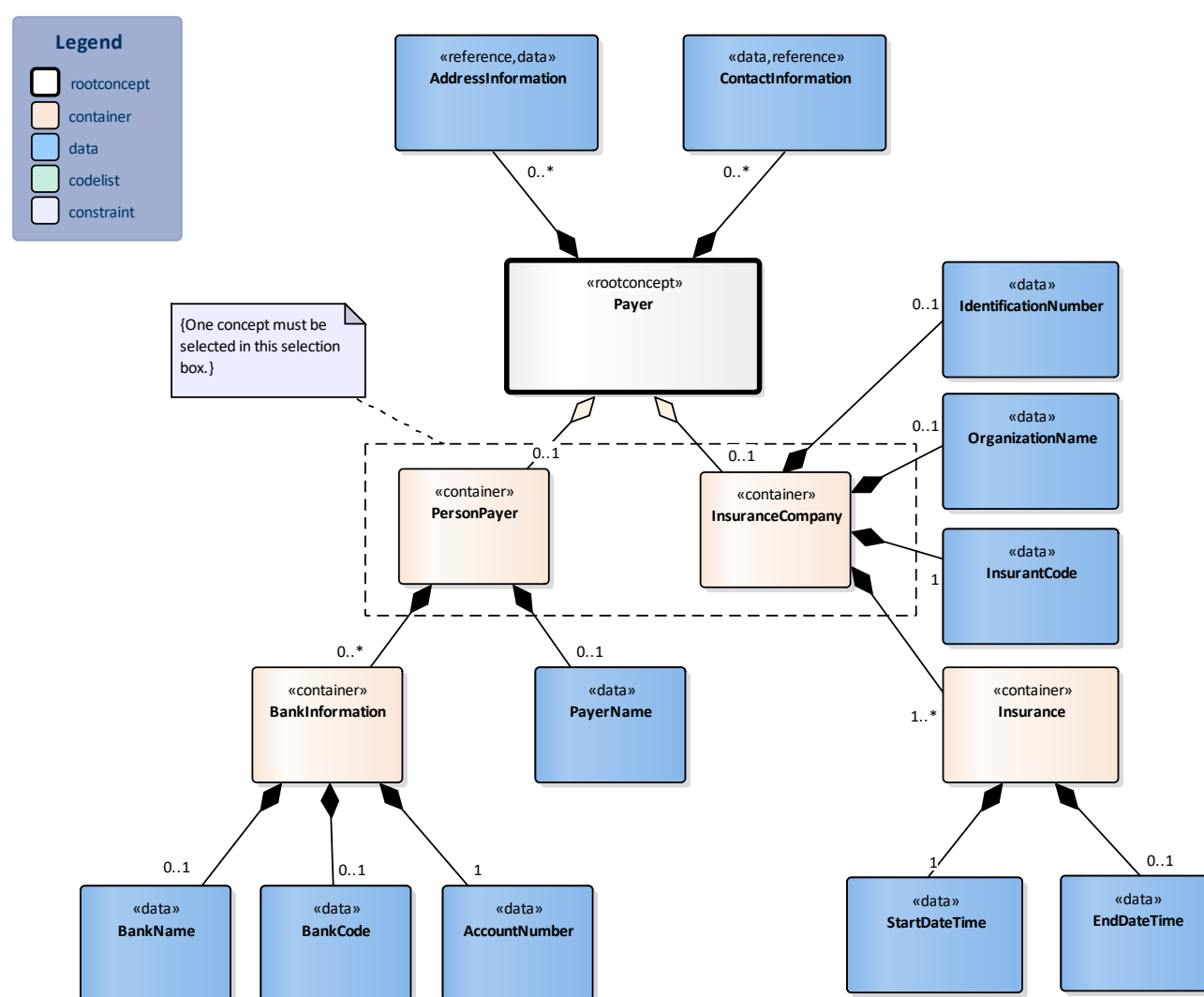


Figure 19: Payer Information Model

Type	Concept	Card	Description
«rootconcept»	Payer		Root concept of the Payer information model. This root concept contains all data elements of the Payer information model.
«data»	AddressInformation	0..*	The payer's address information.
«data»	ContactInformation	0..*	The payer's telephone number and/or e-mail address.
«container»	PersonPayer	0..1	Container of the PersonPayer concept. This container contains all data elements of the PersonPayer concept. A person is a natural person or a juridical person, such as an organization, municipality, etc.
«data»	PayerName	0..1	Full name of the paying person or organization (legal entity).
«container»	BankInformation	0..*	Container of the BankInformation concept. This container contains all data elements of the BankInformation concept.
«data»	BankName	0..1	Name of the financial organization.
«data»	BankCode	0..1	Code indicating the bank and branch. For European countries, this is the organization's BIC or SWIFT code.
«data»	AccountNumber	1	The payer's bank account number at the listed organization. For European countries, this is the IBAN.
«container»	InsuranceCompany	0..1	Container of the InsuranceCompany concept. This container contains all data elements of the InsuranceCompany concept.
«data»	IdentificationNumber	0..1	Unique health insurance company identification code.
«data»	OrganizationName	0..1	Full, official name of the healthcare insurance company.
«data»	InsurantCode	1	Number or code under which the insured person is registered at the insurance company.
«container»	Insurance	1..*	Container of the Insurance concept. This container contains all data elements of the Insurance concept.
«data»	StartDateTime	1	Date from which the insurance policy coverage applies.
«data»	EndDateTime	0..1	Date until which the insurance policy coverage applies.

5.1.5.18 Person Name Information Model

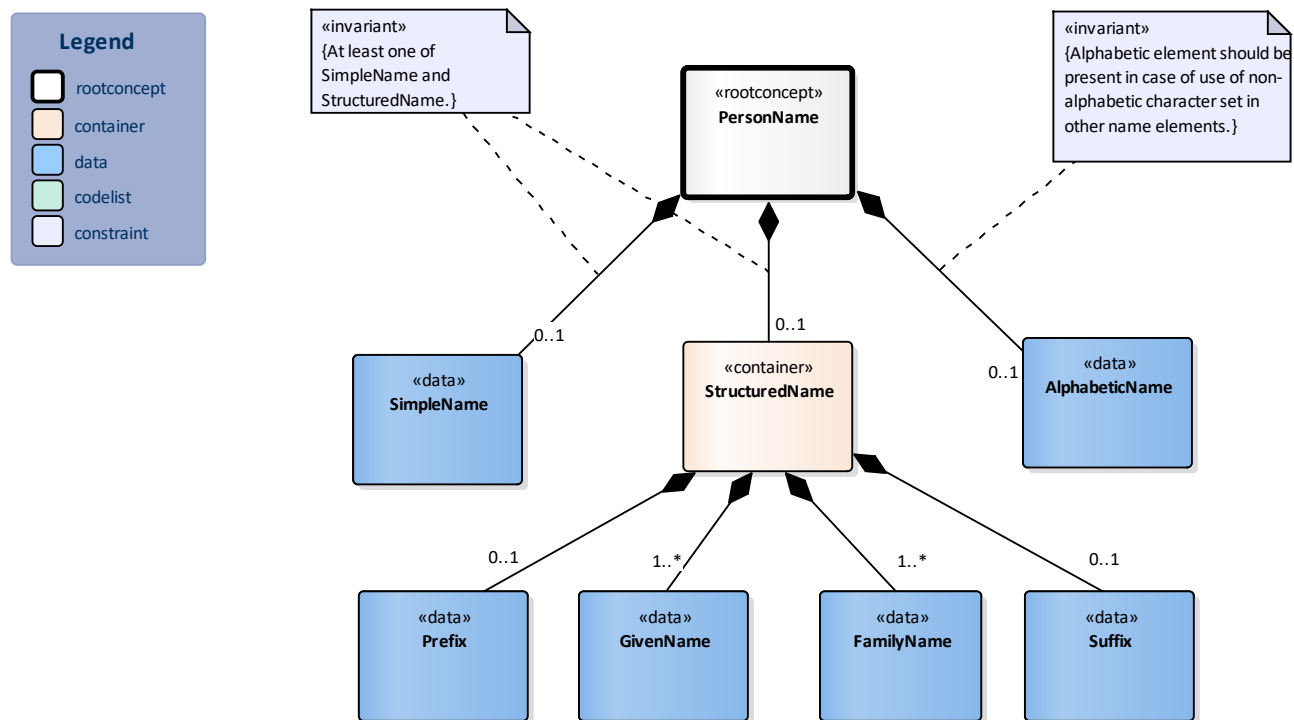


Figure 20: Person Name Information Model

Type	Concept	Card	Description
«rootconcept»	PersonName		Root concept of the NameInformation partial information model. This root concept contains all data elements of the NameInformation partial information model.
«data»	GivenName	1..*	The person's given name.
«data»	Suffix	0..1	A person name scientific/academic suffix.
«data»	AlphabeticName	0..1	Alphabetic transcription of a person Name
«data»	FamilyName	1..*	Family name (surname) of a person.
«data»	SimpleName	0..1	A simple representation of a person's name (without name parts).
«container»	StructuredName	0..1	A container of a StructuredName components. Structured name could be composed from several name parts: <ul style="list-style-type: none"> - optional name Prefix - one or more Given names - one or more Family names (surnames) - optional name Suffix
«data»	Prefix	0..1	Scientific/academic titles. These can assist in formulating oral and formal addressing titles.

5.1.5.19 Specimen Information Model

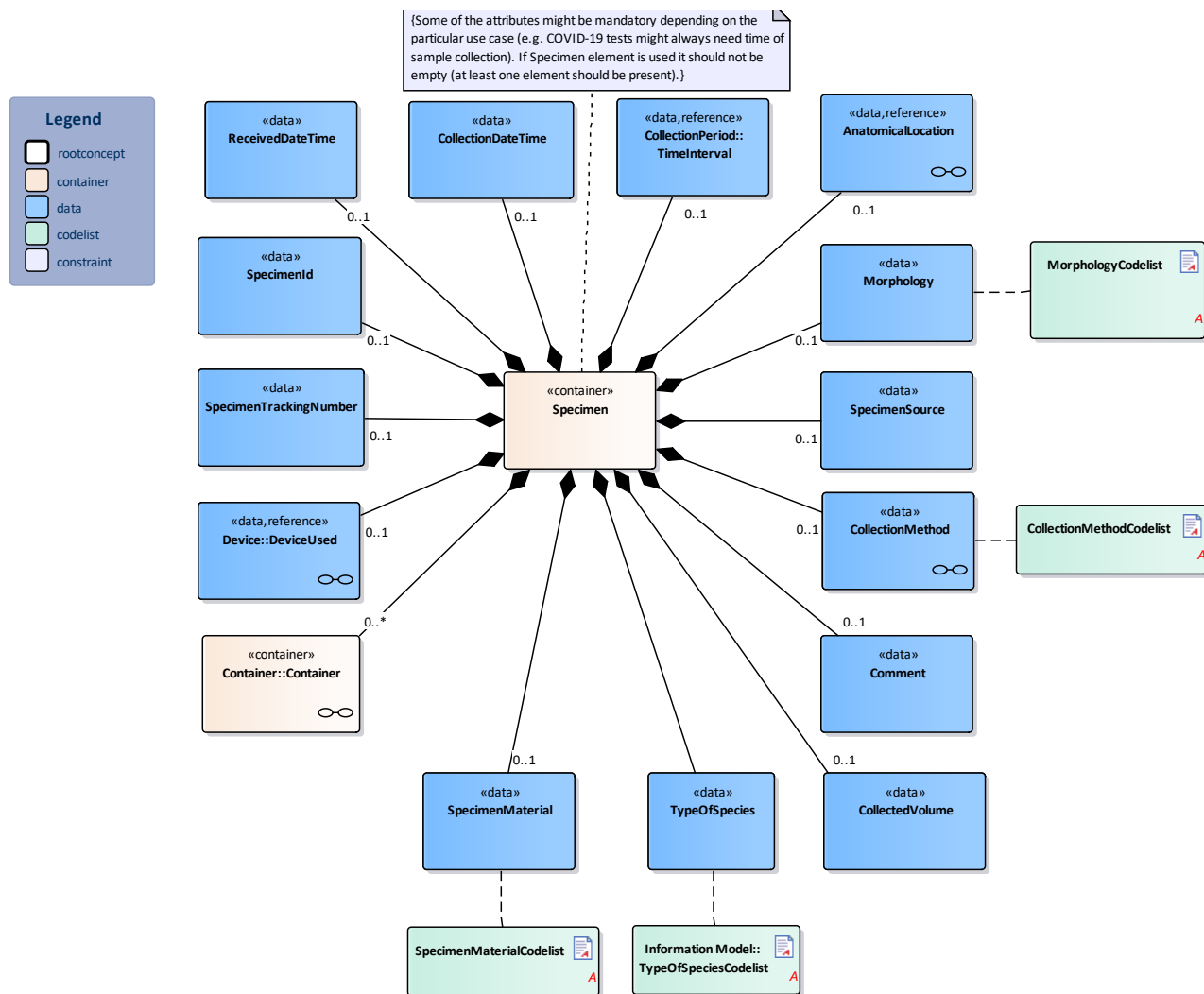


Figure 21: Specimen Information Model

Type	Concept	Card	Description
«container»	Specimen		Container of the Specimen concept. This container contains all data elements of the Specimen concept. «constraint» Some of the attributes might be mandatory depending on the particular use case (e.g. COVID-19 tests might always need time of sample collection). If Specimen element is used it should not be empty (at least one element should be present).
«data»	SpecimenId	0..1	Unique identifier of the material obtained, as a reference for inquiries to the source organization.
«data»	SpecimenTracking Number	0..1	The specimen number extension is used when the collected material is distributed from the original tube or container across multiple tubes. A combination of the specimen Id and extension represents a unique identification of the tube or container.
«data»	TypeOfSpecies	0..1	Biologic type of species which is the source of this specimen. Default is human.
«data»	SpecimenMaterial	0..1	SpecimenMaterial describes the material obtained.

Type	Concept	Card	Description
			If the test is carried out on derived material (such as plasma), this element will still contain the material drawn (in this case, blood).
«data»	CollectedVolume	0..1	Total volume of the collected material. If it is necessary to determine the absolute amount of a particular substance in the collected material, the volume thereof must be given.
«data»	AnatomicalLocation	0..1	Anatomic location where the material is collected, <i>e.g.</i> elbow
«data»	Morphology	0..1	Morphology describes morphological abnormalities of the anatomical location where the material is taken, for example wound, ulcer.
«data»	SpecimenSource	0..1	If the material is not collected directly from the patient but comes from a patient-related object, <i>e.g.</i> a catheter, this source of material can be recorded here.
«data»	Device::DeviceUsed	0..1	Device used during sample collection, or device which was a source of the material.
«data»	CollectionMethod	0..1	If relevant for the results, the method of obtaining the specimen can be entered as well.
«data»	Comment	0..1	Comments on the specimen, such as drawing material after a (glucose) stimulus or taking medicine.
«data»	CollectionPeriod::TimeInterval	0..1	If the material has not been collected at a single point in time but over a certain period, this period can be captured in this concept. An example is 24-hour urine.
«data»	CollectionDateTime	0..1	Date and time at which the material was collected.
«data»	ReceivedDateTime	0..1	Date and time that the material is handed over at the laboratory or specimen collection center. This is the issue with material that is collected by the patient himself.
«container»	Container	0..*	The container holding the specimen. The recursive nature of containers; i.e. blood in tube in tray in rack is not addressed here.

SpecimenMaterialCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 123038009 specimen	SNOMED CT	2.16.840.1.113883.6.96

For a selection of SNOMED CT codes (proposed EU valueset) please refer to Annex

CollectionMethodCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 71388002 Procedure (procedure) (all concepts under procedure)	SNOMED CT	2.16.840.1.113883.6.96

The exact selection of concepts needs to be specified.

MorphologyCode		OID:
Codes	Coding Syst. Name	Coding System OID
SNOMED CT: < 49755003 Morphologically abnormal structure	SNOMED CT	2.16.840.1.113883.6.96

Exact specification of the value set should be further discussed.

5.1.5.20 Test Panel Information Model

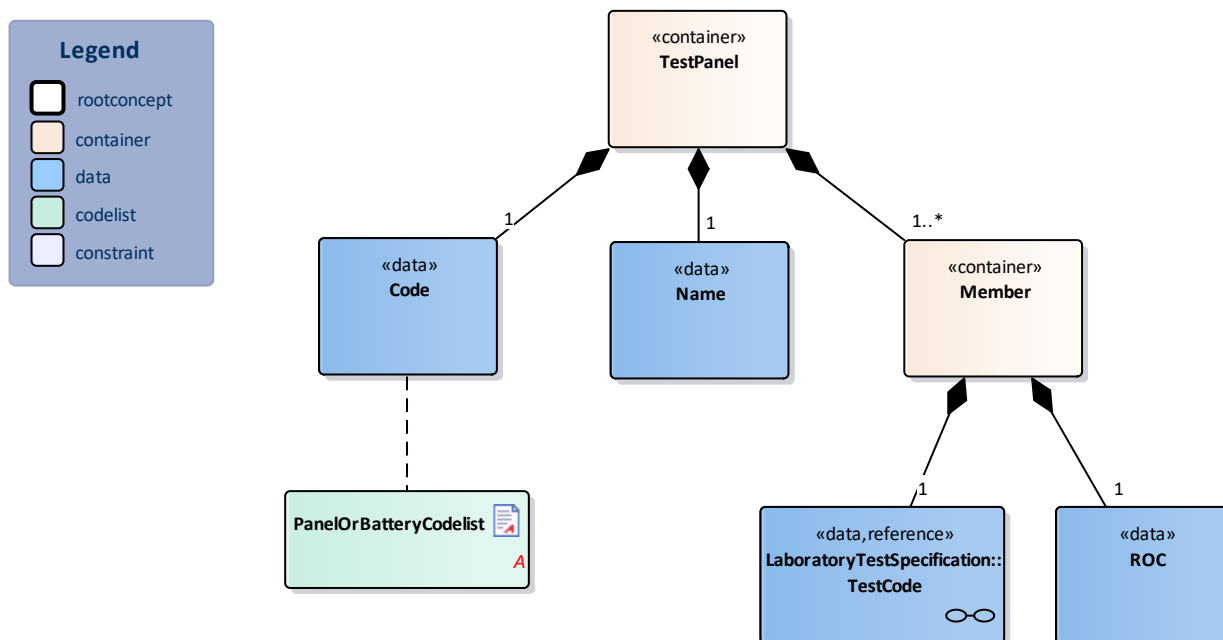


Figure 22: Test Panel Information Model

Type	Concept	Card	Description
«container»	TestPanel		TestPanel (also indicated as 'battery' or 'cluster') represents a grouping mechanism that allows to group tests that are usually ordered and/or reported together. Examples: blood gases and EBV serology.
«data»	Code	1	Test panel Code
«container»	Member	1..*	Test panel Member container.
«data»	LaboratoryTestSpecification::TestCode	1	Code system and code of the test.
«data»	Name	1	Test panel Name
«data»	ROC	1	Information if the test is: R - Required, R-a - Required with alternatives, means required but has alternatives. The alternatives will usually be paired, and both will be marked with the R-a code. Results for at least one member of the pair must be included in the panel to satisfy the required condition, but both may be included. O - Optional. Means the variable may be included or not, but whether it is included or not has no bearing on the whether a given set of result represents

Type	Concept	Card	Description
			the given panel. Simple calculations derived from other reported measurements and ask at order entry questions are almost always optional. C - Conditional (depends on other factors). Rflx - Reflex (will be included only if satisfies reflex condition based on other results in the panel) Rflx-a - Reflex with alternatives

PanelOrBatteryCodelist		OID: 2.16.840.1.113883.2.4.3.11.60.40.2.13.1.5
Codes	Coding Syst. Name	Coding System OID
All values	LOINC	2.16.840.1.113883.6.1
All values	NPU	
< ????	SNOMED-CT	

More specific Value set needs to be developed.

5.1.5.21 Time Interval Information Model

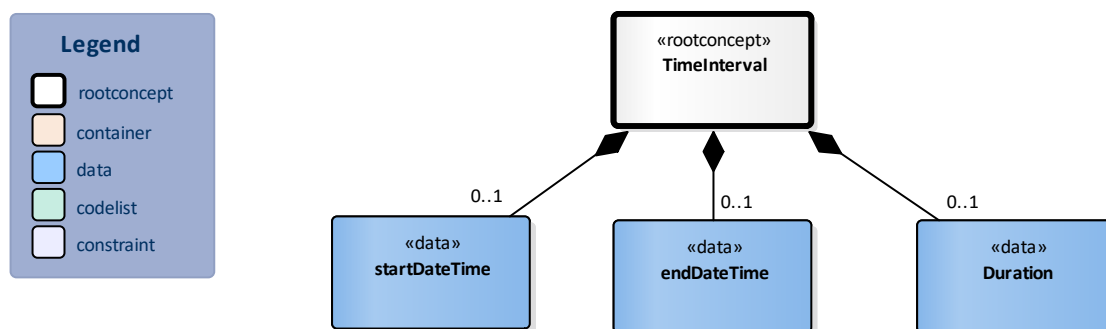


Figure 23: Time Interval Information Model

Type	Concept	Card	Description
«rootconcept»	TimeInterval		Root concept of the TimeInterval partial information model. This root concept contains all data elements of the TimeInterval partial information model.
«data»	startDateTime	0..1	The start date and time of the interval.
«data»	endDateTime	0..1	The end date and time of the interval.
«data»	Duration	0..1	The duration of the interval in appropriate units of time (e.g., days or hours, etc.)

5.1.6 Application

Application of EHR exchange in the laboratory domain vastly depends on local, regional, and national regulatory frameworks, business practices and availability and maturity of digital infrastructure. Generally, following aspects need to be elaborated:

- Unique identification systems for all stakeholders involved (patients, healthcare professionals, healthcare providers, laboratories). Preferably, health professionals shall use eID-based authentication mechanism.
- End user applications shall be available to healthcare professionals. These applications are typically diverse and highly customised regarding specific practice setting, laboratory speciality, clinical path etc. Examples: model lab orders with a set of tests for emergency treatment, blood bank, chronic disease management, standardised set of microbiology tests for surgery etc. Optionally, custom applications can have embedded tools to facilitate the interpretation of the results.
- Mechanisms to develop healthcare professional's digital skills, such as adoption of clinical guidelines, provision of training programmes etc. should be assured.
- In case local and/or national coding standards are applied, mapping catalogues shall be maintained to adjust national semantic standards to international ones. Example: the laboratory needs to implement mapping of the local test catalogue to the agreed international standard LOINC/NPU.
- National translation catalogues to ensure understandability of internationally standardised data elements and code systems exchanged cross-border needs to be established.
- Local, regional and/or national cybersecurity framework to ensure secure telecommunication channels, prevention and management of security incidents. Example: dedicated secure network for healthcare providers and laboratories, Security Operation Centres (SOC) for active monitoring and prevention.
- Applications for patient's access to laboratory orders and results should be available.
- Enhancement of MyHealth@EU infrastructure to support new X-border scenarios for laboratory domain.

5.1.7 Infrastructure

An operative ICT (information and communications technology) infrastructure shall exist to enable ordering entity and laboratory to exchange orders and reports, such as:

- a secure communication network,
- an electronic medical record system (e.g., hospital information system or ambulatory information system) capable of processing orders and results,
- a laboratory information system (LIS) capable of managing orders, producing the reports and submitting them via the mutually agreed channel.

This implies a necessity to establish regional, national, and international infrastructure, and define the respective APIs and communication channels.

Laboratory information systems and/or national infrastructure should provide semantic services to ensure proper mapping of all local code systems and measurement units to a nationally or internationally agreed ones.

Apart from the technical infrastructure, an organisational framework shall exist to support user scenarios. Healthcare providers and laboratories may need to adjust their internal organisation to

support ordering and reporting process. The process may need to be aligned with reimbursement mechanisms. Authorised national nodes need to be identified for cross-border communication.

Technical infrastructure should allow for searching of laboratory services and laboratory results and/or laboratory result reports using combination of predefined search criteria/parameters. Technical infrastructure should allow for aggregation of existing laboratory results into the laboratory summary laboratory reports which includes all recent and/or also historical (cumulative) test results.

5.1.8 Implementation

A common mapping between LOINC and NPU concepts is possible, although complex, and will partly rely on additional information or presumptions about, e.g., measurement technique, specimen type and measurement standard. A mapping table between LOINC and NPU is necessary for a safe exchange of laboratory test results between the two terminologies.

A prerequisite for a safe and secure exchange of laboratory results is a proper mapping between a local laboratory code and either a LOINC or a NPU code. Information about status of the patient (fasting or not), specimen type (capillary blood or venous plasma), measurement technique, and used measurement standards are needed to correctly assign a given measurement to a proper LOINC or NPU code. Errors in the local mapping process will transmit errors in mapping between the LOINC and NPU terminologies.

Once implemented, the mapping from a local measurement to either a LOINC or a NPU code, and subsequently between the LOINC and NPU terminologies, must be quality assessed.

The possibility to map the two terminologies is shown in this project for a subset of the most commonly used codes in Europe, see chapter 5.1.4.8. A further project is proposed to establish and suggest maintenance procedures for a complete mapping between the NPU and LOINC terminologies for the EU member states. The benefits of using common measurement units for laboratory test results across Europe should also be considered.

Even when the agreement on standardisation is reached, implementation is challenging due to complexity and dynamic development of both medical science and laboratory industry. Mapping of the immense number of laboratory test codes used in national implementations may be facilitated by a stepwise approach, focusing on the subset of tests that are most frequently used.

Mapping between national standards (e.g., LOINC to NPU) would be of a common interested and may possibly be addressed by future projects.

5.2 Use case description

5.2.1 Laboratory result report use case

Title	UC5.3.1 Laboratory result report use case
Purpose	<p>The use case describes how the health care provider (ordering entity) receives results from a set of laboratory analyses performed by laboratory. Results might be distributed directly to the ordering entity or to the central/regional or local result repository (EHR) system for later retrieval by the ordering entity or by any other entity involved in the healthcare episode of a patient.</p> <p>The results can also be received and seen by the patient.</p>

Title	UC5.3.1 Laboratory result report use case
	<p>Some samples are sent to another laboratory or to the reference laboratory for confirmation of the results. However, this situation is covered by a separate use case (UC5.3.7).</p>
Relevance	<p>Laboratory medicine is an essential element of the health care system. It is integral to many clinical decisions, providing physicians, nurses, and other health care providers with often pivotal information for the prevention, diagnosis, treatment, and management of disease. (Lewin Group: Julie Wolcott, 2008)</p> <p>The spectrum of testing ranges from highly standardised cost-efficient commodity testing, such as blood counts or clinical chemistry, to innovative, personalised testing procedures for analysis of human genetics. All healthcare professionals involved in the healthcare episode of a patient should have access to the relevant laboratory results for their role in the healthcare process. Laboratory results information often comes from different sources. For the end-users, a transparent, source-independent, combined viewing of these results provides them with the necessary background for their decision-making. The patient should also have access to these laboratory results.</p> <p>Availability of electronic structured laboratory result reports reduce errors in transcription of the results into the patient clinical documentation from paper reports. Ability to access patient's laboratory test results from orders submitted by all ordering entities reduces unnecessary duplicate test examinations, thus saving costs of care services as well as burden on patients. Laboratory results are explicitly noted in Paragraph 11 c of EC Recommendation of 6.2.2019 on a European Electronic Health Record exchange format. (Commission, 2019)</p>
Domain	Laboratory
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational • Citizens at home and on the move
Context	<p>There is a demand for on-line access to lab test results, both from healthcare professionals and as part of an on-line electronic patient record (EHR). Today's solutions mainly involve dedicated point-to-point communication between laboratory and HP's information systems. The HP typically only has access to lab results of tests ordered by him / herself. There is also an increasing demand for secondary use of test results.</p> <p>This use case is applicable to any source of the laboratory result report, either provided by a laboratory or by any other lab result repository system, e.g., central/regional/local EHR system.</p>
Information	Laboratory results report
Participants	Patient Health care provider Health care provider ordering system Laboratory professional

Title	UC5.3.1 Laboratory result report use case
	Laboratory information system
Preconditions	A test order or result report query has been submitted to the laboratory or other source of the laboratory test result report by an authorised entity.
Functional process flow	<p>The laboratory result report workflow³⁶ usually follows the laboratory order use case. The Automation Manager of the clinical laboratory, after performing the test analysis of the specimens, sends the test results to the laboratory application (known as Order Filler) responsible of managing the order where those are consolidated into the appropriate order or order group. The results report, formed according to the requirements and query parameters formulated by the ordering or querying entity or by the internal rules of the laboratory pertinent to the ordering entity, are sent to the application of the clinical practice (known as Order Result Tracker) on the clinical side.</p> <p>The Order Filler Application also notifies both Order Placer (the application of the clinical practice which generates the order) and Order Result Tracker of all status changes of each order and its related results.</p> <div data-bbox="456 954 1417 1258"> <pre> graph LR OP[Order Placer] -- "Placer order" --> OF[Order Filler] OF -- "Filler order" --> OP OF -- "Work order" --> AM[Automation Manager] AM -- "Test results" --> OF OF -- "Results report" --> ORT[Order Result Tracker] </pre> </div> <p>The Order Placer and Order Result Tracker Actors are implemented by the systems used by the clinical practice.</p>

¹ Based on the Laboratory Testing Workflow (LTW) profile of IHE:
https://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_TF_Vol1.pdf

5.2.1.1 Description of Actors

Actors of laboratory result report use case are described in chapter 3.3.1.

5.2.1.2 Result Report Workflow

Result report use case covers workflows related to tests performed and reported by a clinical laboratory in response to in-vitro diagnostic test orders.

5.2.1.2.1 Standard Result Report Workflow

Laboratory, after performing its internal testing workflow, which includes consolidation of all test result orders or order groups and all steps of data quality assurance and validation, forms a

³⁶ Based on the Laboratory Testing Workflow (LTW) profile of IHE:
https://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_TF_Vol1.pdf

complete result report, formed according to the requirements and query parameters formulated by the ordering entity, marks report as “final” (sets Laboratory result report status to “final”) and sends it to the application of the clinical practice (known as Order Result Tracker) as well as to all informants included in the Laboratory test order. A copy of the report might be stored to an attached EHR repository system.

All individual test results which are included in the final laboratory result report should be also marked as Final or Cancelled.

5.2.1.2.2 Partial Result Report Workflow

In some cases, laboratory might release result report which is either incomplete (not all results are available or marked as “final”) or is unverified. This is usually the case when some of the results are known to be produced later (due to the nature of the test or due to organisational or technical reasons in laboratory) while other test results need to be communicated to report recipients due to a specific organisational and/or process rules or due to an urgency of some of the test results. In such case the report status should be always set to “preliminary” or “partial”. For details see Table 10.

5.2.1.2.3 Amended Result Report Workflow

When result report content or referenced resources have been modified (edited or added to) after being released as “final” and the report is complete and verified by an authorised person, report status should be set to “amended”, “corrected” or “appended”, depending on the situation. For details see Table 10.

5.2.1.2.4 Cancelled Result Report Workflow

In some cases, laboratory might not be able to perform any test and deliver a result report. This might have many reasons, e.g., lost sample, broken tube, dysfunction of the analyser etc. In such case the status value should be updated to “cancelled” and the specific details given - preferably as coded values in the TestResultvalue.CodedResult element. Additional information may be provided in the result comment element as well (see also chapter 5.2.1.7.1.1.3).

5.2.1.2.5 Error Result Report Workflow

If the laboratory result report was originally created/issued in error, then its status should be set to “entered-in-error”. This is an amendment that marks that the entire report should not be considered as valid.

5.2.1.2.6 Laboratory result report status

Laboratory result reports, as documented in the previous chapters, could exist in several states depending on a particular workflow. Applications consuming laboratory test result reports must take careful note of updated (revised) reports and ensure that retracted reports are appropriately handled.

For applications providing diagnostic reports, such as laboratory result reports, a report should not be final until all the individual data items reported with it are final or appended.

If the report has been withdrawn following a previous final release, the report and associated observations should be retracted by replacing the status codes with the concept “entered-in-error” and setting the conclusion/comment (if provided) and the text narrative to some text like “This

report has been withdrawn" in the appropriate language. A reason for retraction may be provided in the narrative. A state machine documents possible transitions between states.

Figure 24: Laboratory result report state machine diagram

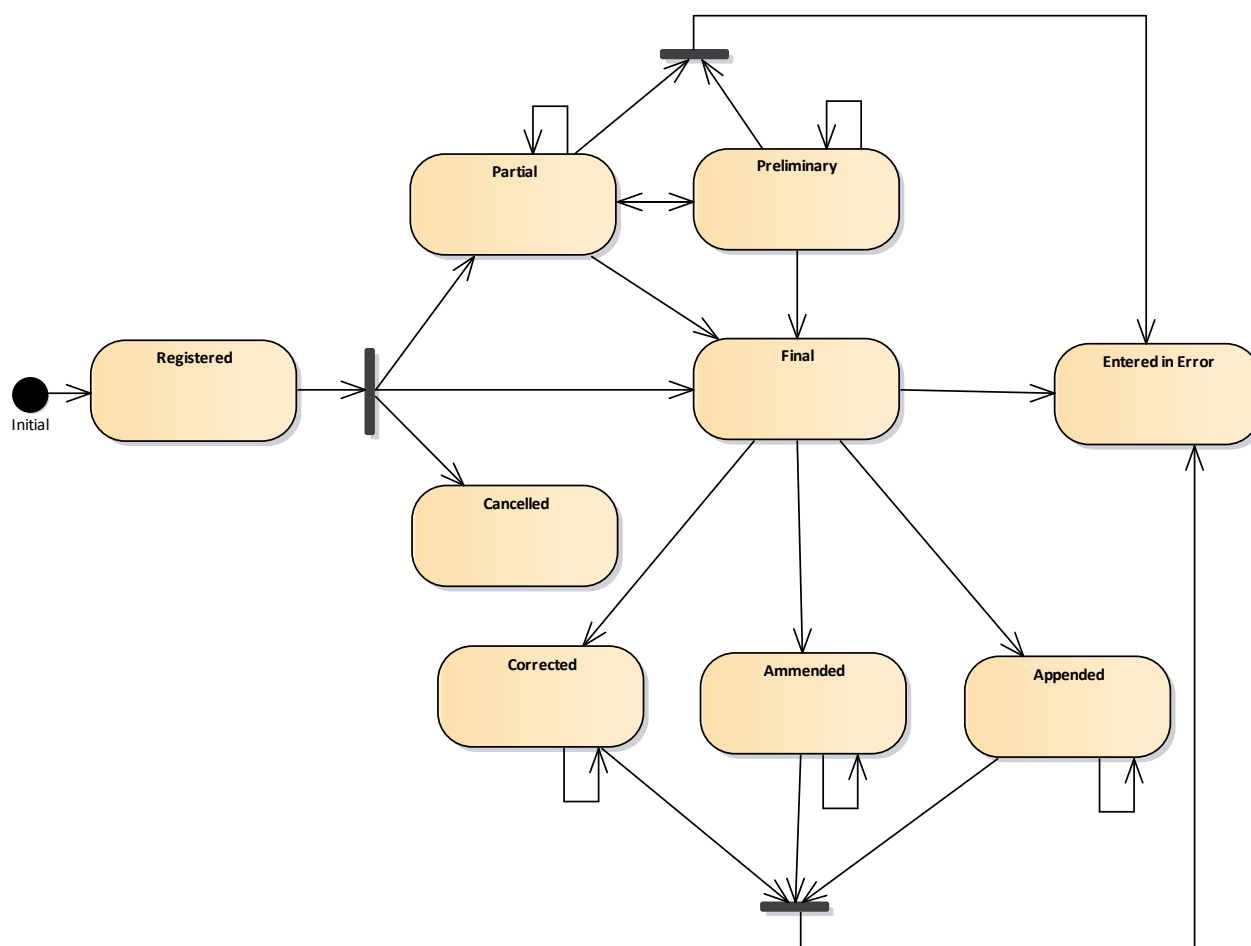


Table 10: Laboratory Result Report States

State	Description
registered	The existence of the report is registered, but there is nothing yet available.
partial	This is a partial (e.g., initial, interim or preliminary) report: data in the report may be incomplete or unverified.
preliminary	Verified early results are available, but not all results are final.
final	The report is complete and verified by an authorised person.
amended	Subsequent to being final, the report has been modified. This includes any change in the results, diagnosis, narrative text, or other content of a report that has been issued.
corrected	Subsequent to being final, the report has been modified to correct an error in the report or referenced results.
appended	Subsequent to being final, the report has been modified by adding new content. The existing content is unchanged.
cancelled	The report is unavailable because the measurement was not started or not completed (also sometimes called "aborted").
entered-in-error	The report has been withdrawn following a previous final release. This electronic record should never have existed, though it is possible that real-world decisions were based on

State	Description
	it. (If real-world activity has occurred, the status should be "cancelled" rather than "entered-in-error".).

5.2.1.2.7 Test result status

Not only the report itself, but also its entries, i.e., individual test results included in the laboratory result report, could be in a different lifecycle stage. This stage could be expressed using a status code as described in the Table 11 with state transitions depicted in Figure 25.

Table 11: Result status

State	Description
Pending	The existence of the observation is registered, but there is no result yet available.
Preliminary	This is an initial or interim observation: data may be incomplete or unverified.
Final	Final result
Amended	Subsequent to being Final, the observation has been modified subsequent. This includes updates/new information and corrections.
Corrected	Subsequent to being Final, the observation has been modified to correct an error in the test result.
Cancelled	The observation is unavailable because the measurement was not started or not completed (also sometimes called "aborted").
Entered-in-error	The observation has been withdrawn following previous final release. This electronic record should never have existed, though it is possible that real-world decisions were based on it. (If real-world activity has occurred, the status should be "cancelled" rather than "entered-in-error".).

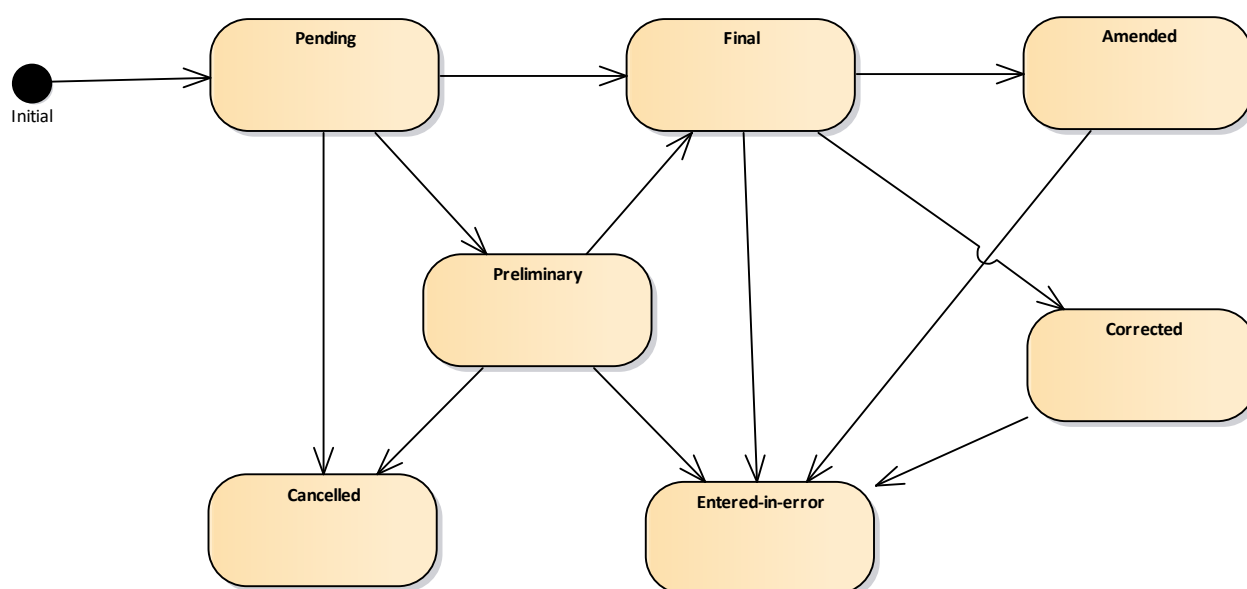


Figure 25: Test result state transition diagram

5.2.1.2.8 Relationship between laboratory report status and test result status

Although the status of the document and status of its entries is partially independent from the workflow point of view, it is possible to formulate basic rules for checking their consistency based on their definition.

Report status	Report status description	Result status consistency rules (for implementers)
registered	The existence of the report is registered, but there is nothing yet available.	ALL registered OR cancelled
partial	This is a partial (e.g., initial, interim or preliminary) report: data in the report may be incomplete or unverified.	SOME (registered, preliminary, final, cancelled) OR SOME NOT verified
preliminary	Verified early results are available, but not all results are final.	SOME (registered, preliminary, final) AND ALL (verified OR cancelled)
final	The report is complete and verified by an authorised person.	ALL (final AND verified) OR SOME cancelled
amended	Subsequent to being final, the report has been modified. This includes any change in the results, diagnosis, narrative text, or other content of a report that has been issued.	SOME amended OR entered-in-error OR other report content changed
corrected	Subsequent to being final, the report has been modified to correct an error in the report or referenced results.	SOME corrected OR entered-in-error
appended	Subsequent to being final, the report has been modified by adding new content. The existing content is unchanged.	ALL (final AND verified)
cancelled	The report is unavailable because the measurement was not started or not completed (also sometimes called "aborted").	ALL cancelled
entered-in-error	The report has been withdrawn following a previous final release. This electronic record should never have existed, though it is possible that real-world decisions were based on it. (If real-world activity has occurred, the status should be "cancelled" rather than "entered-in-error".).	ALL entered-in-error

5.2.1.3 Legal and regulatory

The Commission Recommendation (EU) 2019/243³⁷ identifies laboratory results as one of the baseline domains for European EHR exchange format. First release of the eHN Laboratory report guidelines has been prepared by eHN Subgroup on semantics in collaboration with X-eHealth project and adopted by the eHN.

³⁷ <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019H0243&from=EN>

The forthcoming EHDS regulation (still in proposal) defines laboratory results among minimum categories of personal electronic health data for primary use (Article 7, 1.e). It also establishes obligation to follow standards and common specifications. The information systems processing laboratory results are considered EHR systems in the sense of this regulation and will be subject of conformance assessment. The regulation also implies obligation to provide secure and interoperable access to laboratory results for patients and health professionals.

Laboratory services are subject of Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The Regulation is applicable from 26 May 2020. The harmonisation of national regulations with IVDR is the responsibility of member states. National healthcare systems may apply different conditions, depending on their healthcare organisation and payment models. National regulations should enforce strict requirements on laboratory services to ensure they comply with standards and regulatory requirements. Laboratories may only operate with valid certificates/licencing requirements with a fixed duration and subject to audit and reporting requirements. Laboratories must also ensure GDPR compliance for patient data and privacy, and ensure that specific risks are identified within use cases e.g., transcoding, unit transformation, Interpretation of ranges, relative “unfamiliarity” with methods and results, mutual recognition of test products/methods, etc.

National regulation may define the mandatory elements of the laboratory test report. As an Example, the provisions of Art. 13 of Slovenian Rules on requirements to be met by laboratories performing laboratory medicine tests³⁸ provides requirements on timely issuance, transparent versioning, and distinctive duplicates. It also defines the minimal set of data elements (laboratory name and address, unambiguous patient identification, ordering entity ID, sample type, time of sample collection, report creation time, type of test, test result, reference values, signature of the responsible person).

5.2.1.4 Policy

Healthcare providers require access to a diverse range of general and specialist laboratory services, provided internally or by external resources. Access to laboratory resources is essential and should be digitalised by means of an internationally standardised ordering and reporting procedures, which should be co-ordinated and integrated with laboratory information systems and the patient’s electronic health records.

National policies should foster implementation and uptake of structured and coded laboratory test results in conformance with the recommended international standards. The clinical laboratory is a source of expertise on testing and has an essential role in the leadership and co-ordination of testing for healthcare professions. All testing and laboratory orders in hospital settings should be accredited to ISO 15189/22870 standards and meet the requirements as described in this guideline. Member states, in accordance with laboratory accreditation schemes, should audit and monitor all aspects of electronic laboratory result reporting including laboratory services provided internally and those sourced externally. Payers of laboratory services may require provision of structured and coded laboratory results as a mandatory element of the service.

Education and training of healthcare professionals in all aspects of laboratory work, especially on collection of samples, sample handing procedures, observations, conditions of the subject and interpretation are clearly understood. It is equally critical to raise health professional’s awareness on the specific risks related to variability of observation results produced by different laboratories

³⁸ <http://pisrs.si/Pis.web/pregledPredpisa?id=PRAV5602>

due to, e.g., use of different coding systems, methods of measurement, different calibrators, and measurement units by different laboratory service providers. Health professionals should be educated to be able to detect and cope with such variations.

5.2.1.5 Semantic

Laboratory examinations in Europe must be performed with devices according to the in vitro diagnostic regulation (IVDR) (Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, 2017). One of the principles that follows from the regulation is that properties from examinations should be metrologically traceable to materials or procedures of higher order, with some implications for how examination results are presented.

Medical laboratories performing the examinations do not only examine properties in blood and other tissue samples, but also strive to make their results actionable for patient treatment. They ensure that the laboratory reports are correct and transmitted to the requesting physician with a short turnaround time. Laboratories also assist in the interpretation of their results by providing comments, statements regarding measurement uncertainty, reference intervals, medical decision limits, or other means. (Andreas Bietenbeck*, 2018)

These tasks already require increasing support by information technology. Electronically transmitted laboratory reports reach their recipient faster. Interpretive comments are often added based on complex rules that are evaluated by the laboratory information management system.

Laboratory test results are important part of clinical diagnostic process within an episode of care as well as a longitudinal record of the clinical development of a patient. In many cases, in particular for chronic patients, laboratory test results are indicators of success or failure of the management of the chronic disease and important indicators of the need of clinical intervention. Sample taking, at the other hand, especially in case of children, might represent an unpleasant experience to the patient, not speaking about cost implications in case of unnecessary testing.

That's why it is so important to allow sharing of laboratory test results across different healthcare providers, ensuring their comparability over time (especially if they originate from different laboratories potentially using different examination techniques and measurement units), and clear understanding of their meaning by the physicians.

In practice, we see variability of the test names for the same property and values expressed with different measurement units across laboratories and habits in test naming and units' preferences across healthcare providers. Laboratories are using different examination techniques and assays with different reagents for the measurement of the same property. These factors significantly increase the risk of misinterpretation of the laboratory test results and make comparison of the test results from different laboratories and their proper interpretation a challenge and will need appropriate measures.

Interoperability of clinical data – between labs, institutions, and jurisdictions – is not limited to data transmission alone. The desideratum is semantic interoperability, i.e., the exchange of meaningful data based on a common semantic reference, such as domain terminologies that provide codes and terms together with definitions. Such standards have the potential to facilitate biomedical research and advance learning in laboratory medicine through meaning-preserving inter-laboratory comparisons. (Andreas Bietenbeck*, 2018)

5.2.1.5.1 Conventional and systematic test names

Standard laboratory test coding systems and terminologies have developed naming conventions to identify laboratory tests precisely and unambiguously.

E.g., test names for examination of substance concentration of glucose in plasma measured in millimole per litre and the same test measured 30 minutes as part of the glucose tolerance test.

Code system	Code	Test Name
NPU	NPU02192	FSN ³⁹ = Plasma—Glucose; substance concentration = ? mmol/L
LOINC	14749-6	FSN = Glucose:SCnc:Pt:Ser/Plas:Qn: LCN ⁴⁰ = Glucose [Moles/volume] in Serum or Plasma
SNOMED CT	434911002	Plasma glucose concentration (observable entity)

Code system	Code	Test Name
NPU	NPU04174	FSN = Plasma—Glucose; substance concentration (30 min) = ? mmol/L
LOINC	14763-7	FSN = Glucose^30M post dose glucose:SCnc: Pt:Ser/Plas:Qn: LCN = Glucose [Moles/volume] in Serum or Plasma --30 minutes post dose glucose
SNOMED CT	434911002: 370134009=255241008	434911002 Plasma glucose concentration (observable entity) : 370134009 Time aspect = 255241008 30 minutes post-dose (qualifier value)

As fully specified names could be quite complex, short names are usually parts of the coding system as well.

Code system	Code	Test Short Name or synonym
NPU	NPU02192	P—Glucose; subst.c. = ? mmol/L
LOINC	14749-6	Glucose SerPl-sCnc
SNOMED CT	434911002	Plasma glucose concentration

Code system	Code	Test Short Name or synonym
NPU	NPU04174	P—Glucose; subst.c.(30 min) = ? mmol/L
LOINC	14763-7	Glucose 30M p Glc SerPl-sCnc
SNOMED CT	434911002: 370134009=255241008	434911002 Plasma glucose concentration (observable entity) : 370134009 Time aspect = 255241008 30 minutes post-dose (qualifier value)

Many laboratories are not using standardised test names because of their length and complexity but rather simplified names according to the local or historical conventions. This is a quite broad

³⁹ FSN – Fully specified Name

⁴⁰ LCN = Long Common Name

practice, not necessarily wrong, if some basic rules of laboratory test naming, which ensure semantic clarity of the laboratory test result reports, are followed:

- Name of the test must clearly identify the measurand
- System that has been examined must be clearly identifiable in the test result report
- Laboratory report should include information about examination technique that has been used

5.2.1.5.2 Device

For some less defined measurands, for example concentration of soluble transferrin receptor in plasma, it is not possible to interpret the result without knowledge about the vendor specific measuring system. According to the IVDR the specific device, or measuring system, used to generate the laboratory result should be CE marked according to the IVDR and can be identified by an UDI-DI (or a “single registration number”). UDI is composed of two parts:

- UDI-DI: Device Identifier (DI) – static part. It contains, e.g., the identifier of the selected allocation point, the identifier of the manufacturer / labeller, the reference code of the product and may also contain an identification for a specific packaging level.
- UDI-PI: Production Identifier (PI) – dynamic part. It contains, e.g., on the expiry date, serial number (SN) and sometimes also information on the date of manufacture.

The UDI-DI is used for tracking laboratory results from a specific measuring system which has been found to produce unreliable results which therefore must be withdrawn. Through the UDI-DI it will also be possible to retrieve information about the manufacturer and the name of the measuring system when this is needed for the interpretation of the test results and for better result traceability. This should be certainly only optional information reserved to a specific type of laboratory tests to preserve abuse of lab result information from marketing analysis.

5.2.1.5.3 Laboratory test results

Laboratory test results might be reported using a designated terminology system. The terminology system should be implemented in the lab information system and/or analyser to reduce loss of information due to mapping procedures. For example, LDL cholesterol level may be reported as a quantitative value with a numeric value type, the results of a blood culture might identify an organism using a controlled value set of coded entries, and the results of a genetic mutation or microbiology analysis may be reported as narrative text.

5.2.1.5.4 Quantitative test results

Quantitative test results, in short, are results presented as numeric value together with a unit.

A special case of quantitative result is the titre. The expression “1/150” is interpreted as a value of 150 with the kind of property “arbitrary substance concentration” within the NPU system. Within the LOINC system the titre is regarded as a specific kind-of-property “Titre” for a quantitative result, but the result can be expressed as “1:150” (which is not a numerical value on the ration scale).

Different kind-of properties (such as mass or molar) and units (such as number of cells per litre, number of cells per µL) are in use for reporting laboratory results in the health care systems, often decided by local traditions. Health care personnel and patients become used and familiar with

certain measurement units, and it is strenuous to swift habits and even dangerous to change units because of risk for mistakes. There is no international agreement on which units should be used. On national or regional level some attempts have been done, such as the introduction of SI units in the Scandinavian or Czech health care system in the 1970-ies.

The two main laboratory coding systems on the market differ with respect to units. The NPU terminology include a specification of the unit (only one unit allowed for each NPU code) while the LOINC-system allows for the use of multiple units for the same kind-of-property.

It is important that laboratory result reports should always include standard test result units in addition to the local (conventional) units “in use”, if possible, to ensure semantic interoperability between different information systems and healthcare providers. There are legal reasons in some of the countries to always include results with conventional units originally measured by laboratory in addition to the standard once. This means that laboratories that use conventional units should provide and maintain unit conversion. Unit conversion is a simple mathematical operation (multiplication by a factor) or a simple formula in most cases.

5.2.1.5.4.1 Conversion of results for the same kind of property with different units

Laboratory test result values could be expressed using different units as could be seen from the following examples (proper units according to the SI standard are marked **bold**). Conversion to standard units thus could be achieved through a simple recalculation of the result value by a constant factor or by applying of a simple formula in some cases (see Example 5).

Example 1: The results of a platelet count, that is the number concentration of platelets in a blood sample, can be expressed by different units. The same result can thus be expressed as:

- 150 000 1/ μ L
- 150 x 10³/ μ L
- 150 1/nL
- **150 x 10⁹/L**

Example 2: The mass concentration of haemoglobin in a blood sample can be expressed as:

- 15 g/dL
- **150 g/L**

Example 3: The mass concentration of paracetamol (acetaminophen) can be expressed as:

- 15 μ g/mL
- **15 mg/L**
- 1,5 mg/dL
- 1,5 mg/100mL

According to SI the prefix of a unit should be restricted to the numerator of a unit. Thus “g/L”, “mg/L” and “10⁹/L” are SI units.

Example 4: For enzyme activity both the unit U/L and µkat/L are recognised by SI, with the conversion factor 60.

Example 5: The conversion between degree Fahrenheit and degree Celsius for the measurement of temperature is slightly more complicated:

- Fahrenheit to Celsius: $t (^{\circ}\text{C}) = (t (^{\circ}\text{F}) - 32) / 1.8$

Expressing the unit in a special UCUM format (The Unified Code for Units of Measure⁴¹) allows for automatic conversion between different units for the same kind-of-quantity).

5.2.1.5.4.2 Conversion of results between different properties or dimensions

Different kind of properties of an analyte can be measured. Analytes (e.g., haemoglobin, paracetamol) can be measured with respect to, for example, colour, density, mass, or amount of substance in blood. The substance concentration (units such as mmol/L, µmol/L), mass concentration (units such as g/L, mg/L) and mass fraction (mg/kg) are common within analytical chemistry. For analytes with known molecular structure, such as paracetamol, it is often recommended to express results as substance concentration, while substances with less well-defined molecular structure expression of mass concentration might be preferable. The distinction between “well” and “less well” defined molecular structure is arbitrary. For large and heterogenic molecules, e.g., proteins, the uncertainty for a conversion can be substantial.

Measurement results for many substances are not traceable to SI. The results are instead traceable to an arbitrary agreed calibrator, for example a WHO standard as a higher order reference material, for which results are reported with the unit IU. Conversion factors between results traceable to IU/L (arbitrary substance concentration) to µg/L (mass concentration) or to nmol/L (substance concentration) might have large level of uncertainty and might be highly controversial.

Table 12: Example of unit and dimension conversions (adopted from Mayo clinic)

Analyte	Reported Unit	Conversion Factor	SI Unit
25HDN – 25-Hydroxyvitamin D2 and D3, Serum			
25-Hydroxy D2	ng/mL	2.4271845	nmol/L
25-Hydroxy D3	ng/mL	2.5	nmol/L
25-Hydroxy D Total	ng/mL	2.496	nmol/L
3MT – 3-Methoxytyramine, 24 Hour, Urine			

⁴¹ <https://ucum.org/trac>

Analyte	Reported Unit	Conversion Factor	SI Unit
3-Methoxytyramine, U	mcg/24 h	5.98068240	nmol/d
ACE – Angiotensin Converting Enzyme, Serum			
Angiotensin Converting Enzyme, S	U/L	0.017	kat/L
ACTH – Adrenocorticotrophic Hormone (ACTH), Plasma			
Adrenocorticotrophic Hormone, P	pg/mL	0.22	pmol/L
AL – Aluminum, Serum			
Aluminum, S	ng/mL	0.0371	mol/L
ALB – Albumin, Serum			
Albumin, S	g/dL	10	g/L
ALDS – Aldosterone, Serum			
Aldosterone, S	ng/dL	0.0277431	nmol/L
ALDU – Aldosterone, 24 Hour, Urine			
Aldosterone, U	mcg/24 h	2.77430989	nmol/d
ANST – Androstenedione, Serum			
Androstenedione, S	ng/dL	0.0349144	nmol/L
CA – Calcium, Total, Serum			
Calcium, Total, S	mg/dL	0.25	mmol/L

5.2.1.5.4.3 Calibrators

A calibrator is a solution from a traceable source with a known amount (concentration) of analyte of interest that is pure and only contains that analyte of interest. It is used to adjust and ensure that the analytical instrument is detecting the true value within an established uncertainty. A calibrator might be identified by its Unique Device Identifier UDI-DI. The assigned value should be metrologically traceable to a certified reference material or reference measurement procedure of higher order.

5.2.1.5.4.4 Ordinal scale test result

Some quantitative test result values are preferably being displayed not as an exact numerical value but rather as a grading using conventional expression, e.g., sensitivity expressed using + sign. Results below or over a certain threshold value can be expressed as “negative” or “positive”.

Some examples include:

Measurand	Value	Display format
Urine dip stick test for haemoglobin	2	++
Urine pregnancy test	1	positive
Histopathologic grading of a case of prostatic cancer	3	Gleason grade group 3

5.2.1.5.4.5 Reporting uncertainty of measurement

In general, no measurement or test is perfect, and the imperfections give rise to error of measurement in the result. Consequently, the result of a measurement is only an approximation to the value of the measurand and is only complete when accompanied by a statement of the uncertainty of that approximation. Methods of evaluating and expressing uncertainty of the measurement are described in the literature.

The requirements of ISO/IEC 15189 distinguish between the need for reporting and the need for evaluation of uncertainty of measurement.

According to ((UKAS), 2000), following requirements to the laboratory test result reports apply:

- Reporting is required when information on uncertainty is relevant to the validity or application of the test results, when the client requires it or when the uncertainty affects compliance with a specification limit.
- The methods used to calculate the result and its uncertainty should be available either in the report, or in the records of the test including:
 - (a) Sufficient documentation of the steps and calculations in the data analysis to enable a repeat of the calculation if necessary
 - (b) All corrections and constants used in the analysis, and their sources.
 - (c) Sufficient documentation to show how the uncertainty is calculated.
- The result of the measurement should be reported together with the expanded uncertainty appropriate to the 95% level of confidence, in the following manner:

Measured value	100.1 (units)
Uncertainty of measurement	± 0.1 (units)

- Uncertainty of the measurement might be also expressed in the comment attached to the result or a set of results.

5.2.1.5.4.6 Expression of numeric results of measurement

Numeric result values should be expressed (displayed to the end user) using international standard CEN - EN 12435 Health informatics - Expression of results of measurements in health sciences standard/convention. According to this standard, large or small numerical values shall be displayed or printed with spaces between groups of three digits to the left and right of the decimal mark, for which the comma is preferred but the point in the line is recognized in English texts as an alternative.

5.2.1.5.5 Qualitative test results

Qualitative test results are sometimes used as a term for all results that are not expressed by a number, that is either ordinal or nominal, according to the LOINC and NPU terminologies. In some contexts, “qualitative test results” are limited to nominal test results only.

The non-numeric results can be of type “negative”, “not found”, “Grade 3”, or “E. coli”. In order to present this type of result in a language independent way they need to be well defined and coded. A possibility is to use a subset of SNOMED CT codes for this purpose.

For example, SNOMED CT can be used as a standard terminology system for result values of the test identified by a LOINC code [600-7] Bacteria identified in Blood by Culture or an NPU code NPU06099 B—Bacterium; taxon(proc.) = ?, assuming that the following three bacteria species were identified after culture of the blood in a patient:

1. Neisseria meningitidis,
2. Brucella melitensis, and
3. Staphylococcus aureus.

Although the Latin names of the bacteria species are structured according to the Linnean system of terminology, the names are not code values. The best available code source for the terms is SNOMED CT and the results could be expressed according to the table below:

SNOMED CT Code	Name of bacteria
17872004	Neisseria meningitidis (organism)
72829003	Brucella melitensis (organism)
761983013	Staphylococcus aureus (organism)

5.2.1.5.6 Narrative text results

Laboratory results shall generally not be written in narrative text. Narrative content may be added to structured results as a guide to interpretation. Narrative content is generally not recommended in cross-border scenarios due to risks of semantic misinterpretation, however it is still a preferred method in some type of tests. Use of narrative text result should be as much as possible limited in favour of use of nominal test result types.

5.2.1.5.7 Test result components

Some laboratory observations need a complex structure of results. This is typically a case when the next step in the laboratory process depends on the result of a previous step (nested results), such

as in case of microbiology cultures and subsequent susceptibility testing on antibiotics or Gram staining test.

Using the example from 5.2.1.5.4.6, findings from bacteria culture test could be presented as a set of three elements: {Neisseria meningitidis; Brucella melitensis; and Staphylococcus aureus}. Then the laboratory performs a set of susceptibility tests of each identified species of bacteria to a set of selected antibiotics.

To enable result reporting of such complex laboratory test results, either a reference between different test results needs to be kept, e.g., bacteria culture test result (e.g., Neisseria meningitidis) should be referenced by each result of a susceptibility test to antibiotics (e.g., Tetracycline, Gentamycin, Vancomycin etc.), or each test result should encompass its sub-components. The susceptibility test to the antibiotics can be coded with NPU or LOINC codes. NPU uses different codes for the antibiotic test depending on if the result is reported as ordinal or quantitative result. LOINC codes for susceptibility testing have a “OrdQn” scale, which means that the results can be reported as ordinal or quantitative on the same LOINC code. The LOINC codes also include the primary method used for susceptibility testing, e.g., disc diffusion or minimum inhibitory concentration (MIC).

The results from the bacterial susceptibility tests are either ordinal e.g., (S) susceptible, (I) susceptible with increased exposure or (R) resistant, or quantitative from a minimum inhibitory concentration (MIC) test, e.g., mg/L or µg/mL. The ordinal results can be reported with SNOMED CT codes.

Figure 26: Example of result report from microbiology culture and susceptibility testing, including coding.

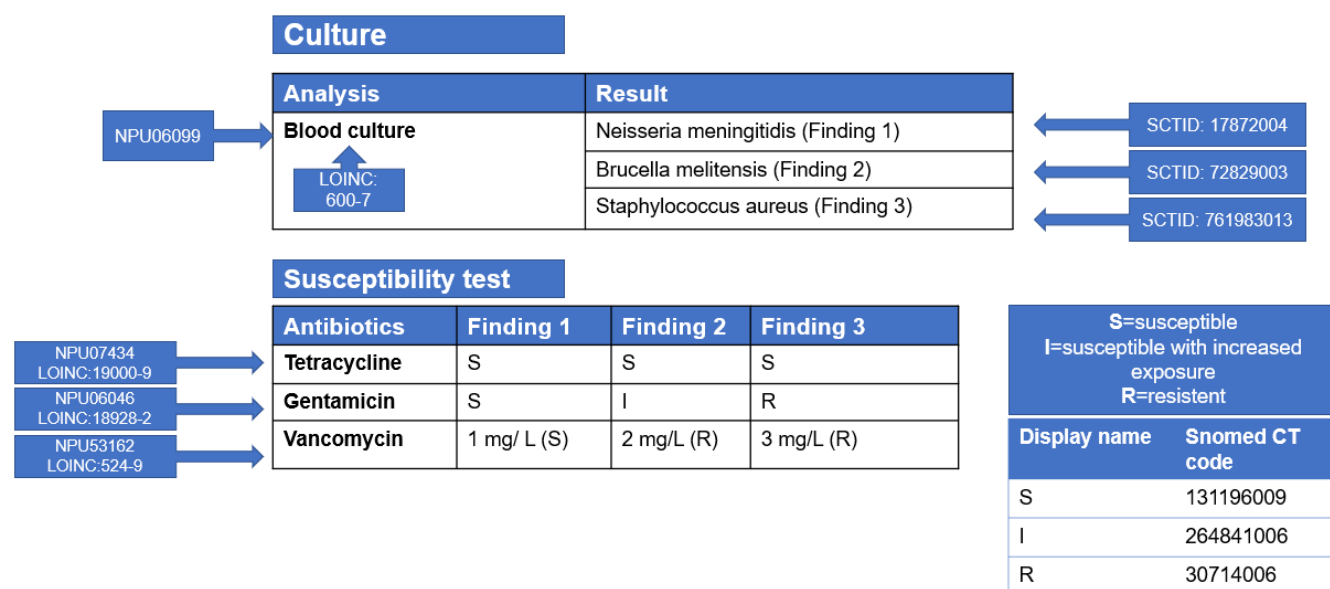


Figure 27: Microbiology result example from Sweden

Slutsvar SKRIV UT

Provtagningsid
2022-01-04 00:00

Svaret skickat till
Kirurgmottagning Gävle

SÅR/SEKRET ODLING 1 ← **Header "Wound culture"**

Om provet
Provmaterial: sårsekret ← **Specimen**
Lokalisation: höger fot ← **Localization**

Header "Analysis" → **Analys**
Referensintervall

Wound culture → **Sår-Bakterieodling**
(2 resultat)

Header "Result" → **Resultat och kommentarer**
* markerar resultat utanför referensintervallet

Finding 1 → **Växt av Staphylococcus aureus (Fynd 1)**
Svar ej vidimerat

Finding 2 → **Växt av E. coli (Fynd 2)**
Svar ej vidimerat

Header "Susceptibility test" → **RESISTENSBESTÄMNING**

Header "Antibiotics" → **Substans**

Antibiotics → **Fynd 1** **Fynd 2**

Substans	Fynd 1	Fynd 2
Betalaktamasresistenta pc	S	
Cefotaxim		S
Cefuroxim		S
Ciprofloxacin (MIC)		0,24 mg/L (S)
Fusidinsyra	S	
Gentamicin	S	S
Klindamycin	S	
Sulfametoxazol+Trimetoprim		S

SIR result → **S**

MIC result → **0,24 mg/L (S)**

S=susceptible
I=susceptible with increased exposure
R=resistent

S: Mikroorganismen är känslig för den här substansen vid normal dosering
I: Mikroorganismen är känslig för den här substansen vid ökad exponering
R: Mikroorganismen är resistent mot den här substansen

5.2.1.5.8 Laboratory interpretation of test results

Laboratories do not only perform diagnostic testing but also assist in the interpretation of their results by providing comments, statements regarding measurement uncertainty, reference intervals, medical decision limits, or other means. (Andreas Bietenbeck*, 2018)

5.2.1.5.8.1 Interpretation scale

Each laboratory test could have an interpretation scale that could be used for evaluation of the quantitative and semi quantitative test results. Interpretation scale could have one or more interpretation intervals:

- Reference range is the range of values that is deemed normal for a physiologic measurement in healthy population.

- Increased range is the range in which the values are deemed to be increased or reduced comparing to the reference range.
- High range is the range within which the values are deemed high or low comparing to the reference range. Values outside the High range are usually considered pathological.
- Limit range; values outside this range are deemed extremely high or low.

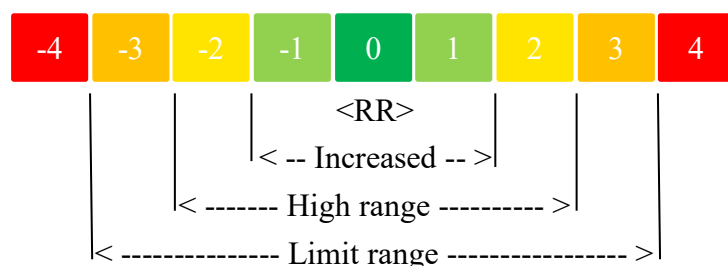
For many tests, there is no single interpretation scale that applies to all specimens because the tests performed may be affected by the age and sex of the patient, as well as many other considerations. So, specific interpretation scales might exist for different sex and age groups, reproduction phases, pregnancy status, drugs taken, etc.

Interpretation scales are available only for limited number of laboratory tests based on clinical outcome studies and expert consensus.

Interpretation scales vary depending on the instrument and the reagents used to perform the test. Therefore, the scales provided by a particular laboratory could be different from another laboratory settings.

Result values could fall into one of up to 9 interpretation intervals (-4 .. 4) as a result of comparison of a test value and interpretation scale endpoints. This could be expressed by a result interpretation code from a suitable code system.

Interpretation interval	Result interpretation
-4	below limit range low point
-3	below high range low point and above or equal to limit range low point
-2	below increased range low point and \geq high range low point
-1	below referential range low point and \geq increased range low point
0	inside referential range (above or equal to low point and below or equal high point)
1	above referential range high point and below or equal to increased range high point
2	above increased range high point and \leq high range high point
3	above high range high point \leq
4	above limit range



5.2.1.5.8.2 Expressing a result trend

Cumulative laboratory result reports might include evaluation of the trend between two consecutive measurements. Trend describes a gradual change of a particular test result over time. It is an indication of the change of the quantitative test result value from the previous measurement. The calculation of a trend or significant change is usually limited to a certain period as trend evaluation makes sense only if the two values have been measured within a meaningful time interval. A significant change is a difference between two values that is larger than a critical difference which depends on the inherent biological variation and on the reproducibility of the observation technique (test method).

Trend can also be expressed using relative values like percentage of change or more often using trend levels and could have a graphical representation attached to the test result value, e.g.:

Level	Interval	Example graphical representation
-3	DELTA% < -45%	<<<
-2	-45% <= DELTA% < -30%	<<
-1	-30% <= DELTA% < -15%	<
0	-15% <= DELTA% <= +15%	
1	+15% < DELTA% <= +30%	>
2	+30% < DELTA% <= +45%	>>
3	+45% < DELTA%	>>>

When evaluating the trend, like in case of interpretation scale, other attributes can be considered – e.g., pregnancy status, week of pregnancy, etc.

5.2.1.5.8.3 Interpretative text

Laboratory test results might be accompanied with an interpretative text in addition to the result value. Interpretative text can be provided on a single test level or on a report level or on both levels. Interpretative text is typically provided in microbiology or for special tests in chemistry (e.g., for electrophoresis oligoclonal bands interpretation). Interpretative text could be in the form of plain or structured text with or without embedded graphical elements or images.

5.2.1.5.9 Result report note

Result reports could also include end notes with various information provided by the laboratory including information about suspicious results generated by internal laboratory rule system, e.g., discrepancy between sodium and chloride result values, etc.

5.2.1.5.10 Interoperable test result sharing principles

- Sharing of the laboratory test results in an interoperable and safe way certainly represents a challenge, especially in the cross-border situation as we described in previous chapters. Certain rules need to be established and followed to minimise risk of misinterpretation of laboratory test results.
- Laboratory test result reports should always include standard test codes and standard names. Short test names might be also provided for display purposes.

- Local (conventional) test names might be provided together with standard test names for legal and traceability reasons.
- All numeric test results should be expressed using agreed test units according to a national or international standard. Result values that were originally produced by laboratory using non-standard units must be recalculated. The original results (when using non-standard units) must be also provided for legal and traceability reasons.
- Reference scales (if provided) should be adjusted accordingly to the standard measurement units and shared together with result values
- Result reports might also include original values and measurement units as produced by the laboratory
- Conversion of results between different properties or dimensions (e.g., substance concentration to mass concentration) might be provided only for analytes with known molecular structure.
- EU wide test code system or set of code systems should be selected. There are two main candidates: LOINC and NPU code system. Both systems have their advantages and disadvantages, and both are in daily use by more than one EU Member state. Mapping between those two systems is a complex task and should be done and maintained in international (EU) collaboration.
- EU wide standard test result units should be agreed.

5.2.1.6 Technical

Users of laboratory result reports and laboratories shall be connected to ICT infrastructure enabling safe and secure EHR exchange.

Clinical information systems (CIS) used by users of laboratory results (ordering parties, clinicians at points of care) shall provide functions for retrieval and provision of laboratory result reports, such as:

- Patient identification
- Patient Consent management (in case the processing of report is based on patient consent)
- Healthcare professional's identification, authentication and authorisation
- Presentation (view) of structured and coded lab result in a form appropriate for healthcare professional. Optionally, implementation in CIS can be facilitated by a common generic application module for lab result presentation (viewer) that can be integrated via a standardised API. Availability of such a standardised viewer on a regional, national or international level can ease adoption of digitalised laboratory reports in diverse Clinical Information Systems. Combined with local mapping/translation services, a common laboratory report viewer can be an effective enabler of semantic interoperability.

Laboratory information systems (LIS) shall provide functions for creating and sharing lab results, such as:

- Patient identification, sample identification and sample tracking
- Provision and recording of structured test reports within the laboratory workflow
- Internal mapping from the original results (e.g., automatically provided by laboratory devices or middleware) to the agreed coding including recalculation to an agreed measurement units in accordance with the valid semantic standards
- Provide a technical interface (API) for the submission of result report to the ordering party (either directly or via shared/centralised establishment for EHR exchange)
- Generation of consolidated lab reports for the given set of tests (provided that a batch of different tests is performed)
- Digital signatures of laboratory professional/legal authenticator and/or digital signature/seal of the laboratory

Optionally, the reporting system may be enhanced by notification services for ordering parties and/or patients. Upon submission of the report, ordering party and/or patient may be notified via e-mail, SMS or mobile app notifications. Such a notification service may either be provided by the laboratory or by common (regional, national) EHR systems (repositories /databases for the exchange of laboratory results). Notification services are especially valuable in case of emergent or critical situations, where the result is urgently needed for further treatments and clinical decisions.

Information systems for processing of test results may be supplemented with mechanisms for automated reporting to national and/or international public health authorities. As an example, microbiology reports identifying specific disease agents may trigger automatic reporting to public health authorities for the purpose of control and surveillance of communicable diseases (e.g. mandatory reporting of confirmed/positive cases). Another example is automatic collection of population data on non-communicable diseases triggered by certain lab results and thresholds (glucose, cholesterol etc.)

CIS and LIS shall provide system functions in accordance with data protection and cybersecurity standards, such as audit trail, transaction logs and data encryption.

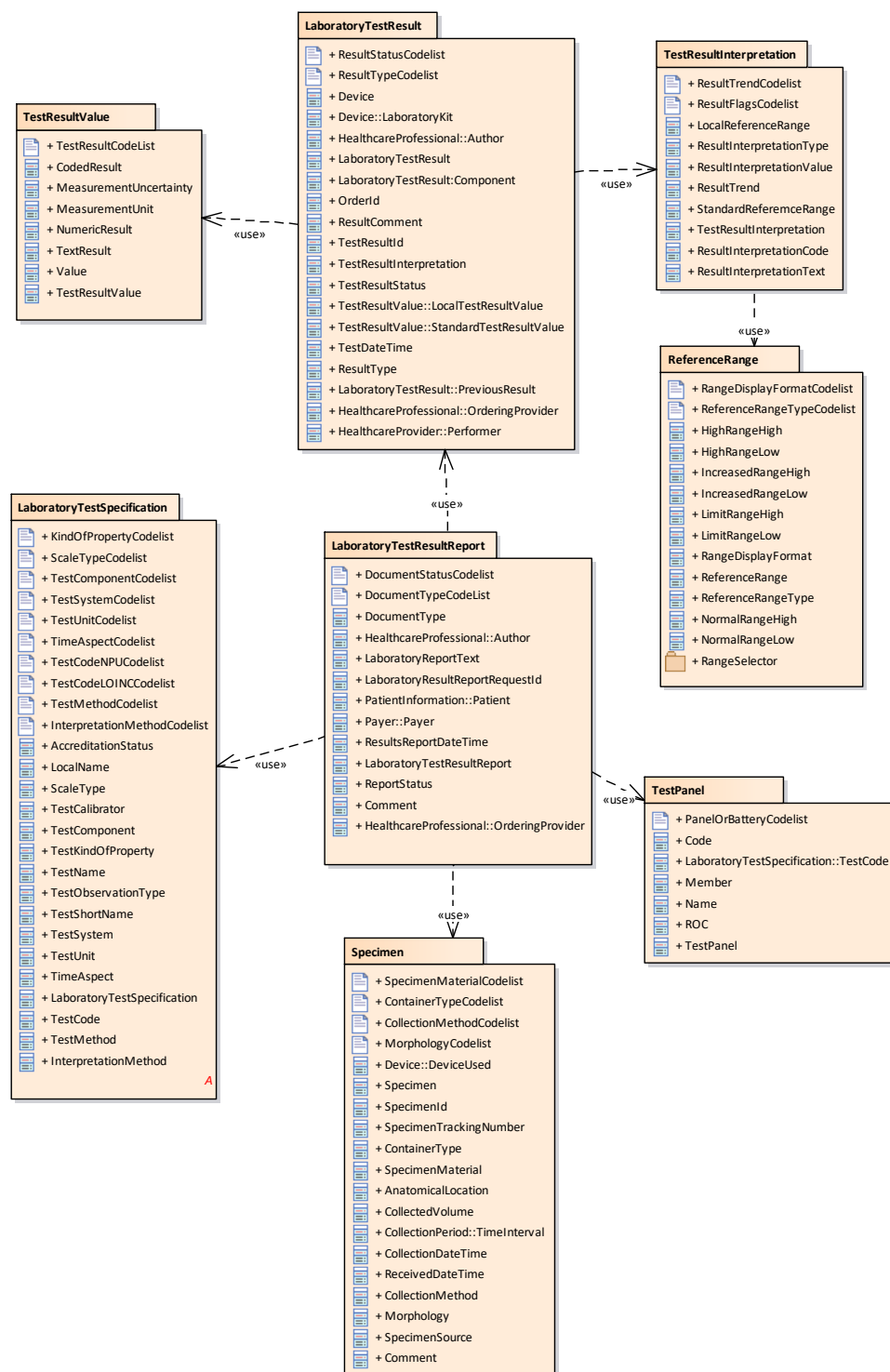
5.2.1.7 Information

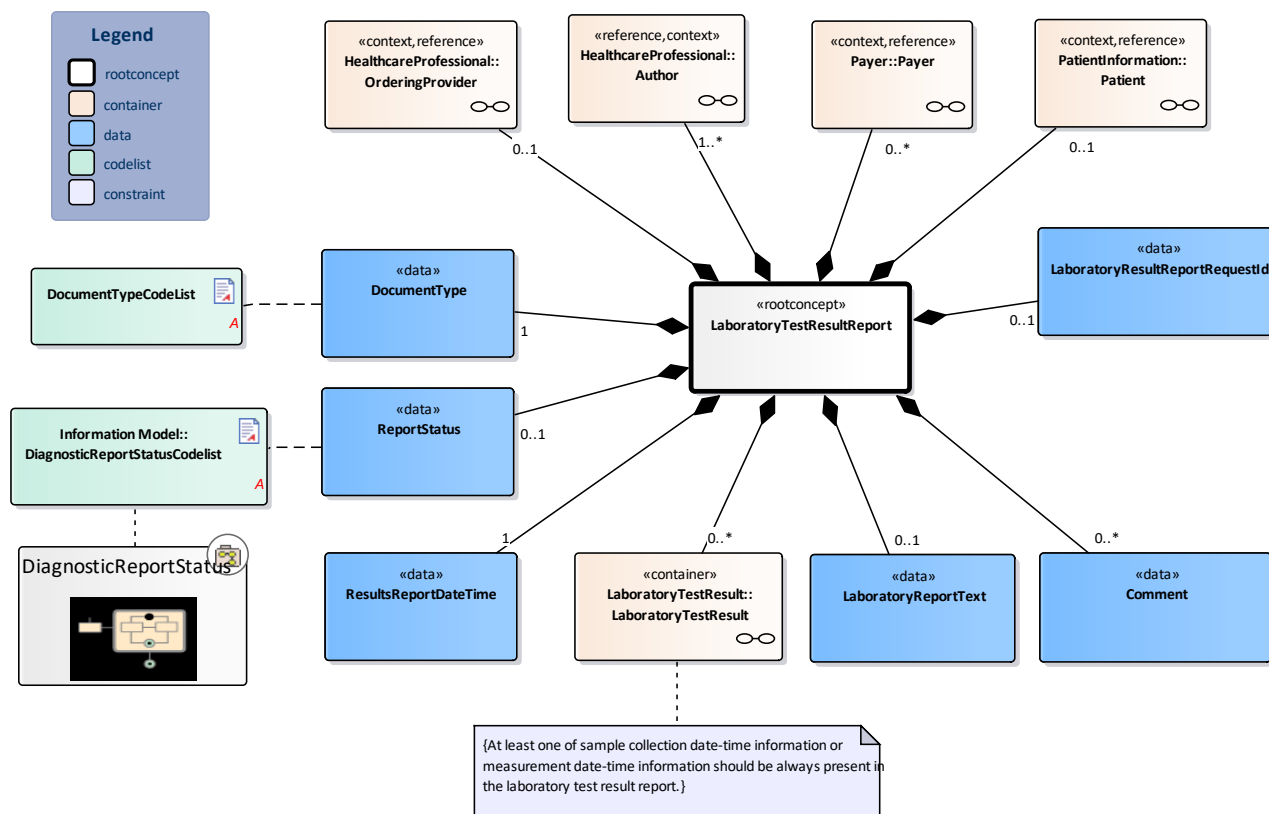
5.2.1.7.1 Information model

5.2.1.7.1.1 Laboratory Information Model

Laboratory information model comprises of several sub-models, as depicted on Figure 28.

Figure 28: Laboratory Information Model Components





Type	Concept	Card	Description
«rootconcept»	LaboratoryTestResultReport		Root concept of the LaboratoryTestResultReport information model. This root concept contains all data elements of the LaboratoryTestResultReport.
«data»	DocumentType	1	A coded type of the document.
«data»	LaboratoryReportText	0..1	A narrative, textual report with laboratory results, reference scales and results interpretation. The report can include current laboratory test results as well as test result history, graphics, images etc. For discussion: Should we model here more in detail? E.g., header, visual attachments etc.?
«data»	LaboratoryResultReportRequestId	0..1	A reference to (identifier of) the laboratory result report request.
«data»	ResultsReportDateTime	1	Date and time of the result report assembly.
«data»	ReportStatus	0..1	The status of the laboratory test result report.
«data»	Comment	0..*	Comments, such as a textual interpretation or advice accompanying the result report, for example.
«reference»	HealthcareProfessional::Author	1..*	The healthcare professional and/or healthcare provider organization by whom the LaboratoryTestResultReport was assembled and authorized.

Type	Concept	Card	Description
«context»	PatientInformation::Patient	0..1	Patient to whom the LaboratoryTestResultReport belongs to. In some cases, patient might not be relevant (e.g. when the lab is performing test on environmental material etc.). Identity of the patient is not always known or is to be hidden in some cases.
«context»	Payer::Payer	0..*	Information about source of reimbursement of the tests.
«context»	HealthcareProfessional::OrderingProvider	0..1	The healthcare professional and/or healthcare provider organization by whom the LaboratoryTestResultReport was ordered.

DiagnosticReportStatusCodelist			OID:		
Levl	Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
1	Registered	registered	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	The existence of the report is registered, but there is nothing yet available.
1	Partial	partial	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	This is a partial (e.g. initial, interim or preliminary) report: data in the report may be incomplete or unverified.
2	Preliminary	preliminary	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	Verified early results are available, but not all results are final.
1	Final	final	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	The report is complete and verified by an authorized person.
1	Amended	amended	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	Subsequent to being final, the report has been modified. This includes any change in the results, diagnosis, narrative text, or other content of a report that has been issued.
2	Corrected	corrected	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	Subsequent to being final, the report has been modified to correct an error in the report or referenced results.
2	Appended	appended	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	Subsequent to being final, the report has been modified by adding new content. The existing content is unchanged.
1	Cancelled	cancelled	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	The report is unavailable because the measurement was not started or not completed (also sometimes called "aborted").
1	Entered in Error	entered-in-error	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	The report has been withdrawn following a previous final release. This electronic record should never have existed, though it is possible that real-

DiagnosticReportStatusCodelist			OID:		
Level	Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
1	Unknown	unknown	hl7:DiagnosticReportStatus	2.16.840.1.11388 3.4.642.4.236	The authoring/source system does not know which of the status values currently applies for this observation. Note: This concept is not to be used for "other" - one of the listed statuses is presumed to apply, but the authoring/source system does not know which.

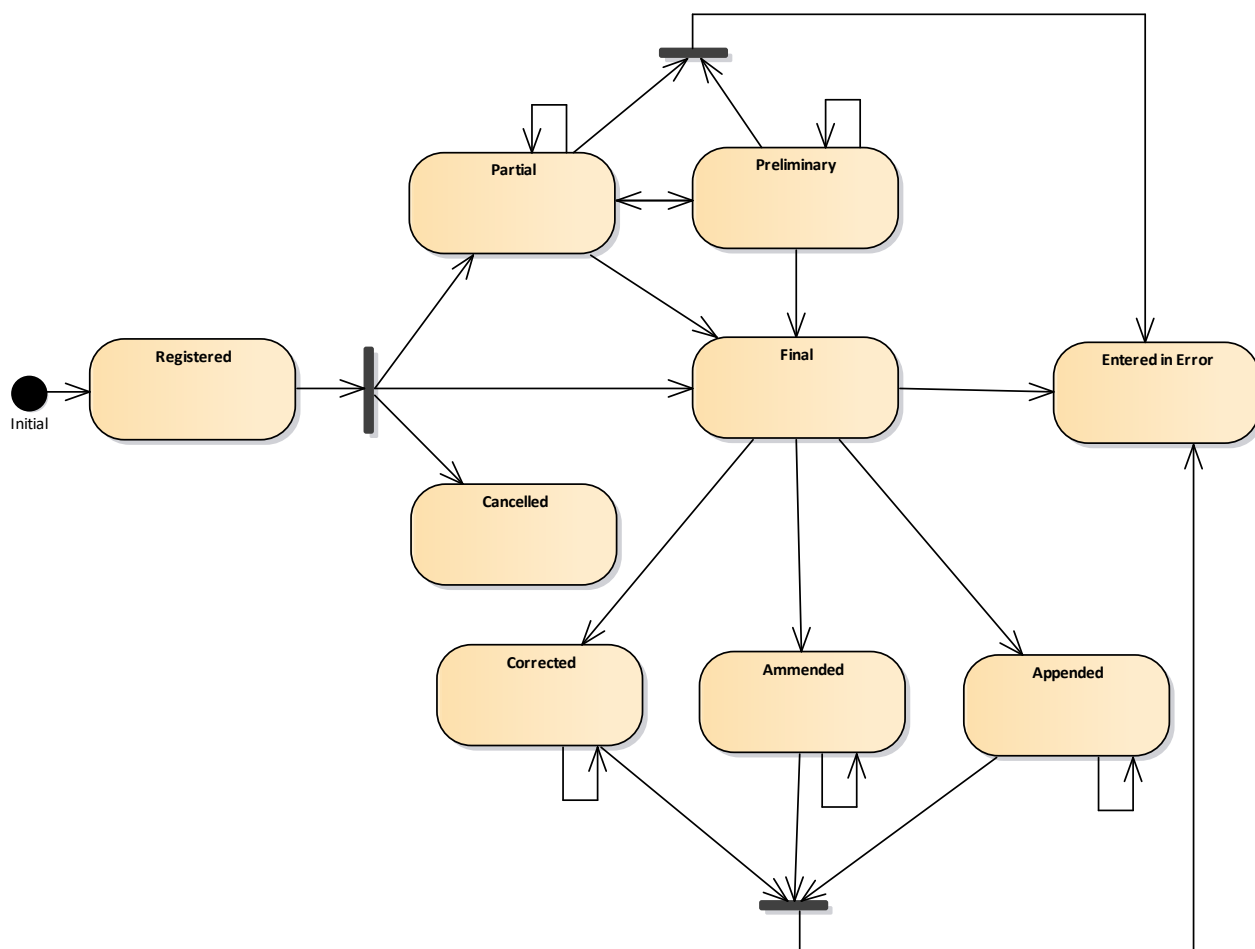
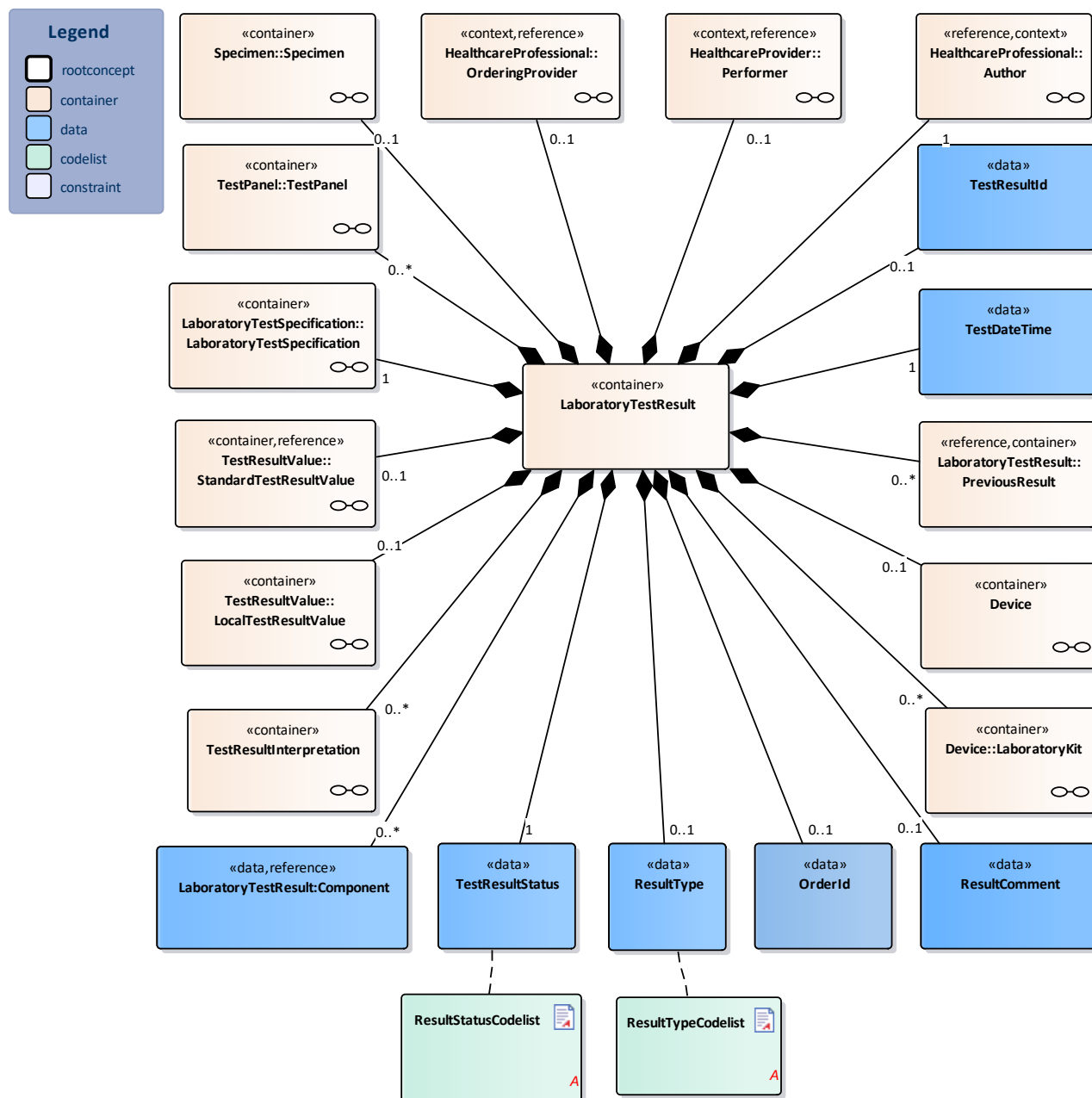


Figure 30: Result report state machine diagram

DocumentTypeCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Laboratory report	11502-2	LOINC		
Laboratory summary report	New code should be proposed	LOINC		

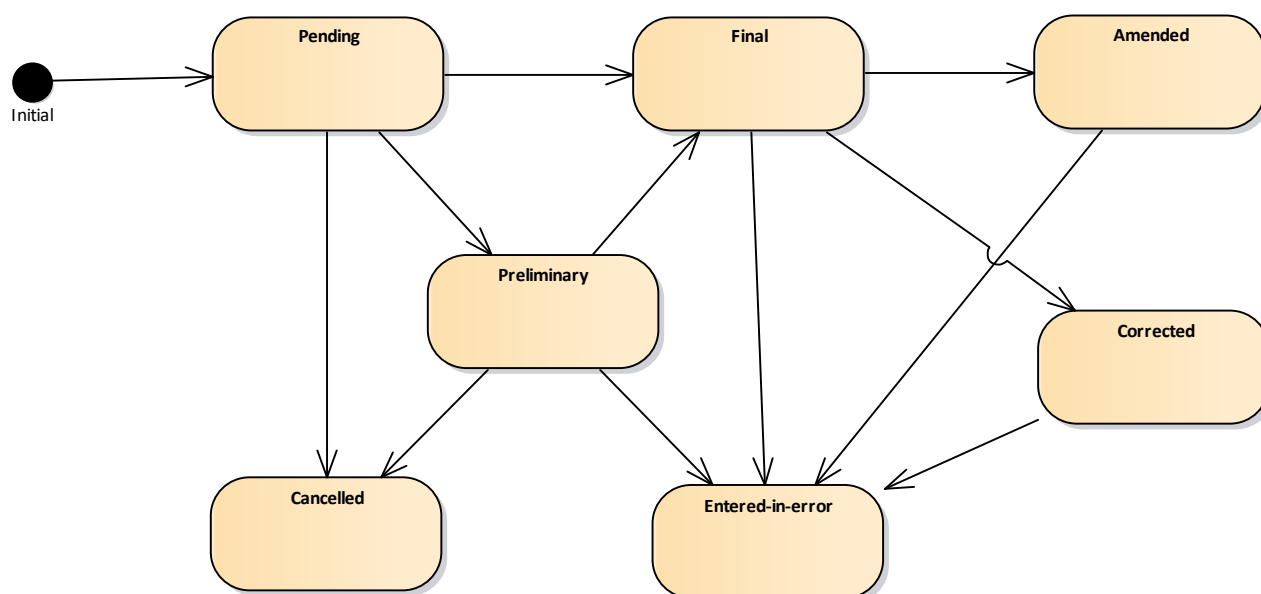
5.2.1.7.1.1.2 Laboratory Test Result



Type	Concept	Card	Description
«container»	LaboratoryTestResult		A container for LaboratoryTestResult elements.
«container»	Device	0..1	Container for information about device (laboratory analyzer) used to measure the test result.
«container»	Device::LaboratoryKit	0..*	Laboratory test kit used during measurement.
«reference»	HealthcareProfessional::Author	1	The healthcare professional and/or healthcare provider organization where or by whom the LaboratoryTestReport or LaboratoryTestResult was authorized.
«data»	LaboratoryTestResult::Component	0..*	Reference to a test result which is a component of the result. These components are expressed as separate code value pairs that share the same attributes. Examples include systolic and diastolic component observations for blood pressure measurement and multiple component observations for genetics observations.
«data»	OrderId	0..1	Id of the original order for this test result. This Id could be different from report order Id if this test result has been ordered by different ordering entity.
«data»	ResultComment	0..1	A free text non-interpretative comment to the test result.
«data»	TestId	0..1	A unique identifier of the test result.
«container»	TestResultInterpretation	0..*	Container of the TestResultInterpretation concept. Test results might have multiple interpretations of different kind, e.g. normal, therapeutic, recommended, etc. interpretations. Each interpretation might consist of human narrative interpretation of the test result value and/or numeric or coded result of the comparison against a reference scale belonging to the given type of interpretation and given target population (conditions of the patient, sampling method and time, and other procedural or clinical circumstances). Test result interpretation should not depend on measurement units (either local or standard).
«data»	TestResultStatus	1	Status of the test result, i.e., preliminary, final etc.
«container»	TestResultValue::LocalTestResultValue	0..1	Container for original test result value and units as produced by the laboratory if different from a standard test result value, kind of property and units.
«container»	TestResultValue::StandardTestResultValue	0..1	Container for TestResultValue expressed using agreed measurement units. Depending on the type of test, the test result will consist of a value with a unit or a coded value (ordinal or nominal) or a free text.
«data»	TestDateTime	1	The date and if possible, the time at which the test was carried out.
«data»	ResultType	0..1	The type of result defines the laboratory specialty under which the test is categorized. For discussion: should it rather define laboratory specialty under which the test has been performed? Category should be rather assigned to the test itself, or to the result?
«reference»	LaboratoryTestResult::PreviousResult	0..*	Reference to previous observations obtained for the same patient, test, kind of property, same examination technique (method), and unit.
«context»	HealthcareProfessional::OrderingProvider	0..1	The health professional and/or healthcare provider organization where or by whom the LaboratoryTestReport or LaboratoryTestResult was ordered.
«context»	HealthcareProvider::Performer	0..1	The healthcare provider and/or organization where or by whom the LaboratoryTestResult was performed or where or by whom the laboratoryResultReport was assembled.

ResultStatusCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Pending	registered	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	The existence of the observation is registered, but there is no result yet available.
Preliminary	preliminary	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	This is an initial or interim observation: data may be incomplete or unverified.
Final	final	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	Final result
Amended	amended	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	Subsequent to being Final, the observation has been modified subsequent. This includes updates/new information and corrections.
Corrected	corrected	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	Subsequent to being Final, the observation has been modified to correct an error in the test result.
Canceled	canceled	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	The observation is unavailable because the measurement was not started or not completed (also sometimes called "aborted").
Entered-in-error	entered-in-error	hl7:Observation Status	2.16.840.1.113883.4.64 2.3.400	The observation has been withdrawn following previous final release. This electronic record should never have existed, though it is possible that real-world decisions were based on it. (If real-world activity has occurred, the status should be "cancelled" rather than "entered-in-error".).

Figure 31: Result status transition diagram



ResultTypeCodeList			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Chemistry studies	18719-5	LOINC		
Coagulation studies	18720-3	LOINC		
Therapeutic drug monitoring studies	18721-1	LOINC		
Fertility studies	18722-9	LOINC		
Hematology studies	18723-7	LOINC		
HLA studies	18724-5	LOINC		
Microbiology studies	18725-2	LOINC		
Serology studies	18727-8	LOINC		
Toxicology studies	18728-6	LOINC		
Urinalysis studies	18729-4	LOINC		
Blood gas studies	18767-4	LOINC		
Cell counts+Differential studies	18768-2	LOINC		
Microbial susceptibility tests	18769-0	LOINC		
Molecular pathology studies	26435-8	LOINC		
Laboratory studies	26436-6	LOINC		
Chemistry challenge studies	26437-4	LOINC		

ResultTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Cytology studies	26438-2	LOINC		
Surgical pathology studies	26439-0	LOINC		
Pathology studies	27898-6	LOINC		
Microbiology - parasitic studies	92892-9	LOINC		
Microbiology - viral studies	92893-7	LOINC		
Microbiology - bacterial studies	92894-5	LOINC		
Endocrinology studies	92895-2	LOINC		
Microbiology - mycobacteriology studies Document	96397-5	LOINC		
Microbiology - mycology studies Document	96398-3	LOINC		

5.2.1.7.1.1.3 Test Result Value

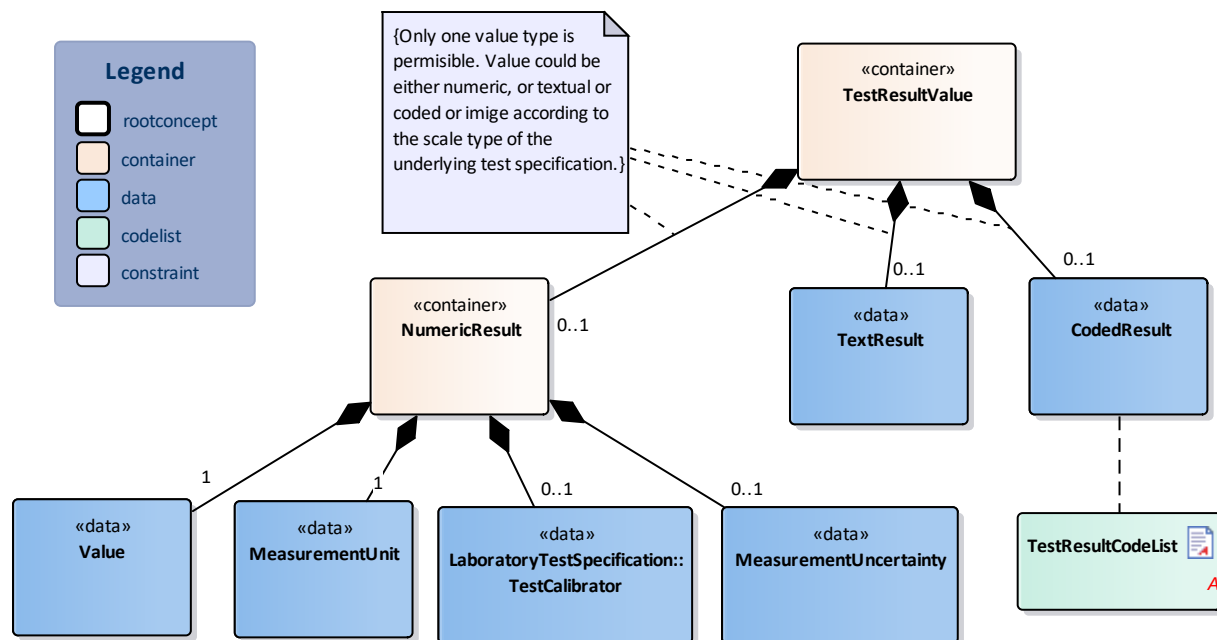


Figure 32: Test Result Value Information Model

Type	Concept	Card	Description
«container»	TestResultValue		Container for TestResultValue. Depending on the type of test, the test result will consist of a value with a unit or a coded value (ordinal or nominal) or a free text.
«data»	CodedResult	0..1	A coded result from a selected coding system(s). This could be a code describing bacteria or other microorganism identified, description of urinary concretum, code explaining technical reason why the test could not be done etc. Coded results could be ordered or unordered.
«data»	TextResult	0..1	Narrative free or structured text result.
«container»	NumericResult	0..1	
«data»	MeasurementUncertainty	0..1	Measurement uncertainty interval.
«data»	MeasurementUnit	1	Result units of the measurement.
«data»	Value	1	A numeric value or interval (open or closed) of the result.

TestResultCodeList	OID:	
Codes	Coding Syst. Name	Coding System OID
All concepts which is an organism	SNOMED CT	
All codes from AnswerList	LOINC	
Additional SNOMED CT codes needs to be identified.	SNOMED CT	

5.2.1.7.1.1.4 Test Result Interpretation

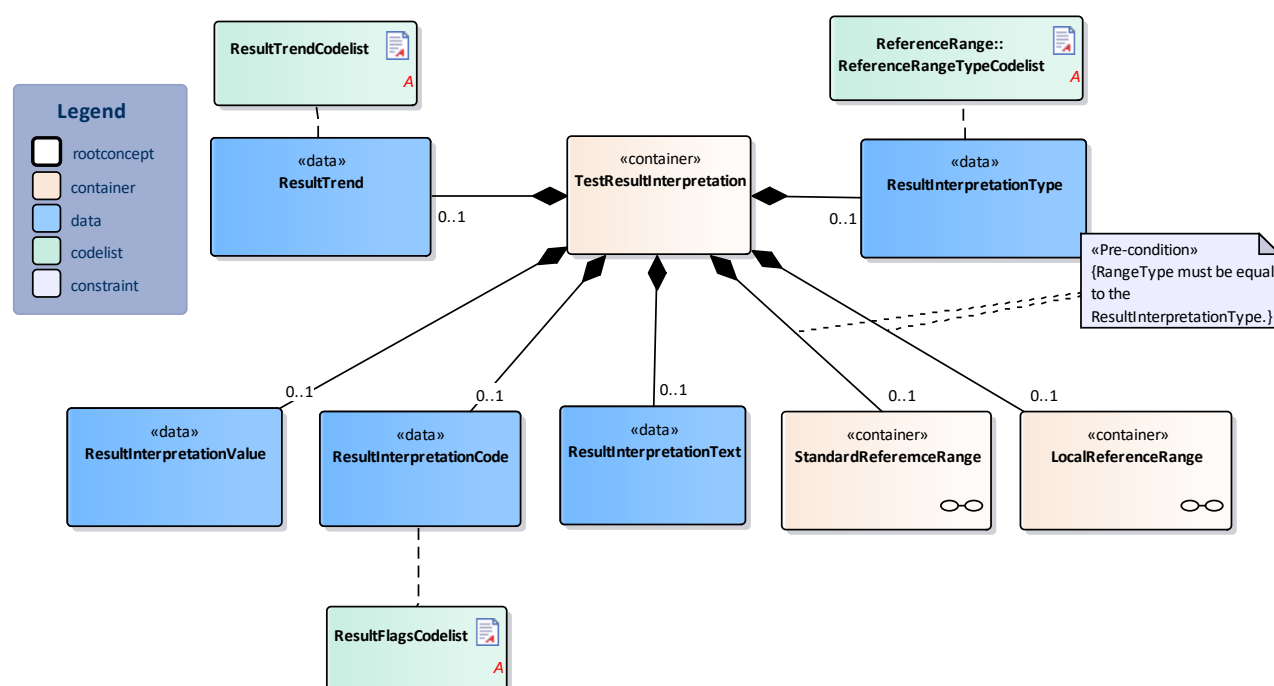


Figure 33: Test Result Interpretation Information Model

Type	Concept	Card	Description																
«container»	TestResultInterpretation		Container of the TestResultInterpretation concept with all its elements.																
«data»	ResultInterpretationType	0..1	Type of the result interpretation indicates what part of the targeted reference population it applies to. For example, interpretation using normal or therapeutic range. Default is "normal" interpretation type.																
«data»	ResultTrend	0..1	<p>Trend describes a gradual change in a particular test result over time. It is an indication of the change of the quantitative test result value from the previous measurement. The trend calculation is usually limited to a certain period of time as it makes sense only if the two values has been measured within a meaningful time interval, e.g., 1 week or similar. Trend can be expressed using relative values like percentage of change or using coded trend levels and could have a graphical representation attached to the test result value, e.g.:</p> <table><tr><td>Level Interval</td><td>example graphical representation</td></tr><tr><td>-3 ... DELTA% < -45%</td><td><<<</td></tr><tr><td>-2 ... -45% <= DELTA% < -30%</td><td><<</td></tr><tr><td>-1 ... -30% <= DELTA% < -15%</td><td><</td></tr><tr><td>0 ... -15% <= DELTA% <= +15%</td><td></td></tr><tr><td>1 ... +15% < DELTA% <= +30%</td><td>></td></tr><tr><td>2 ... +30% < DELTA% <= +45%</td><td>>></td></tr><tr><td>3 ... +45% < DELTA%</td><td>>>></td></tr></table> <p>When evaluating the trend, similar to the selection of the interpretation scale, other attributes can be considered - pregnancy and week of pregnancy, etc.</p>	Level Interval	example graphical representation	-3 ... DELTA% < -45%	<<<	-2 ... -45% <= DELTA% < -30%	<<	-1 ... -30% <= DELTA% < -15%	<	0 ... -15% <= DELTA% <= +15%		1 ... +15% < DELTA% <= +30%	>	2 ... +30% < DELTA% <= +45%	>>	3 ... +45% < DELTA%	>>>
Level Interval	example graphical representation																		
-3 ... DELTA% < -45%	<<<																		
-2 ... -45% <= DELTA% < -30%	<<																		
-1 ... -30% <= DELTA% < -15%	<																		
0 ... -15% <= DELTA% <= +15%																			
1 ... +15% < DELTA% <= +30%	>																		
2 ... +30% < DELTA% <= +45%	>>																		
3 ... +45% < DELTA%	>>>																		
«data»	ResultInterpretationCode	0..1	Attention codes indicating whether the result of a quantitative test is above or below certain reference values or interpreting the result otherwise (Resistant). The values Resistant, Intermediate or Susceptible are used with microbiological test results.																
«data»	ResultInterpretationText	0..1	Comment of the laboratory regarding the interpretation of the result.																
«container»	StandardReferenceRange	0..1	<p>Container of the ReferenceRange concept. Container contains all data elements of the ReferenceRange concept using standard (agreed) measurement units.</p> <p>If LocalReferenceRange is provided then StandardReferenceRange must be provided as well.</p>																
«container»	LocalReferenceRange	0..1	Container of the ReferenceRange concept. Container contains all data elements of the ReferenceRange concept using original (local) measurement units.																

ResultTrendCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Significant change down	D	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The current result has decreased from the previous result for a quantitative observation (the change is significant as defined in the respective test procedure).
Significant change up	U	hl7:v3-ObservationInter	2.16.840.1.113883.4.642.3.399	The current result has increased from the previous result for a

		pretation		quantitative observation (the change is significant as defined in the respective test procedure).
Decreased relative to previous (qualifier value)	442474009	SNOMED CT	2.16.840.1.113883.6.96	
Increased relative to previous (qualifier value)	442387004	SNOMED CT	2.16.840.1.113883.6.96	
Stabilized	409051000	SNOMED CT	2.16.840.1.113883.6.96	

ResultFlagsCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Abnormal	A	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result or observation value is outside the reference range or expected norm (as defined for the respective test procedure). [Note: Typically applies to non-numeric results.]
Critical abnormal	AA	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result or observation value is outside a reference range or expected norm at a level at which immediate action should be considered for patient safety (as defined for the respective test procedure). [Note: Typically applies to non-numeric results. Analogous to critical/panic limits for numeric results.]
Critical high	HH	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result for a quantitative observation is above a reference level at which immediate action should be considered for patient safety (as defined for the respective test procedure). Synonym: Above upper panic limits.
Critical low	LL	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result for a quantitative observation is below a reference level at which immediate action should be considered for patient safety (as defined for the respective test procedure). Synonym: Below lower panic limits.
High	H	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result for a quantitative observation is above the upper limit of the reference range (as defined for the respective test procedure). Synonym: Above high normal

ResultFlagsCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Significantly high	HU	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A test result that is significantly higher than the reference (normal) or therapeutic interval, but has not reached the critically high value and might need special attention, as defined by the laboratory or the clinician.
Low	L	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result for a quantitative observation is below the lower limit of the reference range (as defined for the respective test procedure). Synonym: Below low normal
Significantly low	LU	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A test result that is significantly lower than the reference (normal) or therapeutic interval, but has not reached the critically low value and might need special attention, as defined by the laboratory or the clinician.
Normal	N	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result or observation value is within the reference range or expected norm (as defined for the respective test procedure). [Note: Applies to numeric or non-numeric results.]
Off scale low	<	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result is below the minimum detection limit (the test procedure or equipment is the limiting factor). Synonyms: Below analytical limit, low off scale.
Off scale high	>	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The result is above the maximum quantifiable limit (the test procedure or equipment is the limiting factor). Synonyms: Above analytical limit, high off scale.
Insufficient evidence	IE	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	There is insufficient evidence that the species in question is a good target for therapy with the drug. A categorical interpretation is not possible. [Note: A MIC with "IE" and/or a comment may be reported (without an accompanying S, I or R-categorization).]
Resistant	R	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	Bacterial strain inhibited in vitro by a concentration of an antimicrobial agent that is associated with a high likelihood of therapeutic failure.
Susceptible	S	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	Bacterial strain inhibited in vitro concentration of an antimicrobial

ResultFlagsCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
				agent that is associated with a high likelihood of therapeutic success.
Intermediate	I	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	Bacterial strain inhibited in vitro by a concentration of an antimicrobial agent that is associated with uncertain therapeutic effect.
⁴² Non-susceptible	NS	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	Synonym: decreased susceptibility
No CLSI defined breakpoint	NCL	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	Use when not enough clinical trial data published by the Clinical and Laboratory Standards Institutes (CLSI) is available to establish the breakpoints for susceptible / intermediate and resistant.
Synergy - resistant	SYN-R	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	<p>A category for isolates where the bacteria (e.g. enterococci) are not susceptible in vitro to a combination therapy (e.g., high-level aminoglycoside and cell wall active agent). This is predictive that this combination therapy will not be effective.</p> <p>Usage Note: Since the use of penicillin or ampicillin alone often results in treatment failure of serious enterococcal or other bacterial infections, combination therapy is usually indicated to enhance bactericidal activity. The synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted by screening for high-level bacterial resistance to the aminoglycoside.</p> <p>Open Issue: The print name of the code is very general and the description is very specific to a pair of classes of agents, which may lead to confusion of these concepts in the future should other synergies be found.</p>
Susceptible-dose dependent	SDD	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A category that includes isolates with antimicrobial agent minimum inhibitory concentrations (MICs) that approach usually attainable blood and tissue levels and for which

⁴² https://www.eucast.org/clinical_breakpoints/

ResultFlagsCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
				response rates may be lower than for susceptible isolates. Reference: CLSI document M44-A2 2009 "Method for antifungal disk diffusion susceptibility testing of yeasts; approved guideline - second edition" - page 2.
Synergy - susceptible	SYN-S	hl7:v3- ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A category for isolates where the bacteria (e.g. enterococci) are susceptible in vitro to a combination therapy (e.g., high-level aminoglycoside and cell wall active agent). This is predictive that this combination therapy will be effective. Usage Note: Since the use of penicillin or ampicillin alone often results in treatment failure of serious enterococcal or other bacterial infections, combination therapy is usually indicated to enhance bactericidal activity. The synergy between a cell wall active agent (such as penicillin, ampicillin, or vancomycin) and an aminoglycoside (such as gentamicin, kanamycin or streptomycin) is best predicted by screening for high-level bacterial resistance to the aminoglycoside. Open Issue: The print name of the code is very general, and the description is very specific to a pair of classes of agents, which may lead to confusion of these concepts in the future should other synergies be found.
Indeterminate	IND	hl7:v3- ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The specified component / analyte, organism or clinical sign could neither be declared positive / negative nor detected / not detected by the performed test or procedure. Usage Note: For example, if the specimen was degraded, poorly processed, or was missing the required anatomic structures, then "indeterminate" (i.e. "cannot be determined") is the appropriate response, not "equivocal".
Negative	NEG	hl7:v3- ObservationInterpretation	2.16.840.1.113883.4.642.3.399	An absence finding of the specified component / analyte, organism or clinical sign based on the established

ResultFlagsCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
				threshold of the performed test or procedure. [Note: Negative does not necessarily imply the complete absence of the specified item.]
Not detected	ND	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The presence of the specified component / analyte, organism or clinical sign could not be determined within the limit of detection of the performed test or procedure.
Positive	POS	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A presence finding of the specified component / analyte, organism or clinical sign based on the established threshold of the performed test or procedure.
Detected	DET	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	The measurement of the specified component / analyte, organism or clinical sign above the limit of detection of the performed test or procedure.
Non-reactive	NR	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	An absence finding used to indicate that the specified component / analyte did not react measurably with the reagent.
Reactive	RR	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A presence finding used to indicate that the specified component / analyte reacted with the reagent above the reliably measurable limit of the performed test.
Weakly reactive	WR	hl7:v3-ObservationInterpretation	2.16.840.1.113883.4.642.3.399	A weighted presence finding used to indicate that the specified component / analyte reacted with the reagent, but below the reliably measurable limit of the performed test.

SelectorTypeCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
normal	Normal		hl7:ObservationReferenceRangeMeaningCodes	Values expected for a normal member of the relevant control population being measured. Typically each results producer such as a laboratory has specific normal ranges and they are usually defined as within two standard deviations from the mean and account for 95.45% of this population.
recommended	Recommended		hl7:ObservationReferenceRangeMeaningCodes	The range that is recommended by a relevant professional body.

SelectorTypeCodeList			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
treatment	Treatment		hl7:ObservationReferenceRangeMeaningCodes	The range at which treatment would/should be considered.
therapeutic	Therapeutic		hl7:ObservationReferenceRangeMeaningCodes	The optimal range for best therapeutic outcomes.
pre	Pre Therapeutic Desired Level		hl7:ObservationReferenceRangeMeaningCodes	The optimal range for best therapeutic outcomes for a specimen taken immediately before administration.
post	Post Therapeutic Desired Level		hl7:ObservationReferenceRangeMeaningCodes	The optimal range for best therapeutic outcomes for a specimen taken immediately after administration.
endocrine	Endocrine		hl7:ObservationReferenceRangeMeaningCodes	Endocrine related states that change the expected value.
pre-puberty	Pre-Puberty		hl7:ObservationReferenceRangeMeaningCodes	An expected range in an individual prior to puberty.
follicular	Follicular Stage		hl7:ObservationReferenceRangeMeaningCodes	An expected range in an individual during the follicular stage of the cycle.
midcycle	MidCycle		hl7:ObservationReferenceRangeMeaningCodes	An expected range in an individual during the midcycle stage of the cycle.
luteal	Luteal		hl7:ObservationReferenceRangeMeaningCodes	An expected range in an individual during the luteal stage of the cycle.
postmenopausal	Post-Menopause		hl7:ObservationReferenceRangeMeaningCodes	An expected range in an individual post-menopause.

5.2.1.7.1.1.5 Reference Range

Laboratory tests could have a ReferenceRange with one or more reference intervals:

- Reference range is the range of values that is deemed normal for a physiologic measurement in healthy population.
- Increased range is the range in which the values are deemed to be increased or reduced comparing to the reference range.
- High range is the range within which the values are deemed high or low comparing to the reference range.
- Limit range. Values outside the High range are usually considered pathological.

-4 | -3 | -2 | -1 | 0 | 1 | 2 | 3 | 4

<RR>

< Increased >

< High range >

< Limit range >

For many tests, there is no single interpretation scale that applies to every sample because the tests performed may be affected by the age and sex of the patient, as well as many other considerations. So specific interpretation scales might exist for different sex and age groups, reproduction phases, gravidity status, drugs taken etc.

ReferenceRange are available only for limited number of laboratory tests based on studies and expert consensus.

ReferenceRange might vary depending on the instrument and the reagents used to perform the test. Therefore, laboratories should always adjust their reference range accordingly. Adjusted ranges should be always taken as a base of the test result interpretation.

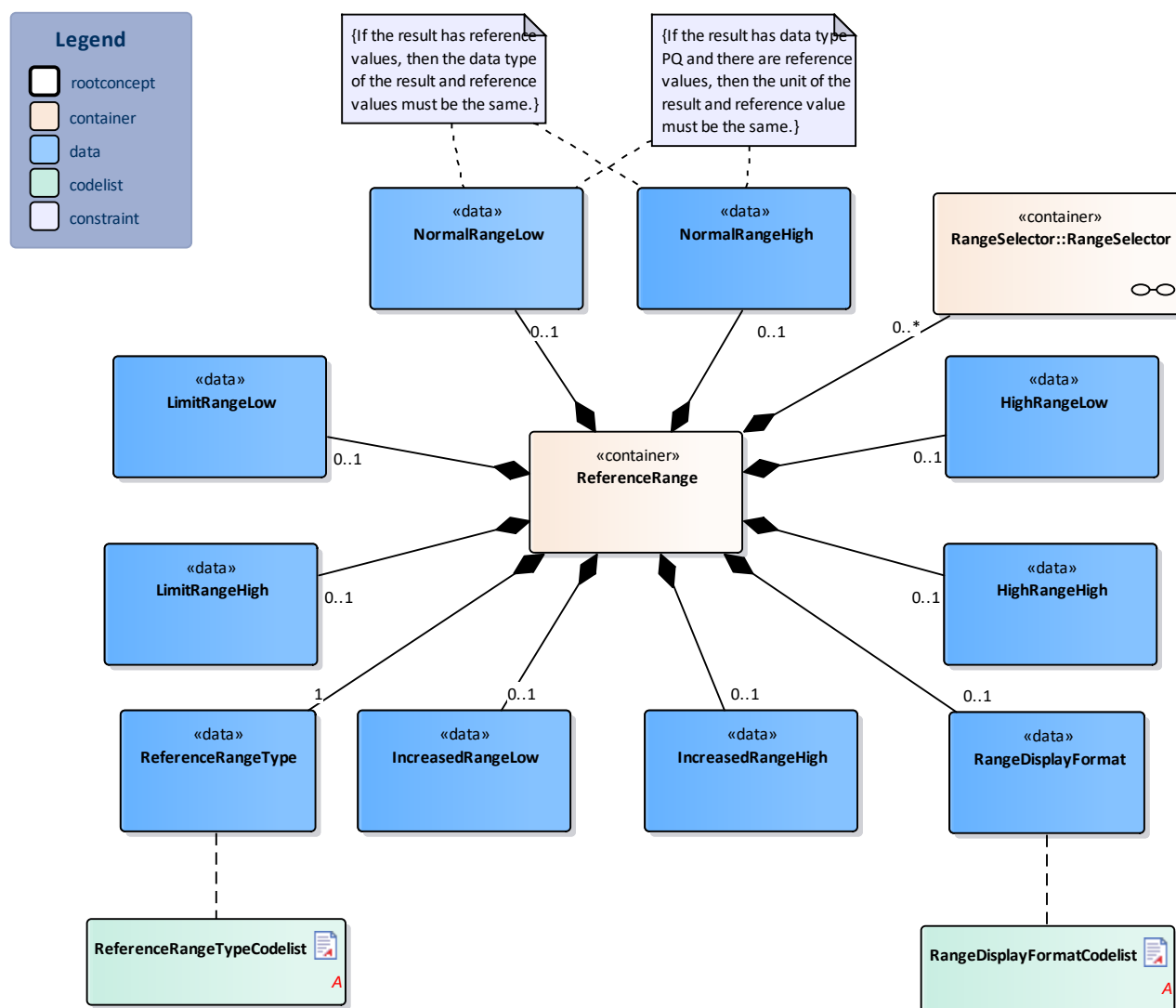


Figure 34: Reference Range Information Model

Type	Concept	Card	Description
«container»	ReferenceRange		Container of the ReferenceRange concept. This container contains all data elements of the selected ReferenceRange concept and belongs to the result value which uses standard measurement units. Reference ranges are usually implied only for a numeric scale type. Use of the same units for reference range and value is implied.
«data»	HighRangeHigh	0..1	High value of the high range or interval.
«data»	HighRangeLow	0..1	Low value of the high range or interval.
«data»	IncreasedRangeHigh	0..1	High value of the increased range or interval.
«data»	IncreasedRangeLow	0..1	Low value of the increased range or interval.
«data»	LimitRangeHigh	0..1	High value of the limit range or interval.
«data»	LimitRangeLow	0..1	Low value of the limit range or interval.
«data»	RangeDisplayFormat	0..1	Range display format determines how the ReferenceRange should be displayed. Reference range can be displayed in following forms: - as a closed interval between low and high cut off values, e.g. ReferenceRangeLow - ReferenceRangeHigh (this is the default option)) - as an open interval from low cut off value to +infinite, e.g. > ReferenceRangeLow - as an open interval from -infinite to a high cut off value, e.g. < ReferenceRangeHigh
«data»	ReferenceRangeType	1	ReferenceRangeType indicates what part of the targeted reference population it applies to. For example, normal or therapeutic range. Default is "normal" reference range type.
«data»	NormalRangeHigh	0..1	The upper reference limit for the patient of the value measured in the test.
«data»	NormalRangeLow	0..1	The lower reference limit for the patient of the value measured with the test.

	RangeDisplayFormatCodelist	OID:	
Concept Code	Concept Name	Coding Syst. Name	Coding System OID
	ReferenceRangeLow-High		
	LargerThenReferenceRangeLow		
	LowerThenReferenceRangeHigh		

	RangeSelectorTypeCodelist	OID:	
Concept Code	Concept Name	Coding Syst. Name	Coding System OID
normal	Normal	hl7:ObservationReferenceRangeMeaningCodes	Values expected for a normal member of the relevant control population being measured. Typically each results producer such as a laboratory has specific normal ranges and they are usually defined as

	RangeSelectorTypeCodelist	OID:	
			within two standard deviations from the mean and account for 95.45% of this population.
recommended	Recommended	hl7:ObservationReferenc eRangeMeaningCodes	The range that is recommended by a relevant professional body.
treatment	Treatment	hl7:ObservationReferenc eRangeMeaningCodes	The range at which treatment would/should be considered.
therapeutic	Therapeutic	hl7:ObservationReferenc eRangeMeaningCodes	The optimal range for best therapeutic outcomes.
pre	Pre Therapeutic Desired Level	hl7:ObservationReferenc eRangeMeaningCodes	The optimal range for best therapeutic outcomes for a specimen taken immediately before administration.
post	Post Therapeutic Desired Level	hl7:ObservationReferenc eRangeMeaningCodes	The optimal range for best therapeutic outcomes for a specimen taken immediately after administration.
endocrine	Endocrine	hl7:ObservationReferenc eRangeMeaningCodes	Endocrine related states that change the expected value.
pre-puberty	Pre-Puberty	hl7:ObservationReferenc eRangeMeaningCodes	An expected range in an individual prior to puberty.
follicular	Follicular Stage	hl7:ObservationReferenc eRangeMeaningCodes	An expected range in an individual during the follicular stage of the cycle.
midcycle	MidCycle	hl7:ObservationReferenc eRangeMeaningCodes	An expected range in an individual during the midcycle stage of the cycle.
luteal	Luteal	hl7:ObservationReferenc eRangeMeaningCodes	An expected range in an individual during the luteal stage of the cycle.
postmenopausal	Post-Menopause	hl7:ObservationReferenc eRangeMeaningCodes	An expected range in an individual post-menopause.

5.2.1.7.1.1.5.1 Range Selector

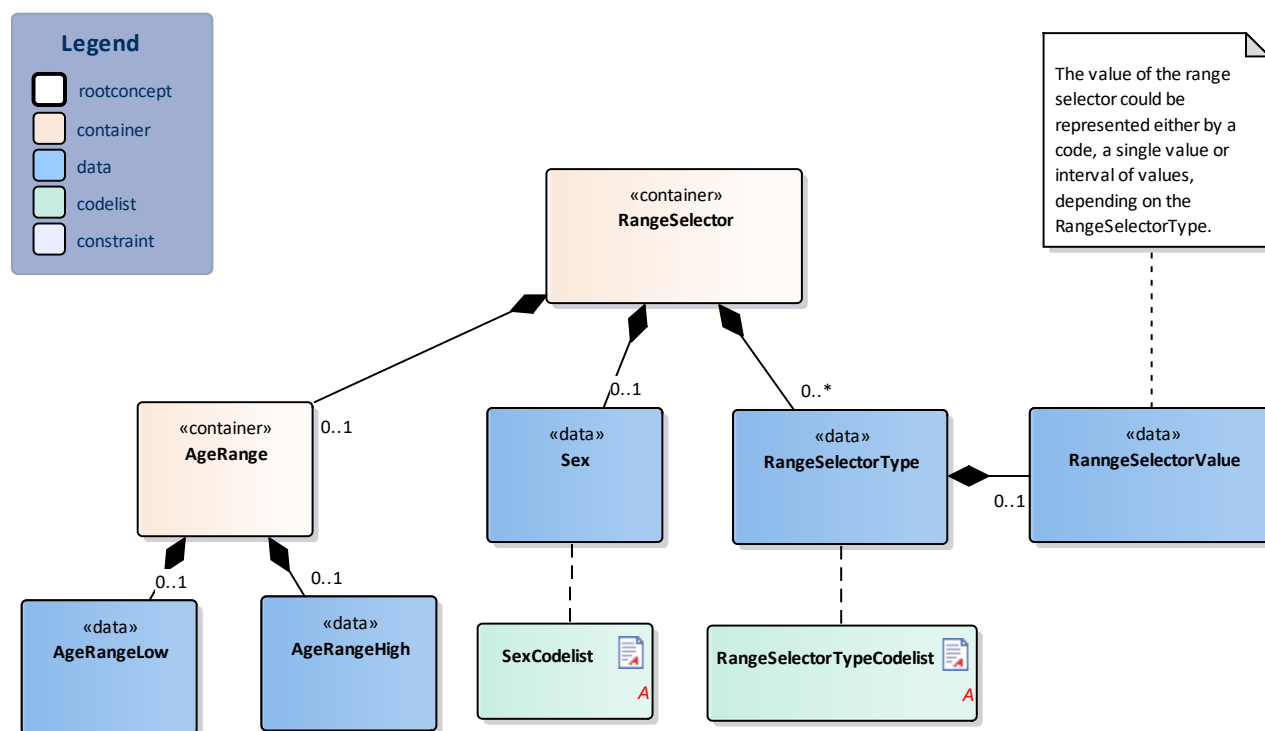


Figure 35: Range Selector Information Model

Type	Concept	Card	Description
«container»	RangeSelector		A container of the RangeSelector. Range selector element includes information to indicate the target population this reference range applies to. For example, a reference range may be based on the normal population or a particular sex or age. Multiple RangeSelectors are interpreted as an "AND" of the target populations. For example, to represent a target population of African American pregnant females, both a code of female and a code for African American would be used.
«data»	RangeSelectorType	0..*	Coded specification of the type of RangeSelectorValue pertinent to the range.
«data»	RanngSelectorValue	0..1	A coded value from a code system pertinent to the range selector type, single value or interval specifying the range for a specific population.
«data»	Sex	0..1	Biological sex as a selector for the range.
«container»	AgeRange	0..1	The age at which this reference range is applicable.
«data»	AgeRangeHigh	0..1	Range high value expressed using time units (e.g. hours, days, weeks, months or years).
«data»	AgeRangeLow	0..1	Range low value expressed using time units (e.g. hours, days, weeks, months or years).

RangeSelectorTypeCodelist		OID:	
Concept Code	Concept Name	Coding Syst. Name	Coding System OID
TypeOfSpecies - patient information element			
337915000	Homo sapiens	SNOMED CT	
Diet - ask at order element?			
717154004	On empty stomach	SNOMED CT	
225758001	After food	SNOMED CT	
169741004	Breast fed	SNOMED CT	
437261000124100	Increased calcium diet	SNOMED CT	
12631007	Low calcium diet	SNOMED CT	
437271000124107	Decreased calcium diet	SNOMED CT	
22745007	Low purine diet	SNOMED CT	
	Time of specimen collection		
Body position - ask at order element?			
17535004	Lying in bed		
33586001	Sitting		
Type of specimen collection - procedure			
70665002	Blood pressure cuff, device	SNOMED CT	
Observation - ask at order element?			
77176002	Smoker	SNOMED CT	
	day of the menstrual cycle		
Phase of the menstrual cycle - ask at order element?			
	Menstruation	?	
	Follicular phase	?	
	Ovulation	?	
	Luteal phase	?	
90369-0	Sample collection timing related to drug dose Nom (Spec)	LOINC	
	before drug administration		
	after drug administration		
	pregnancy status (i.e., week of the gravidity)		
21840007	Date of last menstrual period	SNOMED CT	
8665-2	Last menstrual period start date	LOINC	
Menopause stage			
309606002	Before menopause	SNOMED CT	
303111005	During menopause	SNOMED CT	
307429007	After menopause	SNOMED CT	

SexCodeCodelist		OID:	
Concept Code	Concept Name	Coding Syst. Name	Coding System OID
248153007	Male	SNOMED CT	
248152002	Female	SNOMED CT	

5.2.1.8 Application

Laboratory test result report can have two basic forms:

- An individual report form that includes test results of examination of one or more different specimens collected at the same time or during the same period of time (in case of time sequence of samples that are logically bound together, such as in case of functional tests, e.g., Glucose tolerance test).
- A cumulative report form (laboratory summary), which summarises results for laboratory tests performed within a selected timeframe of sample collection. This type of report might include also graphical representation of the test result values evaluation in time, indication of the value change dynamics between two consecutive results of the same test etc. Optionally, cumulative report may summarise results from different laboratories (e.g., if a primary recipient of lab order has delegated certain tests to subcontracting laboratories or if generated from a patient centric EHR).

Test results as well as the result report as a whole shall be validated by a responsible healthcare professional (QA manager).

5.2.1.8.1 User Interface (UI) requirements

In both cases, the report layout might have many variations depending on the type of the laboratory test (i.e., whether biochemistry, haematology, microbiology, or histopathology) as well as on the layout preferences of the test result report recipient.

Nevertheless, several common rules that should be followed by implementers of the laboratory test result view can be formulated:

- Laboratory test results should be presented to the recipient in a clear and understandable way that would allow for a quick and efficient assessment.
- Presentation of the laboratory results must include all necessary information to clearly identify date of sample collection, type of the test including type of the sample material, result value and measurement units
- Laboratory test result report should include information about uncertainty of the measurement
- Reference range should be present if available, together with optional indication if it was adjusted to the sex, age group or another clinical parameter or event.
- Result report should include information if laboratory that performed the test has or has not accreditation for a particular test
- Display format of results and ref ranges

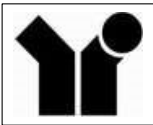
5.2.1.8.2 *Examples of well-formed laboratory result view*

Figure 36: Example cumulative laboratory result report/view (examination of blood)



Blood test	01/02/2012	02/02/2012	03/02/2012	05/02/2012	06/02/2012	08/02/2012
WBC count/ μ L	1090	960	980	1350	1180	6400
Neutrocytes %	25	10	20	28	18	52
Lymphocytes %	47	35	44	33	68	29
Monocytes %	25	55	30	22	14	17
Atypical forms%	3	0	6	13	0	2
Hct %	29.6	28.2	28.8	25.9	27.4	35.8
Hb g/dL	10.2	10.1	9.7	8.2	9.3	12.0
PLT count/ μ L	150,000	140,000	70,000	34,000	200,000	297,000
Urea mg/dL	51	26	12	25	67	95
Creatinine mg/dL	1.2	1.5	0.8	0.8	0.8	1.0
LDH IU/L	207	161	239	300	185	265
AST IU/L	16	42	18	17	12	12
ALT IU/L	12	15	8	14	8	14
γ -GT IU/L	15	15	24	16	23	31
ALP IU/L	48	43	47	49	40	55
TBIL mg/dL	0.8	0.8	0.8	0.9	0.9	1.0
ESR mm/1 h	65					40
CRP mg/L	152.5	103.3	36	10.2	2.7	12.7
Ferritin μ g/L	649.5	-	-	-	-	-
Anti-HIV 1,2	neg	-	-	-	-	-
HBsAg	neg	-	-	-	-	-

This report is composed by the rows associated with the tests requested by the Order placer, and the columns including all the previous tests performed to the patient and the last column with the current analysis.

Figure 37: Example individual laboratory result report/view with reference range



Laboratory of immunology
Center of immunology and mikrobiology
Address tel.: phone no.
www.page.cz, email: imunology@domain.cz

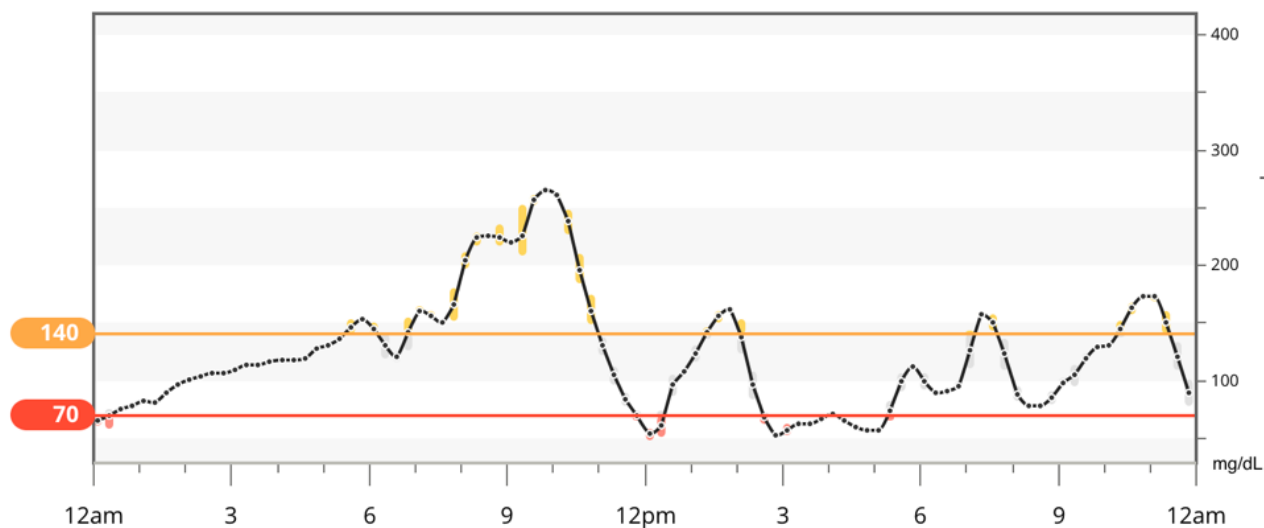
Name: Patient Name		HCP organization: Sample Hospital, surgical department	
ID: 121212121		HCP name : John Physician	
Age: 96		HCP org. ID :	Specialty: 001
Diagnosis: A01	HIH No:111		
Received: 4.6.2009 9:19:00		Submitted: 12.6.2009 7:24:00 Printed: 12.6.2009 7:44:36	

Test	4.6.2009 7:00	Result graphical assessment	Ref. range	Units	Test group or panel
Humoral immunity					
»IgG	10,40	*	7,00 - 16,00	g/l	Test group or panel
»IgA	1,17	*	0,70 - 4,00	g/l	
»IgM	1,11	*	0,30 - 2,40	g/l	
»C-reactive protein	< 3,19	*	< 5,00	mg/l	
»C3-complement	1,09	*	0,75 - 1,40	g/l	
»C4-complement	0,22	*	0,10 - 0,34	g/l	
Infection immunity					
»ASLO	1590	*	0 - 240	IU/ml	Indication of results out of range
»HSV 1+2 IgG	4,60	*	0,00 - 1,00	index	
»HSV 1+2 IgM	0,50	*	0,00 - 1,10	index	
Anamnestic levels of antibodies against HSV 1+2					
»CMV IgG	57,4	*	< 30,0	AU/ml	Reference range with High value only
»CMV IgM	0,17	*	< 0,50	index	
Anamnestic levels of antibodies against CMV					
»EBV-VCA IgM	0,06	*	< 1,05	index	
»EBV-EA (D) IgG	0,00	*	< 1,05	index	
»EBV-VCA IgG	2,31	*	< 1,05	index	
»EBNA-1 IgG	3,30	*	< 1,10	index	
EBV comment	anamnestic titer				
Autoimmunity					
»ANA G,A,M	nuclear matrix				
»ANA G,A,M	80	*	0 - 160	titr	
Total IgE					
»Total IgE	164,0	*	< 150,0	kU/l	
li-13798, Pp-13798					
4.6.2009 7:00:00					
The result should be evaluated in relation to the patient's medical history and clinical condition.					
<p>A list of accredited examinations (») is available on www.imunol-usti.cz</p> <p>For information on collection procedures, transport conditions and an overview of laboratory tests, refer to the laboratory manual available on www.imunol-usti.cz. It also lists the names of the SOPs for individual accredited examinations in full. Measurement uncertainty is expressed in verification protocols and is available on request.</p>					
Results verified by: Name Surname					

Result report end note 2

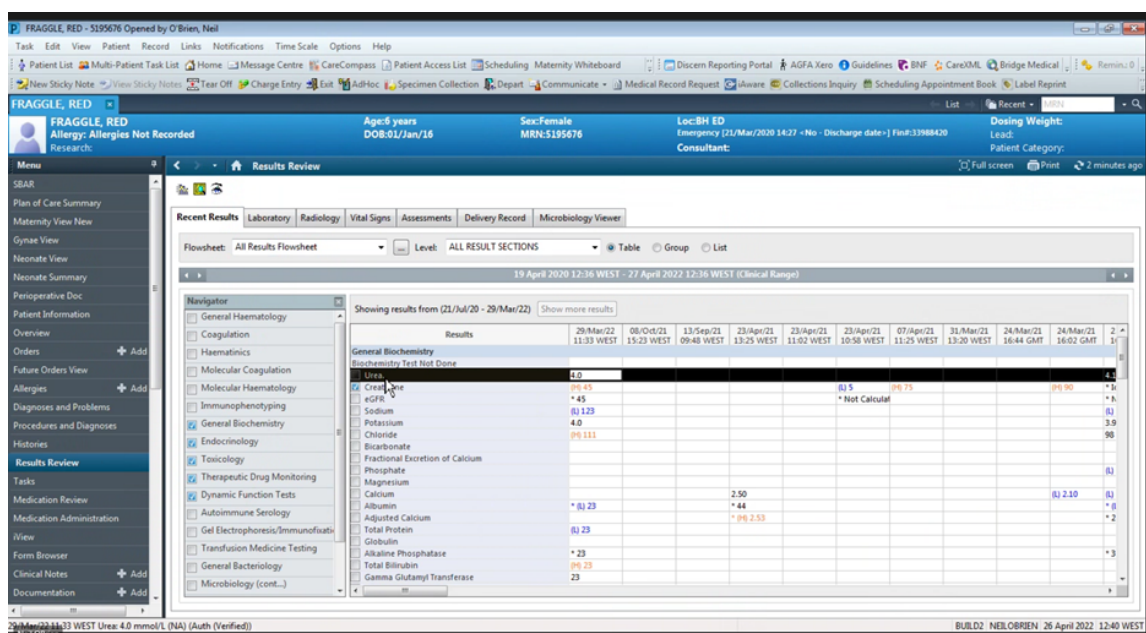
Result report end note 1

Figure 38: Graphical illustration of the test evolution in time (Glucose measured every 3 hours)



Report shows graphically the evolution of lab result to see the progress. In this example glucose evolution is presented.

Figure 39: Sample screenshot of summary laboratory results available from EMR in Ireland.



5.2.1.9 Infrastructure

ICT infrastructure must be in place to enable digital communication between laboratories and ordering parties and to facilitate both submission of reports by laboratories and retrieval of reports by ordering parties. The infrastructure must provide secure communication in accordance with data protection and cybersecurity principles. For cross-border scenarios, all laboratory test report

sources as well as report consumers must be accessible through National Contact Point via secure communication channels.

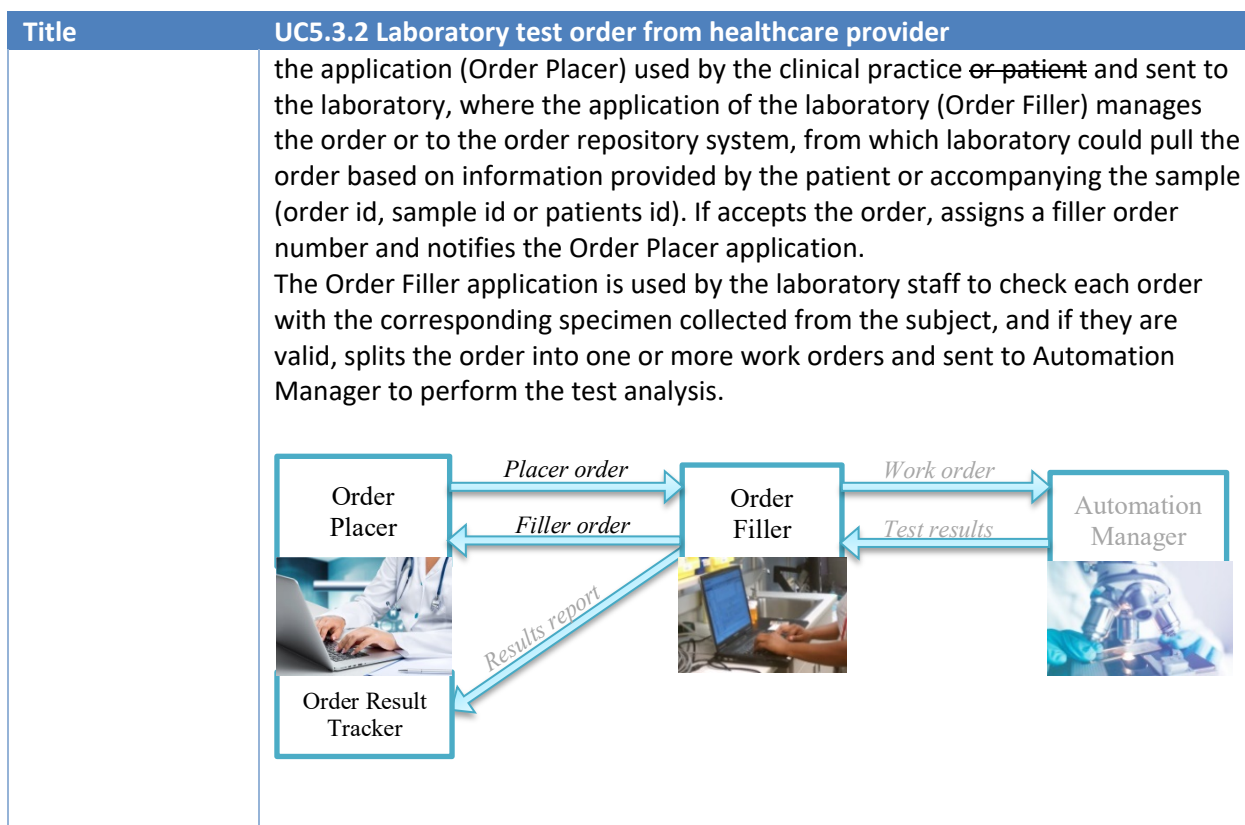
National registries of healthcare providers and accredited laboratories may be used as a baseline for institutional authentication, National registries of health professionals may facilitate authorisation of healthcare professionals, Implementation of eID is recommended for authentication of healthcare professionals.

Result reports might be submitted directly to the ordering parties and/or to additional intended recipients or to a centralised or distributed EHR repositories for later retrieval by order placer or any authorised querying entity.

5.2.2 Laboratory order from healthcare provider use case

Title	
UC5.3.2 Laboratory test order from healthcare provider	
Purpose	Healthcare providers as well as patients and other clients are requesting laboratory services by creation of a laboratory test order with specification of the laboratory service to be provided. Laboratory test orders might be directed (ordering entity knows which laboratory will provide the service) or undirected (laboratory will be selected later in the workflow either by ordering entity or by the patient or client him selves). This use case describes electronic laboratory ordering process by healthcare providers.
Relevance	Laboratory testing is an important clinical act with a valuable role in screening, diagnosis, management and monitoring of diseases or therapies. However, inappropriate laboratory test ordering is frequent, burdening health care spending and negatively influencing quality of care (Delvaux, 2017). Inappropriate tests may also result in false-positive results and potentially cause excessive downstream activities.
Domain	Laboratory
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational
Context	Currently, most laboratory test orders are still done through a paper-based ordering system. Practitioners request or take a blood sample from a patient, order tests by marking them on a paper form, add the patient contact details and send both the form and labelled sample containers to the laboratory. Slowly, ambulatory laboratories in primary care have started adopting Electronic Laboratory Order for ordering laboratory tests. Computerised Laboratory Orders have several benefits for both laboratories and practitioners. They reduce mistakes during the pre-analytical phase, improve timeliness of reporting, reduce mistakes during additional orders on the same sample and reduce the overall turnaround time of samples (Delvaux, 2017).
Information	Laboratory test order
Participants	Patient Healthcare practitioner Laboratory
Preconditions	The patient visited a practitioner during an outpatient visit or in case of hospitalisation. The physician must have access to a Healthcare Information System related with his institution to allow the creation of clinical order to be delivered to the associated laboratory or order repository system. A list of laboratory services (tests) ready for electronic ordering must be agreed and available. A secure communication channel between ordering healthcare provider and laboratory (order filler) or order repository must be available.
Functional process flow	The laboratory test order workflow ⁴³ , starts when a physician requests a set of laboratory tests or test batteries for a patient to be performed and reported by a clinical laboratory. The order (a single one or a group of orders for the same subject) is entered into

⁴³ Based on the Laboratory Testing Workflow (LTW) profile of IHE:
https://www.ihe.net/uploadedFiles/Documents/PaLM/IHE_PaLM_TF_Vol1.pdf



5.2.2.1 Description of Actors

Actors of laboratory order use case are described in chapter 3.3.1.

5.2.2.2 Order Workflow

Laboratory order use case covers different workflows related to selected specimens and the origin of the order. Workflow description is adopted from IHE Laboratory (LAB) Technical Framework, volume 1, LAB TF revision 6.0⁴⁴.

5.2.2.2.1 Order placed with identified specimens

Initial part of the scenario:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group (or single Order) is entered into the Order Placer application with pertinent information needed. The Order Placer determines what specimens are required to perform the tests, with collection (container type, preservative/anticoagulant, volume, time and patient status) and transportation conditions.

The Order Placer provides specimen identification labels with a unique specimen ID (usually bar coded), and other relevant information (e.g., patient name, encounter ID).

A medical staff in the ward collects the specimens, identifies each one by placing the appropriate label on the container(s). This use case assumes a specimen identification scheme that ensures

⁴⁴ https://www.ihe.net/uploadedFiles/Documents/Laboratory/IHE_LAB_TF_Rev6.0_Vol1_FT_2015-07-14.pdf

enterprise-wide unique identifiers to all specimens. The format and length of specimen IDs must be compatible with the laboratory organisation and automation constraints.

The Order Placer sends a “New Order” message to the Order Filler, delivering the Order Group (or single Order) with associated relevant information.

Upon reception, the Order Filler application controls the content of each Order, and if accepted, assigns a Filler Order Number to it, and notifies that number in the acknowledgement message sent back to the Order Placer application. If for some reason a battery or test cannot be accepted by the laboratory, the corresponding Order is rejected and notified as such to the Order Placer.

Specimens are brought to the laboratory after or before the related Order is accepted by the Order Filler application. The sequencing of the material flow (specimens/containers) and of the messaging flow depends upon the healthcare organisation.

Using the Order Filler application, the laboratory staff checks each Order with the corresponding specimens. If the specimens are available and valid the Order is started and notified as such to the Order Placer application. In case a specimen is invalid or damaged (e.g., serum haemolyzed) this specimen is rejected and the Order(s) depending upon it may not be started.

Middle part of the scenario:

The Order Filler splits the Order Group (or the single Order) into one or more Work Orders sent to the Automation Manager. The technical staff of the laboratory fulfils the various Work Orders using the Automation Manager and all accurate devices (aliquoters, robotic systems, analysers, ...). The splitting of specimens (aliquoting) may require the printing of additional secondary labels (either by the Order Filler or by the Automation Manager), for the identification of aliquot containers. After technical validation the results are sent from the Automation Manager to the Order Filler.

Final part of the scenario (see use case UC5.3.1 in chapter 5.2.1 for details):

At various steps (depending on the organisation), the Order Filler sends results to the Order Result Tracker and notifies both Order Placer and Order Result Tracker of all status changes of each Order and its related results, and optionally a facsimile of the report fulfilling the Order Group.

5.2.2.2.2 Order placed with specimens identified by the laboratory or by a third party

Initial part of the scenario, specific to this workflow:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group (or single Order) is entered into the Order Placer application with all pertinent information.

The Order Placer does not identify the specimens. Three different sub-use cases should be considered for the identification and collection of specimens:

1. The ward collects and supplies specimens labelled with an identification limited to patient ID and Placer Group Number or Placer Order Number. The Specimens are subsequently re-identified by the Order Filler application, and labelled with bar coded specimen ID, by the laboratory staff for processing.
2. The laboratory is in charge of the collection and identification of specimens.
3. The required specimens are determined and identified by the LIS and sent back in real time to the Order Placer in the acknowledgment of the order request message or in due time by

use of the query transaction from the IHE Laboratory Specimen Barcode Labelling (LBL) Integration Profile.

The middle and final part of this workflow is the same as in workflow 5.2.2.2.1.

5.2.2.2.3 Filler Order created by the laboratory

Initial part of the scenario, specific to this workflow:

Two different sub-use cases are to be considered:

1. The laboratory staff receives an Order in paper form from a ward unable to access the Order Placer application.
2. During the processing of an Order Group, the laboratory decides to add an additional battery or test to that Order Group. The new Order is to be performed on one of the existing specimens of the group.

In both sub-use cases, the generated Order has a Filler Order Number. The Order Filler application notifies it to the Order Placer application, which allocated a Placer Order number to it, and sends it back to the Order Filler.

The middle and final part of this workflow is the same as in workflow 5.2.2.2.1.

5.2.2.2.4 Order Filler rejects a specimen prior to result testing

This workflow generalises the above workflows with the focus on the process when laboratory staff checks each order with the corresponding specimens and finds a non-conformity resulting in a rejection of a specimen.

Case:

A physician in a ward requests a set of laboratory tests (or batteries) for a patient. The Order Group is entered into the Order Placer application with pertinent information.

The Order Placer sends a “New Order” message to the Order Filler, delivering the Order Group with associated relevant information.

Upon reception, the Order Filler application controls the content of each Order, and if accepted, assigns a Filler Order Number to it and notifies that number in the acknowledgement message sent back to the Order Placer application.

Using the Order Filler application, the laboratory staff checks each Order with the corresponding specimens. If the specimens are available and valid the Order is started and notified as such to the Order Placer application.

In case a specimen is invalid or damaged (e.g., tube is broken) this specimen is rejected and the Order(s) depending upon it are cancelled by the Order Filler application.

Upon rejection of a specimen, the Order Filler may inform the Order Placer with supplemental information why the specimen is seen as not valid.

The physician in a ward reviewing the rejection reason may decide to collect a new Specimen and re-order the missing set of laboratory tests (or batteries) for this patient.

The Order Placer sends a “New Order” message to the Order Filler containing the re-order requests within the already known Order Group.

5.2.2.3 Legal and regulatory

This work group undertook extensive research into the legal and regulatory requirements for laboratory orders. We found a lack of legal or regulatory requirements for laboratory orders – the whole focus of legal and regulatory appears to be on laboratory results and testing medical devices, the output of laboratory orders and not on the order specifications required to deliver the test results.

The upcoming EU Regulation on EHDS is relevant for all EHR processing and may also be relevant for laboratory orders. The legal requirements concerning the structure, functions, personnel, and other related aspects for laboratories should be stated in a minimal number of legislative acts to facilitate their implementation. Preferably, there is a publicly available compilation of all applicable laws and regulations for laboratories.

Some countries regulate all these elements in their licensing legislation. Other countries regulate the elements of the substantive part in other parts of the legislation. The choice of which elements the licensing legislation of each country should include remains the country’s decision.

Legal framework may impose the conditions and obligation pertaining to digitalisation of laboratory orders, e.g.:

- Obligation of ordering parties to digitalise ordering process;
- Adoption of semantic and technical standards for laboratory orders;
- Licensing and registration of laboratories (implying that laboratory orders may only be addressed to the licensed laboratories)
- Authorising national contact points to process cross-border laboratory orders

5.2.2.4 Policy

This work group undertook extensive research into the policy guidelines for laboratory orders. We found limited policy guidelines exist for laboratory orders – the whole focus of policy guidelines has been on laboratory results, the output of laboratory orders and not on the request specifications and requirements. Traditionally laboratory orders could only be requested by healthcare professionals, and there was a strict order process built on the laboratory order specifying patient name, date of birth, type of test(s), frequency etc. The advent of self-testing and enabling citizens to order on demand has resulted in a more “open” laboratory ordering process based on individual laboratory requirements and not governed by national policy or professional bodies. National authorities shall take policy measures to enforce application of digital orders. Optionally, a national entry point or gateway may be provided for healthcare providers who have not yet implemented appropriate computerised provider order entry (CPOE) system. Digital ordering system must be adopted by both ordering parties (healthcare providers) and laboratories. Standardised catalogues of laboratory tests and/or test order groups shall be published by laboratories. Optionally, the publication of such catalogues can be managed on a national level.

5.2.2.5 Technical

The systems involved in the order workflow are:

- **Clinical Information Systems (CIS).** Each of these systems is operated by a clinical facility and provides a number of features such as order entry, order placing, placer order management and follow-up, order result tracking, management of patient biologic history, specimen calculation, specimen identification, etc. A CIS usually implements the **Order Placer** and **Order Result Tracker**.
- **Laboratory Information Systems (LIS).** Each of these systems is operated by a number of clinical laboratories inside the institution. The LIS offers features such as order reception, specimen calculation, specimen identification or specimen acceptance, order check, scheduling, filler order management, production of worklists, result manual entry for non-connected tests, clinical validation and interpretation of results, result reporting. Each LIS implements an **Order Filler**. Optionally, LIS can also implement some ordering features that are usually implemented by CIS (e.g., Order Placer, Order Result Tracker), thus providing add-on service to healthcare providers that are not yet able to place digital orders.
- **Laboratory Automation Systems (LAS)** operated in each laboratory. A LAS manages a set of automated laboratory devices (pre-analytical devices, analysers, post-analytical devices). The LAS receives Work Orders related to a specimen and processes the various steps of a Work Order on its set of devices, to eventually get the test results, perform the technical validation thereof, and upload them back to the LIS. LAS Implements **Automation Manager**.
- **Computerised provider order entry (CPOE) system** is an application which allows creation of an electronic laboratory orders. This is usually part of the CIS but could be implemented as a regional/national gateway for creation of electronic lab orders. CPOE systems should provide necessary information and instructions for the pre-analytical phase.

Integration of LIS and LAS is an important success factor for efficiency of laboratories and quality of laboratory services. Ideally, end-to-end integration of CIS, LIS and LAS enables a fully automated ordering and reporting process, ensuring greater availability and quality of data, and shortening time to provide the results.

5.2.2.6 Semantic

Electronic laboratory test orders must contain all necessary administrative information (patient details, information about ordering parties, order reason and intended recipients of results), detail information about sample or samples (sample type, sample identification, sample location, amount or quantity of sample) and sample collection process and other pre-analytics information, identification of the ordered services as well as information about patient conditions having implications on test measurement and interpretation of results. Formally, the order should include:

- Administrative data
- Order reason
- Pre-analytical information
 - Specific conditions of the patients

- Primary sample(s) (specimen(s)) specification including sampling process details and specimen source
- Tests to be performed

5.2.2.6.1 Administrative data

Following administrative information are usual part of the order:

- Patient identification including (optional) payment information
- Order placer (Ordering clinician and/or provider)
- Additional intended recipient(s)
- Order creation date/time
- Order sent date/time
- Order priority, etc.
- Intended laboratory (optional)

5.2.2.6.2 Order reason

Reason for order might include condition(s) and/or observation(s) that justify or explain reason for a laboratory service request. Typically includes symptoms or diagnostic codes or narrative description.

5.2.2.6.3 Pre-analytics

All determining factors and processes, which influence the specimen material before it is analysed in the laboratory, are part of pre-analytics. This covers preparation of the patient, sample collection, pre-processing, storage, and transport of specimen material as well as handling in the laboratory prior to analysis. It should be noted that the majority of the preanalytical phase is outside of the control of the laboratory, so it is important that robust procedure/policies are defined for these processes.

Pre-analytics is crucial part of ensuring that there is no detrimental effect on the specimen material which could affect the result. Once the correct set of tests is selected with all the appropriate details, CPOE should provide the ordering clinician information on required sample type, container, volume, and any special handling (e.g., freeze ASAP), such as:

- Patient status (e.g., patient fasting for Fasting Glucose, patient position during sampling – sitting, laying)
- Sample collection process (e.g., dynamic function test, sample collection period, medication prior sampling, etc.)
- Sampling devices and containers (e.g., use metal free needle for heavy metals, capillary sample for glucose, ensure acidified urinary bottle is available for Urinary Catecholamines, the anticoagulants EDTA, citrate or heparin for collection of whole blood)
- Storage and transport of specimen material (e.g., Send to lab on ice for Ammonia)
- Handling in the laboratory prior to analysis (e.g., Allow serum tubes to stand for 30 minutes)

5.2.2.6.3.1 Specimen (primary sample) specification

Laboratory order must specify all necessary details about primary sample (specimen) sent to the laboratory for investigation, such as sample time and date, sampling conditions, specimen type and specimen source, which are necessary for some types of investigations, mainly in microbiology.

Note:

During our work we found that there are many different definitions of “sample” and “specimen”. However, the following represents the most widely used definition and is used throughout this document:

ISO 15189

primary sample, specimen

discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

- Note 1 to entry: The Global Harmonisation Task Force (GHTF) uses the term specimen in its harmonised guidance documents to mean a sample of biological origin intended for examination by a medical laboratory.
- Note 2 to entry: In some ISO and CEN documents, a specimen is defined as “a biological sample derived from the human body”.
- Note 3 to entry: In some countries, the term “specimen” is used instead of primary sample (or a subsample of it), which is the sample prepared for sending to, or as received by, the laboratory and which is intended for examination.

ISO 15193 (In vitro diagnostic medical devices)

laboratory sample

primary sample, or a subsample of it, as prepared for sending to or as received by the laboratory and intended for measurement

analytical sample

sample prepared from the laboratory sample and from which analytical portions can be taken

Note 1 to entry: The analytical sample can be subjected to various treatments before an analytical portion is taken.

Specimen type can be used as a filter of the CPOE system to reduce number of test codes which ordering professional could select from or vice versa could be derived from set of ordered tests.

Example of sample types (non-exhaustive):

- Blood
- Tissue biopsy
- CSF
- Urine
- Saliva
- Stool

- Oral fluid
- Sweat
- Semen
- Secretions & fluids from female reproductive system
- Secretions & fluids from nose and throat
- Samples from open wounds and sores
- Other body fluids (e.g., synovial, peritoneal, etc.)
- Other (e.g., hair, fingernail clippings, etc.)

Each of these sample types can be further divided into subtypes depending on the particular requirements for sampling e.g., Blood:

- Arterial
- Venipuncture
- Fingerstick

The LOINC 'system' does not specifically correlate with the sample type, in that it gives a broad definition of the sample type. As an example, LOINC 'system' doesn't differentiate between serum and plasma as it names it 'Ser/Plas' as the sample type. Some reference ranges differ depending on the sample type e.g., serum potassium reference range is different relative to plasma potassium. In this case the sample type is essential to correlate with the reference range. (The difference between serum and plasma is that plasma container has an anticoagulant to prevent clotting whereas the serum sample does not.)

However, the US CDC as well as vendors of IVD devices provide sets of sample types corresponding to LOINC test codes in some healthcare areas, including HIV and COVID-19. Tables are published where IVD tests are listed with their corresponding order and result LOINC codes, SNOMED CT specimen codes, and relevant SNOMED CT result codes. E.g.:

Order LOINC code	94531-1 SARS-CoV-2 (COVID-19) RNA panel - Respiratory specimen by NAA with probe detection
Specimen SNOMED CT codes	anterior nasal swabs (697989009^Anterior nares swab^SCT) mid-turbinate nasal swabs (871810001^Mid-turbinate nasal swab^SCT) nasopharyngeal swabs (258500001^Nasopharyngeal swab^SCT) oropharyngeal swabs (258529004^Throat swab^SCT) nasopharyngeal wash (258467004^Nasopharyngeal washings^SCT) nasopharyngeal aspirate (258411007^Nasopharyngeal aspirate^SCT) nasal aspirate (429931000124105^Nasal aspirate specimen^SCT)
Result LOINC test code	94500-6 SARS coronavirus 2 RNA [Presence] in Respiratory specimen by NAA with probe detection

Result SNOMED CT codes	Positive (260373001^Detected^SCT) Presumptive positive (720735008^Presumptive positive^SCT) Negative (260415000^Not detected^SCT) Invalid (455371000124106^Invalid result^SCT or 125154007^Specimen unsatisfactory for evaluation^SCT)
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By intention the NPU terminology covers no information about sample collection and specimen requirements.

For the above-mentioned reasons, we recommend using SNOMED CT to specify the sample type.

5.2.2.6.3.1.1 Specimen source

In general, the disciplines of biochemistry, haematology, and immunology do not require extensive collation of order information at point of order when compared to other disciplines like Microbiology.

In Microbiology certain orders require additional information to ensure that the correct specimen is taken. This requires the clinician to provide information on the sample anatomical location e.g., right eye corneal scrape. Providing this information will benefit the scientist in assessing the sample for further analysis and decision making on correct diagnosis of the patient's disease.

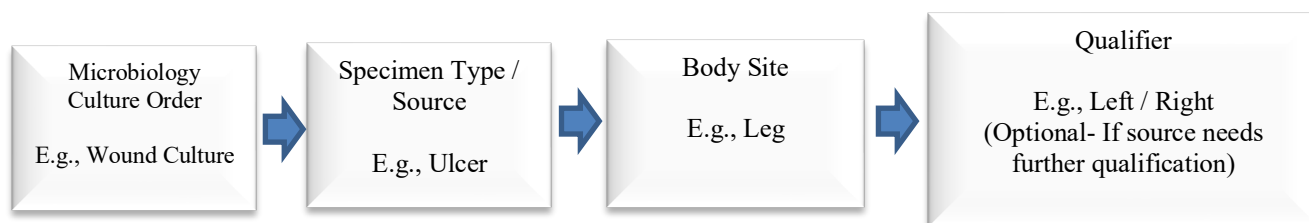


Table 13: Examples of additional information required in Microbiology

Sample Site	Required Site Information
Lower Respiratory	Bronchoalveolar lavage or brush, endotracheal aspirate
	Sputum, expectorated
	Sputum, induced
Upper Respiratory	Oral
	Sinus aspirates
	Throat

For this type of information SNOMED CT is recommended.

5.2.2.6.3.2 Patient conditions

Patient conditions not only justify reason for lab services but are also necessary for proper interpretation of lab results. That is why laboratory order should include information about the condition(s) of the patient, that might be important for the correct interpretation of test results, such as:

- pregnancy status or trimester,
- reproduction phase – luteal, pre-menarche, ...,
- disease(s) and condition(s)
- medication

Various coding systems could be used to provide information about conditions including SNOMED CT, ICD-10, ICD-11 etc.

5.2.2.6.4 Ordering of tests

Ordering and reporting in blood science disciplines is straightforward in that an order can be codified, and this can be related to the result. Ordering and resulting relationships can be either:

- One-to-one (e.g., C-Reactive Protein)
- One-to-many with known set of result tests (e.g., Full Blood Count Panel)
- One to many with open set of results: e.g., reflex testing from the primary order in either of the cases below (e.g., result of the Thyroid Panel analysis requires an add on assay, Microbiology culture)

Example	Order	Result
One-to-one	C Reactive Protein	C Reactive Protein
Panel (One to Many)	Full Blood Count	Red Blood Cell Count
		Haemoglobin
		Haematocrit
		Platelet Count
		White Blood Cells
Reflex	Thyroid Panel	TSH
		ft4
		Reflex on ft3*
Microbiology culture test example	Cultivation of bacteria in urine	Based on cultivation results: <ul style="list-style-type: none"> • E.coli • Klebsiella Pneumoniae •

*ft3 is added on based on certain results of the TSH and ft4.

Typical laboratory test order then includes of one or more laboratory tests with or without specification of a particular measurement principle (method) to be used by the laboratory, however in some cases required measurement principle might be important part of the test specification.

A priority of each test (either routine, urgent or statim) could also be specified.

5.2.2.6.4.1 Test names and codes

Mapping of locally understood test names to an agreed terminology is a non-trivial task and maintenance of this mapping is a costly process. Historically many providers use locally agreed and shared codes with local laboratories. This however creates problems when data sharing crosses local or regional borders. Provider information systems would then have to maintain mapping between locally used codes and externally agreed code systems or would have to abandon use of local code systems and switch to a nationally or internationally agreed one.

The two prominent international code systems (LOINC, NPU) used in laboratory domain are described in chapter 5.1.4.1 and 5.1.4.2.

Laboratory test orders could come from many different systems, and this can lead to an inconsistency in the presentation of clinically important information. Furthermore, a “laboratory test” might denote either a procedure, such as measurement of glucose in a sample of blood, or a definition of what is observed or measured by the procedure, such as the substance concentration of glucose in the blood plasma (blood plasma is a part of the blood containing higher concentration of glucose than blood).

Historically, different physicians and laboratories use different names for the same laboratory tests. These differences are usually reflected by electronic provider order systems. Different names for the same test (meaning) could be considered as synonyms that refer to a certain preferred test name which could be then codified using an agreed terminology system. Using an agreed coding systems to encode unambiguously the meaning of a laboratory test and other components of the lab order is central to achieving semantic interoperability enabling a common understanding and interpretation of data.

Taking glucose as an example:

Synonyms (AKA)	Primary Name
Fasting Blood Sugar Fasting Blood Glucose Non Random Glucose	Fasting Glucose
Random Glucose Random Blood Sugar Non Fasting Glucose	Non-Fasting Glucose

5.2.2.6.4.2 Test batteries (panels, profiles)

It is common practice in laboratories to group tests together into specific profiles or panels from an ordering point of view. A commonly encountered example of a profile is a Full Blood Count or Complete Blood Count where all the elements of the blood are elevated and reported together.

Panels or profiles can be created to focus on a specific organs or system or to investigate particular clinical signs and symptoms. For example, an appropriate panel order to investigate clinical signs and symptoms of leathery skin and weight gain would be Thyroid Function Tests.

In terms of available laboratory coding systems, the only system currently in use to effectively facilitate coded Orders panel is the LOINC coding system.

In LOINC the term panel is used to mean a collector terms within which contains discrete child elements. This can relate to a battery, profile, data set, etc.

Table 14: Complete blood count panel

Panel	Discrete elements	Optional
Full Blood Count	Haemoglobin	Required
	Red Blood Cell Count	Required
	Haematocrit	Required
	Mean Cell Volume	Required
	Mean Cell Haemoglobin	Required
	Mean Cell Haemoglobin Conc	Required
	Red Cell Distribution Width	Not Required
	Platelet Count	Required
	White Blood Cells	Required
	Neutrophils	Required
	Lymphocytes	Required
	Monocytes	Required
	Eosinophils	Required
	Basophils	Required
	Nucleated Red Blood cells	Not Required
	Mean Platelet Volume	Not Required
	Platelet Distribution Width	Not Required

Limitations of Coded Panels

Whilst collation of ordering panels is common clinical practice there is little in place in terms of standardisation of the constituent test elements of these panels when compared across laboratories.

The main factors underpinning this lack of standardisation and differences in Panel constituents across laboratories are:

1. Target patient populations, i.e., patients attending major transplant centres will have very different testing requirements when compared to those patients attending small non acute regional hospitals
2. Limitations of analytic platforms in use at laboratories and the ability of each LIMS to perform appropriate duplicate checks and reflex tests.
3. Commercial considerations, i.e., significant cost in the addition of extra tests to particular panel, i.e., adding an AST to all Liver profiles if there is no clinical need to when targeting specific patient populations

This inherent lack of standardisation in Panel orders across individual laboratories represents a significant challenge/barrier to the adoption of coding for Panel ordering. It is for this reason that the WP5.3 recommendation is to encode each of the discrete child elements of a panel order rather than a panel order itself. This allows for laboratory panels in each member state laboratory to remain dynamic and change their respective constituents where required in response to locally developing clinical needs or in response to emergence of newer test platforms and technologies.

5.2.2.7 Information

5.2.2.7.1 Laboratory Order Information Model

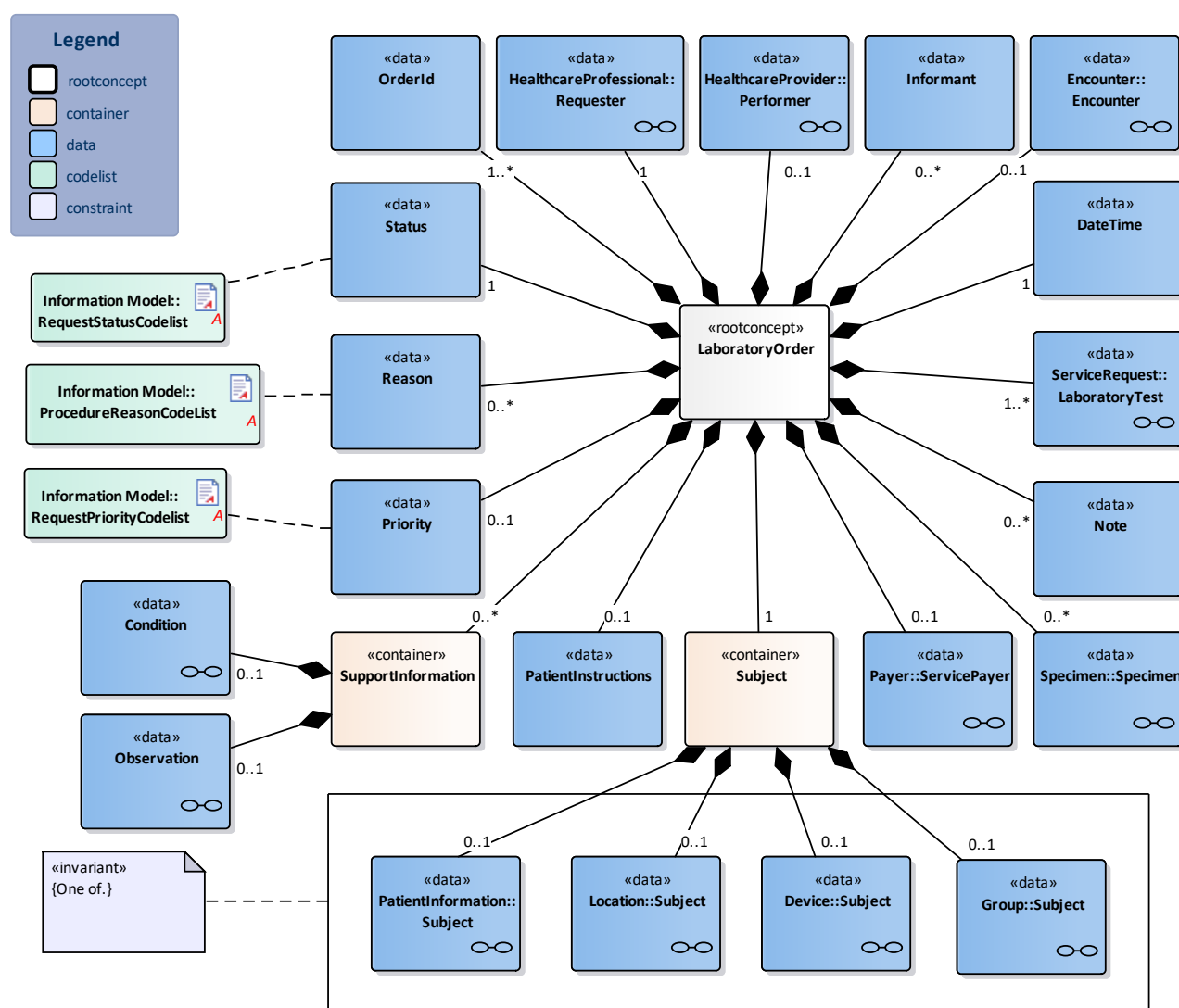


Figure 40: Laboratory Order Information Model

Type	Concept	Card	Description
«rootconcept»	LaboratoryOrder		A root concept of the LaboratoryOrder information model.
«data»	OrderId	1..*	An identifier of the laboratory test order.
«data»	HealthcareProfessional::Requester	1	The healthcare professional and/or healthcare provider organization by whom the LaboratoryOrder was created.
«data»	HealthcareProvider::Performer	0..1	The healthcare provider organization to whom the LaboratoryOrder is addressed.
«data»	LaboratorySpecialty	0..1	Laboratory specialty required in this order.
«data»	Encounter::Encounter	0..1	An encounter that provides additional information about the healthcare context in which this request is made.
«data»	DateTime	1	Date and time when order was signed.
«data»	ServiceRequest::LaboratoryTest	1..*	A laboratory test specification.
«data»	Note	0..*	Notes and comments made about the service request.
«data»	Priority	0..1	Priority of the request (e.g. statim, routine). If order priority is specified, then applies to all requested lab services with possible local override on service (lab test) level. Specific conditions, e.g., turnaround time constraints, could be specified for specific order priority.
«data»	Reason	0..*	An explanation or justification for why this service is being requested in coded or textual form.
«data»	Specimen::Specimen	0..*	Information about specimen that is sent to laboratory for investigation. Specimen might not be specified in case when specimen collection will be performed by the laboratory.
«data»	Payer::ServicePayer	0..1	Insurance plans, coverage extensions, pre-authorizations and/or pre-determinations that may be needed for delivering the requested service.
«data»	PatientInstructions	0..1	Instructions in terms that are understood by the patient or consumer.
«data»	Status	1	Order status: similar to document status, with additional status code "in progress" to indicate that order is being processed by laboratory.
«container»	Subject	1	On whom the service is to be performed. This is usually a human patient, but can also be requested on animals, groups of humans or animals, devices such as dialysis machines, or even locations (typically for environmental scans).
«data»	PatientInformation::Subject	0..1	Individual (human or animal) or Entity (water, food) the service is ordered for.
«data»	Location::Subject	0..1	A location information (typically for environmental scans).
«data»	Device::Subject	0..1	A device which is a subject of investigation.
«data»	Group::Subject	0..1	
«container»	SupportInformation	0..*	Additional clinical information about the patient or specimen that may influence the services or their interpretations. This information includes diagnosis, clinical findings and other observations. In laboratory ordering these are typically referred to as "ask at order entry questions (AOEs)". This includes observations explicitly requested by the producer (filler) to provide context or supporting information needed to complete the order. For example, reporting the amount of inspired oxygen for blood gas measurements.
«data»	Condition	0..1	Conditions (diagnosis) that may influence the services or their interpretations.

Type	Concept	Card	Description
«data»	Observation	0..1	Observation about the patient or specimen that may influence the services or their interpretations.

ProcedureReasonCodelist		OID:	
Codes	Coding Syst. Name	Coding System OID	
All codes where concept is-a 404684003 (Clinical finding)	SNOMED CT	2.16.840.1.113883.6.96	
All codes where concept is-a 71388002 (Procedure)	SNOMED CT	2.16.840.1.113883.6.96	
All codes where concept name is-a 363675004(Intents (nature of procedure values))	SNOMED CT	2.16.840.1.113883.6.96	
All ICD-10 codes	ICD-10 WHO		
All OrphaCodes	ORPHACode		
All ICD-11 codes	ICD-11 WHO		

RequestPriorityCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Routine	routine	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request has normal priority.
Urgent	urgent	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned promptly - higher priority than routine.
ASAP	asap	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned as soon as possible - higher priority than urgent.
STAT	stat	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned immediately - highest possible priority. E.g. an emergency.

RequestStatusCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Draft	draft	http://hl7.org/fhir/request-status	2.16.840.1.113883.4.642.4.112	The request has been created but is not yet complete or ready for action.
Active	active			The request is in force and ready to be acted upon.
On Hold	on-hold			The request (and any implicit authorization to act) has been temporarily withdrawn but is expected to resume in the future.

RequestStatusCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Revoked	revoked			The request (and any implicit authorization to act) has been terminated prior to the known full completion of the intended actions. No further activity should occur.
Completed	completed			The activity described by the request has been fully performed. No further activity will occur.
Entered in Error	entered-in-error			This request should never have existed and should be considered 'void'. (It is possible that real-world decisions were based on it. If real-world activity has occurred, the status should be "revoked" rather than "entered-in-error".).
Unknown	unknown			The authoring/source system does not know which of the status values currently applies for this request. Note: This concept is not to be used for "other" - one of the listed statuses is presumed to apply, but the authoring/source system does not know which.

5.2.2.7.2 Service Request Information Model

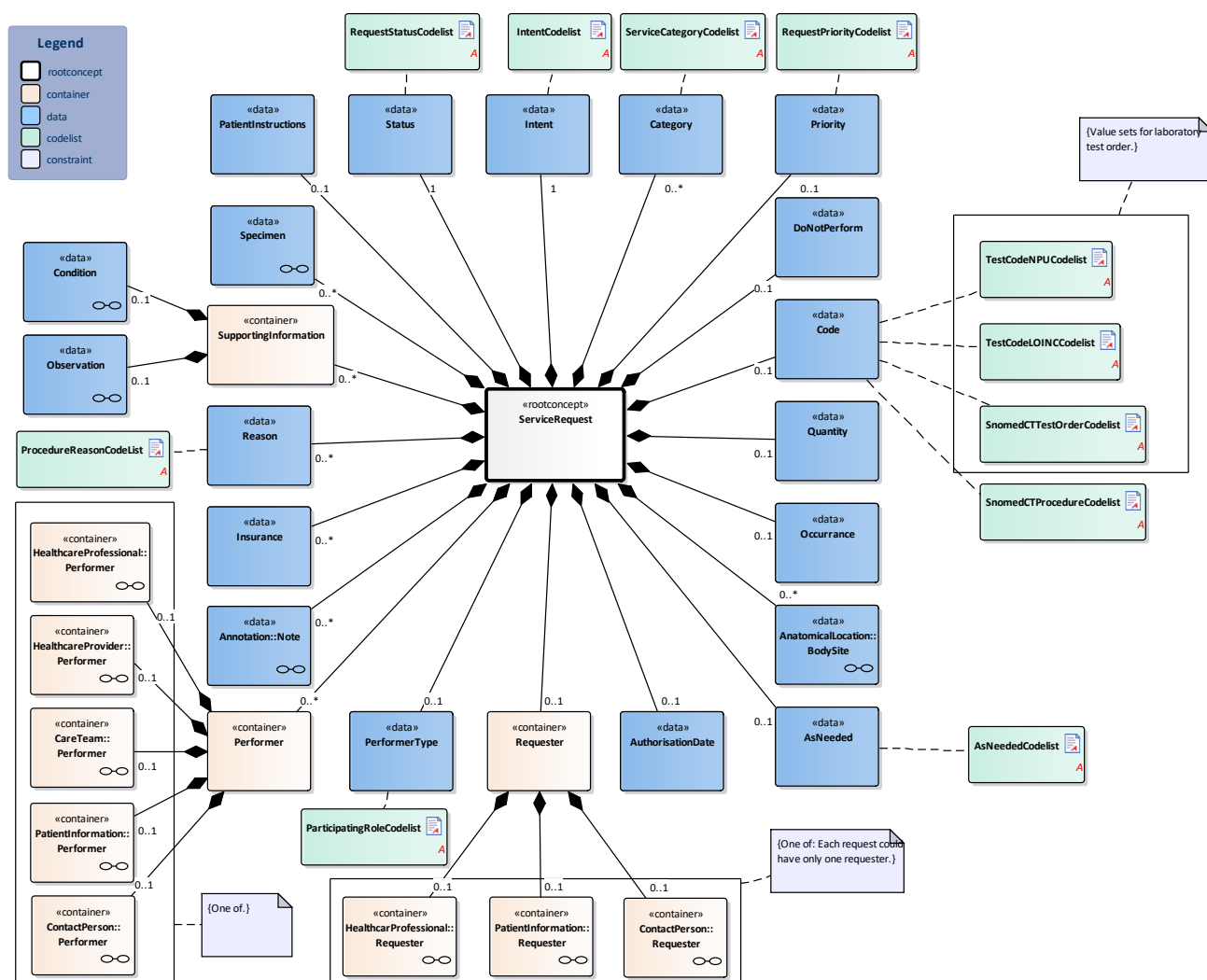


Figure 41:Information Model

Type	Concept	Card	Description
«rootconcept»	ServiceRequest		Root concept of the ServiceRequest information model. This concept contains all data elements of the ServiceRequest information model.
«data»	AnatomicalLocation::BodySite	0..*	Anatomic location where the procedure should be performed. This is the target site.
«data»	Annotation::Note	0..*	Any other notes and comments made about the service request.
«data»	AsNeeded	0..1	A boolean indication or a code indicating the pre-condition for performing the service. For example "pain", "on flare-up", etc.
«data»	AuthorisationDate	0..1	Date and time when request was authorized (signed).
«data»	Category	0..*	A code that classifies the service for searching, sorting and display purposes (e.g. "Surgical Procedure").
«data»	Code	0..1	A code that identifies a particular service (i.e., procedure, diagnostic investigation, or panel of investigations) that have been requested.

Type	Concept	Card	Description
			Many laboratory and radiology procedure codes embed the specimen/organ system in the test order name, for example, serum or serum/plasma glucose, or a chest x-ray. The specimen might not be recorded separately from the test code.
«data»	DoNotPerform	0..1	Set this to true if the record is saying that the service/procedure should NOT be performed. Used for do not ambulate, do not elevate head of bed, do not flush NG tube, do not take blood pressure on a certain arm, etc. In general, only the code and timeframe will be present, though occasional additional qualifiers such as body site or even performer could be included to narrow the scope of the prohibition. If the ServiceRequest.code and ServiceRequest.doNotPerform both contain negation, that will reinforce prohibition and should not have a double negative interpretation.
«data»	Insurance	0..*	Insurance plans, coverage extensions, pre-authorizations and/or pre-determinations that may be needed for delivering the requested service.
«data»	Intent	1	Whether the request is a proposal, plan, an original order or a reflex order.
«data»	Occurrence	0..1	The date/time, period or timing at which the requested service should occur.
«data»	PatientInstructions	0..1	Instructions in terms that are understood by the patient or consumer.
«data»	PerformerType	0..1	Desired type of performer for doing the requested service.
«data»	Specimen	0..*	One or more specimens that the laboratory procedure will use.
«data»	Status	1	The status of the order.
«data»	Priority	0..1	Indicates how quickly the ServiceRequest should be addressed with respect to other requests.
«data»	Quantity	0..1	An amount of service being requested which can be a quantity (for example \$1,500 home modification), a ratio (for example, 20 half day visits per month), or a range (2.0 to 1.8 Gy per fraction).
«data»	Reason	0..*	An explanation or justification for why this service is being requested in coded or textual form.
«container»	Performer	0..*	The desired performer for doing the requested service. For example, the surgeon, dermatopathologist, endoscopist, etc. If multiple performers are present, it is interpreted as a list of alternative performers without any preference regardless of order. I
«container»	PatientInformation::Performer	0..1	Patient who is the desired performer for doing the requested service.
«container»	HealthcareProfessional::Performer	0..1	HealthcareProfessional who is the desired performer for doing the requested service.
«container»	CareTeam::Performer	0..1	CareTeam who is the desired performer for doing the requested service.
«container»	HealthcareProvider::Performer	0..1	HealthcareProvider who is the desired performer for doing the requested service.
«container»	ContactPerson::Performer	0..1	Related person who is the desired performer for doing the requested service.
«container»	Requester	0..1	The individual who initiated the request and has responsibility for its activation.

Type	Concept	Card	Description
«container»	PatientInformation::Requester	0..1	Patient who initiated the request and has responsibility for its activation.
«container»	ContactPerson::Requester	0..1	Contact person who initiated the request and has responsibility for its activation.
«container»	HealthcareProfessional::Requester	0..1	Healthcare practitioner who initiated the request and has responsibility for its activation.
«container»	SupportingInformation	0..*	Additional clinical information about the patient or specimen that may influence the services or their interpretations. This information includes diagnosis, clinical findings and other observations. In laboratory ordering these are typically referred to as "ask at order entry questions (AOEs)". This includes observations explicitly requested by the producer (filler) to provide context or supporting information needed to complete the order. For example, reporting the amount of inspired oxygen for blood gas measurements.
«data»	Observation	0..1	Observation (test result) about the patient or specimen that may influence the services or their interpretations.
«data»	Condition	0..1	Conditions (diagnosis) that may influence the services or their interpretations.

AsNeededCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All code from < 404684003 (Clinical finding)	SNOMED CT	

ParticipatingRoleCodelist		OID:
Codes	Coding Syst. Name	Coding System OID
All code from < 125676002 (Person) or < 223366009 (Healthcare professional) or < 394730007 (Healthcare related organisation)	SNOMED CT	

RequestPriorityCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
Routine	routine	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request has normal priority.
Urgent	urgent	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned promptly - higher priority than routine.
ASAP	asap	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned as soon as possible - higher priority than urgent.

RequestPriorityCodelist			OID:	
Concept Name	Concept Code	Coding Syst. Name	Coding System OID	Description
STAT	stat	http://hl7.org/fhir/request-priority	2.16.840.1.113883.4.642.1.116	The request should be actioned immediately - highest possible priority. E.g. an emergency.

RequestStatusCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Draft	draft	http://hl7.org/fhir/request-status	2.16.840.1.113883.4.642.4.112	The request has been created but is not yet complete or ready for action.
Active	active			The request is in force and ready to be acted upon.
On Hold	on-hold			The request (and any implicit authorization to act) has been temporarily withdrawn but is expected to resume in the future.
Revoked	revoked			The request (and any implicit authorization to act) has been terminated prior to the known full completion of the intended actions. No further activity should occur.
Completed	completed			The activity described by the request has been fully performed. No further activity will occur.
Entered in Error	entered-in-error			This request should never have existed and should be considered 'void'. (It is possible that real-world decisions were based on it. If real-world activity has occurred, the status should be "revoked" rather than "entered-in-error".).
Unknown	unknown			The authoring/source system does not know which of the status values currently applies for this request. Note: This concept is not to be used for "other" - one of the listed statuses is presumed to apply, but the authoring/source system does not know which.

ServiceCategoryCodelist		OID:		
Concept Name	Concept Code	CodeSys. Name	CodeSystem OID	Description
Laboratory procedure	10825200	SNOMED CT		
Imaging	363679005			
Counselling	409063005			
Education	409073007			
Surgical procedure	387713003			

This is an example value set.

SnomedCTProcedureCodelist		OID:	
Codes	Coding Syst. Name	Coding System OID	
All codes from < 71388002 Procedure (procedure)	SNOMED CT		

SnomedCTTestOrderCodelist		OID:	
Codes	Coding Syst. Name	Coding System OID	
All code from < 15220000 Laboratory test or < 363787002 Observable entity	SNOMED CT		

5.2.2.8 Application


Traditionally, healthcare professionals are using paper laboratory order forms like the one presented on the following figure.

Figure 42: Example of paper order form

Patient name: <u>Shown after selecting a patient</u>	Date of birth: <u>information about patient</u>	
Physician/Practitioner: <u>Shown by default</u>	Procedure date/time: <u>Current date</u>	
Mailing Address: _____	Fax # _____	Phone # _____

Test	Test	Test
<input type="checkbox"/> Albumin	<input type="checkbox"/> FSH	<input type="checkbox"/> Renal panel
<input type="checkbox"/> Alk Phos	<input type="checkbox"/> GGT	<input type="checkbox"/> Retic count
<input type="checkbox"/> Amylase	<input type="checkbox"/> Glucose, fasting	<input type="checkbox"/> RF
<input type="checkbox"/> ANA	<input type="checkbox"/> HCG, qual	<input type="checkbox"/> RPR
<input type="checkbox"/> ALT	<input type="checkbox"/> HCG, quant	<input type="checkbox"/> Sed rate (ESR)
<input type="checkbox"/> AST	<input type="checkbox"/> Hemoglobin	<input type="checkbox"/> Sodium
<input type="checkbox"/> B12	<input type="checkbox"/> Hematocrit	<input type="checkbox"/> T3 free
<input type="checkbox"/> Bili, neo profile	<input type="checkbox"/> Hep A AB, IGM	<input type="checkbox"/> T4 free
	<input type="checkbox"/> Hep B Surface Ag	<input type="checkbox"/> Tegretol <i>Carbamazepine</i>
<input type="checkbox"/> Bili, direct	<input type="checkbox"/> Hep B core AB, IGM	<input type="checkbox"/> Total protein
<input type="checkbox"/> Bili, total	<input type="checkbox"/> Hep C AB	<input type="checkbox"/> Triglycerides
<input type="checkbox"/> BMP	<input type="checkbox"/> Hep panel, acute	<input type="checkbox"/> TSH
<input type="checkbox"/> BTNP	<input type="checkbox"/> HGB A1C	<input type="checkbox"/> Type & screen

Figure 43: Another example of paper order form



3910 Washington Parkway, Suite B
 Idaho Falls, ID 83404
 Ph: 208.529.8330 Fax: 208.523.3318

444 Hospital Way, Ste. 611
 Pocatello, ID 83201
 Ph: 208.529.8330 Fax: 208.232.0755

2001 S Woodruff Ave. Ste 15B
 Idaho Falls, ID 83404
 Ph: 208.529.8330 Fax: 208.523.3318

101 E Main Street
 Rexburg, ID 83440
 Ph: 208.529.8330 Fax: 208.523.3318

Location: _____
Patient Name _____
Date of Birth _____ **Male / Female**

PANELS	
Hepatitis Panel SST(2)	
Basic Metabolic Panel SST	
Comprehensive Metabolic Panel SST	
Cardiac Panel (CKMB, TROP I) SST	
Electrolyte Panel SST	
Hepatic Panel SST	
Lipid Panel SST	
*Prenatal Panel SST(2) PRPL(2)	
Renal Panel SST	

INDIVIDUAL TESTS	
24 Hr. Protein URINE	
24 Hr. Urine Calcium URINE	
**24 Hr. Urine Creat Clearance URINE	
ABO/Rh PRPL	
Antibody Screen PRPL	
Albumin SST	

Glucose SST	
H Pylori PRPL	
HCG, Quant SST	
Hemogram PRPL	
Hep B Sur Ag SST	
Hep C AB SST	
Herpes Simplex Virus 1/2 IgG SST	
HgA1C PRPL	
HIV SST	
Homocysteine, Cardio SST	
Insulin SST	
Iron, TIBC SST	
Iron, Total SST	
LDH SST	
Lipase SST	
Lithium SST	
Magnesium SST	

REFERRING DOCTOR
Authorizing Signature
Date

**Patient Instructions
IR & GTT**
 Fast (do not eat) 10–12
 hours before.
 No coffee, tea, smoking
 or gum.
 You may have water.
 Bring order, insurance card
 and a good book.

Taking a classical paper order form as an example, the main information to create laboratory test order must include at least:

- Patient information: Patient information about the patient who practitioner is visiting
- Ordering practitioner information: Practitioner who is performing the order
- Sample identification (if sampling performed by ordering party)
- Tests requested: the practitioner must select the tests to be performed to the patient according to the possible diagnostic goal.
- Patient conditions (e.g., fasting)
- Patient information/instructions (e.g., don't eat for at least 12 hours, drink only water)

Model orders (panels, group of tests) containing standard test profiles (panels, batteries) may be locally or regionally/nationally defined for specific use-cases or medical conditions (e.g., basic blood/urine tests for primary care; chronic disease management; emergency-blood bank; prior to certain surgical procedures etc.). Such model orders can be linked to related clinical guidelines. This model orders would serve for a quick selection of one test or group of relevant tests which will be then expanded into its elements by the CPOE application to form a laboratory test order.

Based on test order selection, CPOE application should provide information on specimen collection and handling, this could include information on:

- Patient conditions (fasting, after physical exercise, etc.)
- Required minimal amount of sample
- Type and number of containers and stabilising additives
- Sample collection instructions (e.g., procedure, device to be used, sample collection period, sample collection time, location, morphology)
- Storage and transportation conditions

Additionally, based on the selection of laboratory tests, CPOE should ask to provide additional clinical information about the patient relevant for test measurement and result interpretation, such as:

- Diagnosis and/or other clinically relevant information
- Reason for investigation, clinical question to be answered, order comments
- Medication
- Reproduction phase
- Pregnancy status
- Fasting duration
- Weight and height
- Sex and age of the patient (if cannot be derived from the patient details)
- Etc.

Additional information might be provided using the same coding system as used to encode ordered tests (e.g., LOINC) or using SNOMED CT terminology.

5.2.2.8.1 User interface (UI) requirements

Lab order application should allow to select lab tests using profiles or allow search lab tests using an easy way to find them according to Figure 44. This figure shows an example of how the selection of tests should be carried out.

Figure 44: Laboratory test request UI sample

Lab Individual Test	Test Profiles
<input type="checkbox"/>	<input type="checkbox"/> Diabetes mellitus
<input type="checkbox"/>	<input type="checkbox"/> Arterial hypertension
<input type="checkbox"/>	<input type="checkbox"/> Hepatitis
<input type="checkbox"/>

CPOE applications should provide all necessary details about specimen collection and other factors influencing quality of measurement and result interpretation and should also ask for any additional information that should be provided to the laboratory.

5.2.2.8.2 Examples of the CPOE systems

The screenshot displays a CPOE system interface. At the top, there is a table with columns: Order Name, Status, Start, and Details. Below this, a section titled 'Laboratory' shows a list of orders. Two orders are visible: 'Blood Culture' and 'Eye Culture', both with a status of 'Order' and a start time of '24/Mar/2022 16:42...' and '24/Mar/2022 16:43...' respectively. The 'Eye Culture' order is selected, and its details are shown in a pop-up window. The 'Details for Eye Culture' window has tabs for 'Details', 'Order Comments', and 'Diagnoses'. The 'Details' tab is active, showing a form with fields for '*Specimen type:', '*Clinical Details:', 'Bleep/Telephone Number:', '*Collection priority:', and '*Proposed Sample Collection date/time:'. The '*Specimen type:' dropdown menu is open, showing options: 'Conjunctival swab', 'Contact lens fl', 'Contact Lens LT', 'Contact Lens RT', 'Corneal Scrape LT', 'Corneal Scrape RT', 'Eye swab (Left)', and 'Eye swab (Rt)'. The 'Conjunctival swab' option is selected. At the bottom of the window, there is a status bar indicating '5 Missing Required Details' and a 'Div Table' button.

Figure 45: Selection of the specimen type based on order definition

Figure 46: Swab Culture order with additional details to be provided by ordering practitioner

5.2.2.9 Infrastructure

Technical and organisational infrastructure shall be in place to facilitate communication between ordering parties and laboratory. Minimal requirement is to enable bilateral communication to the target laboratory. Optionally, centralised (regional, national) multi-thread nodes or gateways may be in place to distribute laboratory orders to laboratories. Identification system shall be established to ensure unique identification of laboratories and ordering parties (healthcare providers). Depending on legal and organisational framework, laboratories can be considered healthcare providers and thus incorporated in a common registry. If laboratories are considered an autonomous domain, a specific registry of laboratories can be managed in relation with licensing procedures to ensure that only licensed laboratories can participate in the ordering system.

As lab orders and results extensively use code systems to express various aspects of the laboratory investigation process, use of terminology services is essential. Terminology services should be established to ensure distribution of up-to-date terminologies and terminology mappings if heterogeneous terminologies are being used in the infrastructure.

5.2.3 Querying for laboratory results

Title UC5.3.3 - Querying for laboratory results	
Purpose	Query the lab or EHR repository for a laboratory summary and/or result report or for extract of the lab result data based on combination of query parameters (selection criteria).
Relevance	Once a repository of multiple laboratory reports or registry of existing laboratory data together with infrastructure for retrieval of such data is available, there is a need to select specific laboratory reports or results that are required for a particular medical treatment or clinical decision. Browsing through a multitude of potentially irrelevant records is time consuming and may not provide the desired information. Therefore, a query needs to provide selection criteria to narrow the results to specific timeframe and content.
Domain	Laboratory
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational • Citizens at home and on the move
Context	Searching and querying for laboratory data requires common policies and business rules to be defined. They include how patients are identified, consent is obtained, and access is controlled, as well as the format, content, structure, organisation, and representation of clinical information and related metadata.
Information	Document query
Participants	Healthcare practitioner (physician) Patient Laboratories and/or document registries/repositories of laboratory results
Preconditions	<p>Infrastructure allowing for registration of sources of laboratory result reports and querying of laboratory result reports based on an agreed set of query parameters must be established.</p> <p>Policies and business rules specifying authentication, authorisation, access rights, data protection rules and cyber security measures as well as data format, content and structure needs to be agreed and implemented.</p> <p>The availability of a source (repository) of single or multiple laboratory result reports for a given patient.</p>
Functional process flow	<ol style="list-style-type: none"> 1. A laboratory result report document consumer uses an existing infrastructure to specify searching/query parameters which include specification of the subject, relevant period of care services, type of the documents and other metadata, forms a query request which then sends to a document registry or similar system. 2. Document registry or similar system in the infrastructure filters its document entries and returns list of records matching the query parameters. This list contains metadata describing characteristics of each document entry in the document registry obtained from registered document sources as well as information about end points from which laboratory data could be retrieved. 3. Document consumer reviews the list of matching records, selects one or more entries of interest and retrieves laboratory result report or reports from the document repository using the end point information provided by document registry.

5.2.3.1 Actors' description

Actors of laboratory result query use case are described in chapter 3.3.1.

5.2.3.2 Workflow

- Authorised actor (e.g., treating physician) in Country B sends the request to list all laboratory reports or laboratory summary available for given patient from Country A. Ideally a list of filters i.e., date range, lab specialty or study type(s) should be specified, to limit search range.
- As a reply, the list of laboratory reports is given, containing information on all reports available in the national infrastructure (such as XDS registry), to include:
 - Type(s) of laboratory study included
 - What condition is covered in the report (reason for laboratory investigation), if known
 - When and where was the laboratory report performed (laboratory, country, city)
 - By whom was the laboratory service ordered (name, specialty)
- From the list, requestor can select which laboratory reports and conditions are relevant to the patient care and ask for their retrieval
- In some EU countries, specific Reports, e.g., Histology results, should only be made available to HCP with specific access relevant to their role
- The requestor retrieves selected laboratory reports
- Access to the laboratory reports should be recorded in an audit log or similar evidence

5.2.3.3 Legal and regulatory

General provisions for clinical document queries apply. National regulations may define authorization rules for health care providers and professionals. Restrictions may apply depending on speciality (e.g., only authorised specialists may receive microbiology and pathology lab reports in the query results list).

5.2.3.4 Policy

No specific policy requirements for this use case.

5.2.3.5 Technical

No specific technical requirements.

5.2.3.6 Semantic

Lab result query parameters follow XDS Metadata model. Metadata attributes can be categorised according to specific document-handling purposes. Each metadata attribute typically has more than one purpose, although some have only one. Metadata in the Document Sharing profiles has one or more of these purposes.

- **Patient Identity** – Attributes that describe the subject of the document. This includes patient Id, patient name, and other demographics.

- **Provenance** – Attributes that describe where the document comes from. These items are highly influenced by medical records regulations. This includes human author, identification of system that authored, the organisation that authored, predecessor documents, successor documents, and the pathway that the document took.
- **Security & Privacy** – Attributes that are used by Privacy and Security rules to appropriately control the document. These values enable conformance to Privacy and Security regulations. These characteristics would be those referenced in Privacy or Security rules. These characteristics would also be used to protect against security risks to confidentiality, integrity, and availability.
- **Descriptive** – Attributes that are used to describe the clinical value, so they are expressly healthcare-specific. These values are critical for query models and enable workflows in all exchange models. The number of attributes in this category is kept to minimum so the metadata does not simply duplicate the document, and to keep disclosure risk to a minimum. Thus, the metadata attribute values tend to be from a small set of codes. Because this category is close to the clinical values it tends to have few mandatory attributes, allowing policy to choose to not populate. For healthcare documents, this is typically very closely associated with the clinical workflows but also must recognise other uses of healthcare documents such as quality reporting, public health reporting, authorised clinical research, patient access, etc.
- **Object Lifecycle** – Attributes that describe the current lifecycle state of the document including relationships to other documents. This would include classic lifecycle states of created, published, replaced, transformed, and deprecated.
- **Exchange** - Attributes that enable the transfer of the document for both push type transfers and pull type transfers. These attributes are used for low-level automated processing of the document. These attributes are not the workflow routing, but rather the administrative overhead necessary to make the transfer. This includes the document unique Id, location, size, MIME types, and document format.

IHE XDS.b profile specifies metadata that can be used for querying of any type of a document (including lab result reports). Users searching for metadata might use combination of search parameters including SQL-like wildcards searching.

The following table provides a conceptual view of the metadata attributes associated with a DocumentEntry object and applicable for both XD* and XCA (used in NCP-to-NCP communication) profiles.

DocumentEntry Metadata Attribute	Description
author	The humans and/or machines that authored the document. This attribute contains the sub-attributes: authorInstitution, authorPerson, authorRole, authorSpecialty and authorTelecommunication.
availabilityStatus	The lifecycle status of the DocumentEntry
classCode	The code specifying the high-level use classification of the document type (e.g., Report, Summary, Images, Treatment Plan, Patient Preferences, Workflow).
comments	Comments associated with the document.

DocumentEntry Metadata Attribute	Description
confidentialityCode	The code specifying the level of confidentiality of the document.
creationTime	The time the author created the document.
entryUUID	A globally unique identifier used to manage the entry.
eventCodeList	This list of codes represents the main clinical acts, such as a colonoscopy or an appendectomy, being documented.
formatCode	The code specifying the detailed technical format of the document.
hash	The hash of the contents of the document.
healthcareFacility TypeCode	This code represents the type of organizational setting of the clinical encounter during which the documented act occurred.
homeCommunityId	A globally unique identifier for a community.
languageCode	Specifies the human language of character data in the document.
legalAuthenticator	Represents a participant within an authorInstitution who has legally authenticated or attested the document.
limitedMetadata	Indicates whether the DocumentEntry was created using the less rigorous requirements of metadata as defined for the Metadata-Limited Document Source.
contentType	MIME type of the document.
objectType	The type of DocumentEntry (e.g., On-Demand DocumentEntry).
patientId	The patientId represents the subject of care of the document.
practiceSettingCode	The code specifying the clinical specialty where the act that resulted in the document was performed (e.g., Family Practice, Laboratory, Radiology).
referenceIdList	A list of identifiers related to the document
repositoryUniqueId	The globally unique identifier of the repository where the document can be accessed.
serviceStartTime	The start time of the service being documented.
serviceStopTime	The stop time of the service being documented.
size	Size in bytes of the document.
sourcePatientId	The sourcePatientId represents the subject of care's medical record identifier (e.g., Patient Id) in the local patient identifier domain of the creating entity.
sourcePatientInfo	This attribute contains demographic information of the source patient to whose medical record this document belongs.
title	The title of the document.
typeCode	The code specifying the precise type of document from the user perspective (e.g., LOINC code).
uniqueId	Globally unique identifier assigned to the document by its creator.
URI	The URI for the document.

For laboratory result querying following parameters are the most relevant ones:

- Order Id (uniqueId)

- Patient Id (patientId)
- Patient demography (sourcePatientInfo)
- Document type code (typeCode)
- Document format code (classCode)
- Order placer institution Id (not in IHE metadata profile, needs to be further discussed)
- Order placer institution name (not in IHE metadata profile, needs to be further discussed)
- Order placer person Id (not in IHE metadata profile, needs to be further discussed)
- Order placer person name (not in IHE metadata profile, needs to be further discussed)
- Order placer specialty (not in IHE metadata profile, needs to be further discussed)
- Order placer telecommunication (not in IHE metadata profile, needs to be further discussed)
- Laboratory speciality (currently not included in XDS Metadata specification, needs to be discussed with IHE)
- Sample Id (referenceIdList)
- Sample type (eventCodeList)
- Time interval of service order request (creationTime)

A proposal of a harmonised European document metadata value sets is provided in a separate WP5 deliverable.

5.2.3.7 Information

Information model is specified in the IHE XDS.b profile and is based on ebXML Registry Information Model Version 3.0⁴⁵. IHE XDS.b profile actors and transactions are depicted on Figure 47 (reprinted from IHE_ITI_Suppl_XDS_Metadata_Update.pdf).

⁴⁵ <https://docs.oasis-open.org/regrep/v3.0/specs/regrep-rim-3.0-os.pdf>

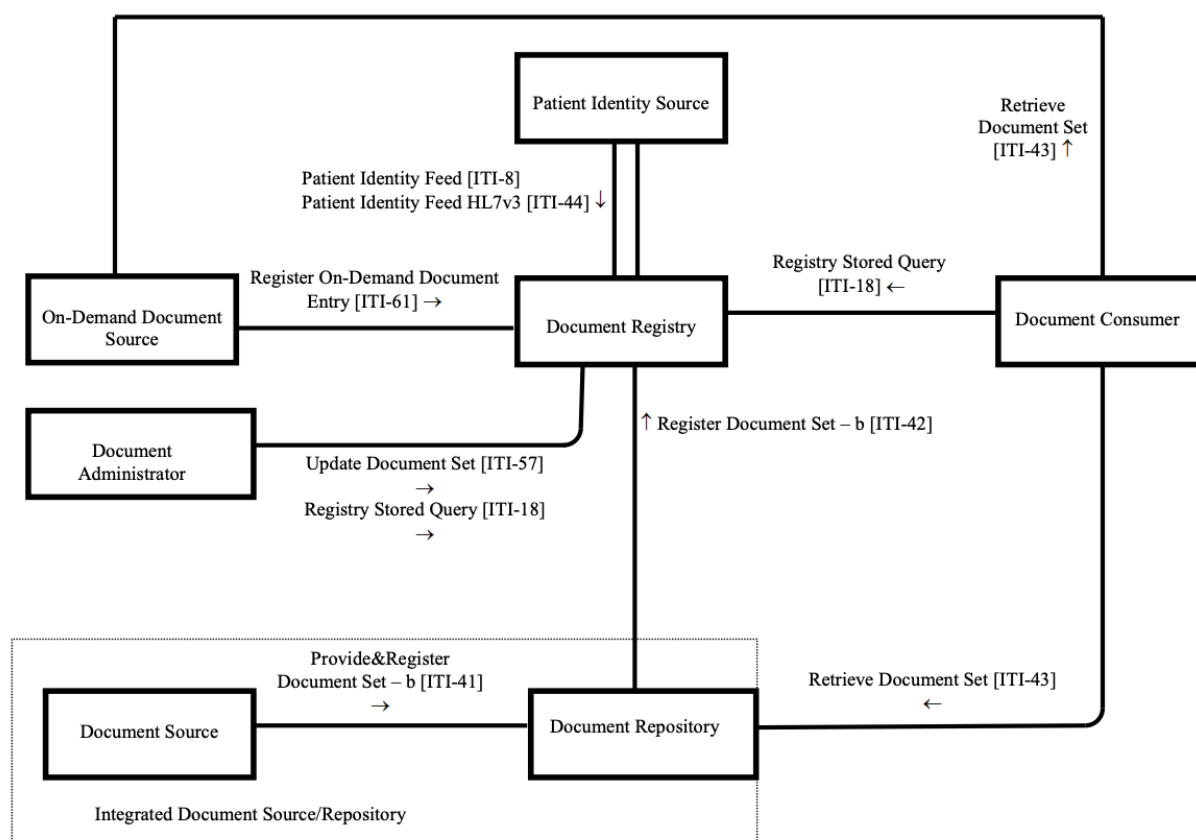


Figure 47: Cross-Enterprise Document Sharing - b (XDS.b) Diagram

For laboratory result querying following parameters are the most relevant

- Order Id (uniqueId)
- Patient Id (patientId)
- Patient demography (sourcePatientInfo)
- Document Type Code (typeCode)
- Document format code (classCode)
- Laboratory order status (currently not included in XDS Metadata specification, needs to be discussed with IHE)
- Order placer institution Id (AuthorInstitution.organizationIdentifier)
- Order placer institution name (AuthorInstitution.organizationName)
- Order placer person Id (AuthorPerson.identifier)
- Order placer person name (AuthorPerson.lastName, AuthorPerson.givenName)
- Order placer specialty (authorSpecialty)
- Order placer telecommunication (authorTelecommunication)

- Laboratory speciality (currently not included in XDS Metadata specification, needs to be discussed with IHE)
- Sample Id (referenceIdList)
- Sample type (eventCodeList)
- Time interval of service order request (creationTime)

5.2.3.8 Application

A user facing application needs to be available to laboratories, ordering parties and patients. As an example, web portal may be available for doctors to place orders and for the laboratories for search and retrieve. Patient may have access via web portal or mobile application. As an example, the aforementioned parties may be connected by implementation of the IHE Cross Enterprise Document Sharing (XDS.b) integration profile within a common Affinity Domain for the laboratory domain. To make querying and searching possible, a common set of metadata (attributes) must be agreed. Query result can then be filtered against the specified metadata such as document type (laboratory result) and practice setting. For a more specific selections, the application shall enable content specific search, e.g., by laboratory test codes, value range, specimen ID etc.

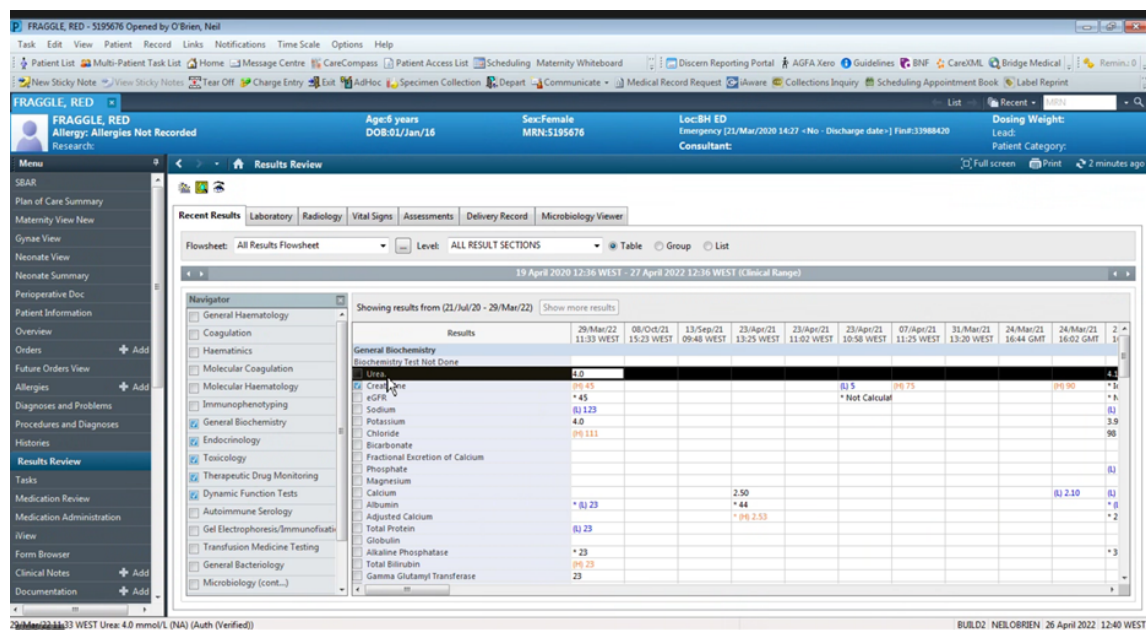
Laboratory results should be present to the user in a clear form that ensures that all information relevant for proper understanding and interpretation of laboratory results are available, at minimum the following information should be available:

- Identification of the test (test name, including system, component and measured property)
- Result value and units
- Reference range and result interpretation

A real-life example of presentation laboratory result from Ireland is shown in Figure 48. As you can see, this example does not comply fully with a minimal requirements specified above as units are not displayed.

Other information about measurement (sample information, measurement principle and device, author, validator, used calibrator, measurement error etc.) should be available on user's request.

Figure 48: Sample screenshot of summary laboratory results available from EMR in Ireland.



5.2.3.9 Infrastructure

An ICT infrastructure must be available to allow registration of laboratory reports, searching and retrieving of reports by authorised users (IHE domain-like or similar infrastructure). The architecture can either be centralised or distributed (federated). Centralised architecture is based on a central repository (database) of laboratory result reports. In the case of distributed architecture, local repositories (databases) of or laboratory reports are connected via a communication node (gateway). Secure telecommunication network must be ensured for end-to-end communication.

5.2.4 Querying for laboratory orders

Title UC5.3.4 - Querying for laboratory orders	
Purpose	Query a laboratory order upon patient visit to the laboratory of choice or upon reception of the sample by laboratory
Relevance	Upon receipt of a laboratory order by the healthcare care provider, the patient may be free to choose a laboratory to provide the service. Upon visiting the laboratory of choice, the laboratory professional queries for the respective laboratory order. Once the order is collected the laboratory proceeds with sample collection.
Domain	Laboratory
Scale	<ul style="list-style-type: none"> • Cross-border • National/Regional • Intra-organisational • Citizens at home and on the move
Context	Querying for laboratory orders implies the availability of common gateway or repository, accessible by ordering parties and laboratories
Information	Submit/Query laboratory order
Participants	Healthcare professional (medical doctor) Patient Laboratories and/or document registries/repositories of laboratory orders
Preconditions	The existence of network or platform connecting laboratories and ordering parties and the ability of laboratories to access the repository of laboratory orders from multiple sources.
Functional process flow	<ol style="list-style-type: none"> 1. Healthcare provider or patient himself creates the order and submits it to the gateway / repository 2. Patient visits the laboratory and provides his/her ID, alternatively, laboratory receives specimen and/or order ID 3. The laboratory queries for the order for the given patient ID or order ID or specimen ID 4. Laboratory collects specimen and processes it according to the retrieved order

5.2.4.1 Description of Actors

Actors of laboratory query use case are described in chapter 3.3.1.

5.2.4.2 Workflow

- Authorised Actor (HCP and/or Patient) generates electronic laboratory order
- Following authentication, lab order is stored in an electronic document repository
- Document repository registers the laboratory order document with the document registry.
- Audit record is generated
- Patient (and/or sample) received by laboratory is identified and identity verified by laboratory staff

- Laboratory order filler queries order via Document Registry using a combination of search parameters, e.g.:
 - Order Id
 - Patient details and/or identifier
 - Sample Id or sample type
 - Laboratory speciality (biochemistry, microbiology...)
 - Time interval of service order request
- Document registry processes the query and returns a list of matching orders, if available
- Lab professional or laboratory order filler selects one or more orders matching the criteria and retrieves the order information
- Audit record is updated to detail access to the patient record
- Laboratory filler processes the order according to the order information, updates order status as accepted and later as complete once order is processed, and generates one, or more, laboratory results reports
- Audit process is updated to confirm laboratory order report(s) has been updated.

5.2.4.3 Legal and regulatory

General regulations for laboratory domain apply. National regulations apply for personal data procession (sector specific law, patient consent, contractual obligations). The relations between ordering parties and laboratories may be formalised by means of a multilateral agreement or policies.

The free choice of laboratory may be restricted for specific laboratory tests or domains due to special requirements regarding sample handling and transportation (e.g., orders may only be addressed to the nearest laboratory).

5.2.4.4 Policy

Various policies for this use case might apply including contractual settlement between ordering parties and laboratories. Policies might further specify types of laboratories that are eligible for receiving test orders, rules on selection of test batteries and their required and optional components including reflex tests, time validity of orders etc.

5.2.4.5 Technical

Laboratory information systems and clinical information systems need to implement technical interfaces (APIs) to connect to the electronic order sharing and exchange framework.

5.2.4.6 Semantic

It is critical to establish a common set of metadata within a cooperative domain (region, country, or EU) that can be used for querying of laboratory orders. This set should be universal to cover other types of clinical documents and should follow relevant international standards (e.g., IHE XDS

Metadata). Following attributes are relevant for order query use case (IHE XDS Metadata elements are present in brackets):

- Order Id (uniqueId)
- Patient Id (patientId)
- Patient demography (sourcePatientInfo)
- Document Type Code (typeCode)
- Document format code (classCode)
- Laboratory order status (currently not included in XDS Metadata specification, needs to be discussed with IHE)
- Order placer institution Id (AuthorInstitution.organizationIdentifier)
- Order placer institution name (AuthorInstitution.organizationName)
- Order placer person Id (AuthorPerson.identifier)
- Order placer person name (AuthorPerson.lastName, AuthorPerson.givenName)
- Order placer specialty (authorSpecialty)
- Order placer telecommunication (authorTelecommunication)
- Laboratory speciality (currently not included in XDS Metadata specification, needs to be discussed with IHE)
- Sample Id (referenceIdList)
- Sample type (eventCodeList)
- Time interval of service order request (creationTime)

Draft for harmonised European Value sets for XDS document metadata will be delivered in a separate deliverable by WP5.

5.2.4.7 Information

Query for laboratory orders follows the same document search and retrieve information model as in previous use case UC5.3.3 Query for laboratory results.

5.2.4.8 Application

A user facing application shall be available to the actors, either by means of a common application (web portal) or application modules in the local information systems (CIS, LIS).




 Provtagningar	 Grafer	 Analysöversikt
55 provsvar hittades		Filtrera provtagningar ▼
Klicka på en rad för att se mer detaljer		Visar 10 av 55
Provtagningstid ▼	Typ av svar ▼	Svaret skickat till ▼
2021-11-20 10:00	Slutsvar OVIDIMERAD	GLOO4 Anna Cronenberg Intervallens vårdcentral
2021-11-13 08:50	Slutsvar OVIDIMERAD	Anna Andersson (Läkare) Kirurgkliniken, Sjukhus COSMIC
2021-11-03 08:00	Svar	Margot Wallström 1 Labbet A1

Figure 49: An example order query result from Sweden

5.2.4.9 Infrastructure

An ICT infrastructure must be available to connect laboratories and ordering parties (IHE domain-like or similar infrastructure). The architecture can either be centralised or distributed (federated). Centralised architecture is based on a central repository (database) of laboratory orders. In the case of distributed architecture, local repositories (databases) of or laboratory orders are connected via a communication node (gateway). Secure telecommunication network must be ensured for end-to-end communication.

6 Summary and Discussion

Clinical laboratory results play an important role in diagnosis, treatment, and follow-up of patients. Sharing of laboratory results in cross-border health information exchange across member states is an expected and wanted further extension within the CEF eHDSI. The benefits of standardised cross-border exchange of laboratory requests and laboratory test results and their transmission in cross-border context are significant to include delivering better patient outcomes and efficiencies in healthcare.

This document provides a functional specification for cross-border and cross-enterprise exchange of laboratory test results. While mainly focused on semantic interoperability, this document elaborated on general legal, regulatory, and organisational aspects that are important for sharing documents and data within the laboratory domain. The scope of the document was focused on laboratory test requests and results as the most common laboratory use cases. LOINC, NPU, UCUM and SNOMED-CT were identified as baseline standards. Code systems are required for coding of specimen types, anatomic specification, specimen collection, processing and examination techniques, devices, containers, measurement units, and ordinal or nominal-scale test results.

A brief comparative analysis of the existing standards was provided in addition to examples of mapping terminologies. Illustrative data models and process diagrams are presented. This document provided a broad overview of the laboratory domain and guidelines for further development of functional building blocks and semantic elements.

In use case description section, we focus on the key legal, semantic, technical requirements for laboratory orders and laboratory result reports, querying for laboratory reports and querying for laboratory results. We identified priority use cases and outlined several which should be researched in future studies.

This document will be the main input for the WP6 Task 6.1 - Definition of technical specification for the Laboratory Domain but it will be also used by task T5.5 - Hospital Discharge Report and T5.6 – Patient summary.

6.1 Laboratory data exchange requirements

Main functional and non-functional requirements are summarised in this chapter. The chapter is divided into sub-chapters with common requirements that apply to all laboratory use cases and sub-chapters that summarise use case specific requirements. Requirements specified in the chapter are applicable mainly for cross-border data exchange but could be applied to in-country use as well.

6.1.1 Common requirements

As laboratory order and test result report are specific types of clinical document, similar general functional requirements to other clinical document types will apply:

- The information exchanged between Healthcare Service Providers must be understandable in both institutions involved in the interaction. This will require agreement on:
 - Naming of laboratory tests
 - Measurement units – for each quantitative test result value an agreed measurement units should be set

- Common value sets for all coded parts of the laboratory result report, e.g., result values (identified virus or bacteria, blood groups, cell morphology findings and other types of observations), sample container types, result interpretation codes etc.
- Ensure the comprehensibility of the information to the person who receives it (patient or healthcare professional, or any other relevant party involved).
- The above requirement must take priority over the completeness/exhaustiveness of the provided information.
- Unambiguous identification of the patient must be assured.
- The protection of personal data, privacy, and confidentiality of both the patient, healthcare professional and any other relevant party involved must be assured.
- Additional requirements for interoperable exchange of laboratory test results are specified in chapter 5.1.4.9 Generic requirements for interoperable laboratory test ordering and result sharing and chapter 5.2.1.5.10 Interoperable test result sharing principles

6.1.1.1 Non-functional requirements

Exchange of laboratory orders and results will need a technical infrastructure that will allow searching/querying for and retrieval of laboratory information objects (orders and reports). Such infrastructure should comply with many technical, operational, and other non-functional requirements, e.g., requirements on:

- Service availability
- Communication infrastructure
- Interoperability infrastructure (semantic services) - Standardised catalogues of laboratory tests, coded result values etc. shall be available, regularly maintained and transparently published
- Response time
- Confidentiality
- Access control
- Audit Trail
- Integrity
- Nonrepudiation
- Guaranteed delivery
- Supervision services

These requirements are well described in many healthcare communication frameworks (e.g., MyHealth@EU). We are not further describing them in this chapter and rather refer the interested reader to other sources.

6.1.2 Laboratory result report

6.1.2.1 Functional requirements

- Result report availability: Make laboratory result report available – laboratory result report sources – laboratory information systems - must be able to provide laboratory test result reports in a digital form
- Result report exchange: Laboratory information systems or EHR repositories should allow exchange of digital laboratory result reports between authorised parties (healthcare professional for ensuring continuity of care) using established secure communication infrastructure
- Structured information:
 - The exchanged laboratory test result reports should be structured in modular data groups (i.e., sorted under the appropriate nesting headlines) each of them containing related items of information with a unified meaning of fields (e.g., specimen, result values, result interpretation, graphical attachments, etc.).
 - Test results should be structured containing all necessary elements, i.e., at least, result values (qualitative and/or quantitative), measurement units (if applicable), referential intervals and result interpretation should always be provided. Optionally, additional information (uncertainty of measurement, calibrators used, device used etc.) might be provided.
- Ideally, the information that is exchanged should be represented to the recipient as it is usually done (or otherwise expected by the Healthcare Professional), for ease of use.
- Equivalent information: The information exchanged must be equivalent in their meaning, i.e., a unified meaning of the information must be coherent with that system (e.g., laboratory test identification and test result (value, units, etc.) are interpreted equally by sender and recipient).
- Information understandability: The information exchanged must be fully understandable to human actors to facilitate correct interpretation of information (e.g., numerical result values should be present in agreed measurement units, test names and coded result values should be translated in language understandable to the human actors that will make use of it).
- Optionally, notification service for ordering party and patient
- Optionally, patient access via web portal or mobile application

6.1.2.2 Non-functional requirements

There are no additional use case specific non-functional requirements. General requirements will apply.

6.1.3 Laboratory order from healthcare provider

6.1.3.1 Functional requirements

- Capacity to create digital laboratory orders by the ordering party
- Capacity to receive and process digital laboratory orders in the party performing laboratory study (laboratory)
- Equivalent information: The information exchanged must be equivalent in their meaning, i.e., a unified meaning of the information must be coherent with that system (e.g., laboratory test identification is interpreted equally by ordering and service performing party).
- Information understandability: The information exchange must be fully understandable to human actors as well as to the information systems to facilitate correct interpretation (e.g., use of standard test codes and test names)
- Optionally, enabling of patient's access to laboratory orders

6.1.3.2 Non-functional requirements

Appropriate computerised provider order entry (CPOE) systems should be available. Digital ordering system must be adopted by both ordering parties (healthcare providers) and laboratories.

6.1.4 Querying for laboratory results

6.1.4.1 Functional requirements

- Capacity of laboratories (authors of lab results) to make results available via gateways/nodes or to submit results to an EHR repository
- Agreed metadata set for laboratory results to facilitate query/filtering/selection
- Capacity of healthcare providers (querying parties) to access gateway or EHR repository with available laboratory results
- Capacity of healthcare providers to apply query/select/retrieve function
- Equivalent information: The information exchanged must be equivalent in their meaning, i.e., a unified meaning of the information must be coherent with that system (e.g., laboratory test result content and metadata is interpreted equally by querying and service performing party).
- Information understandability: The information exchange must be fully understandable to human actors as well as to the information systems to facilitate correct interpretation (e.g., use of standard metadata set, test codes test names, etc.)
- Optionally, processing patient's consent to enable querying for their laboratory orders

6.1.4.2 Non-functional requirements

- Authentication and authorisation mechanisms for healthcare providers and professionals eligible to perform queries

- Appropriate auditing mechanisms, including logging of query attributes, query results (list of laboratory results) and retrievals of laboratory results
- Cybersecurity and data protection mechanisms to ensure secure end-to-end data exchange

6.1.5 Querying for laboratory orders

6.1.5.1 Functional requirements

- Capacity of healthcare providers (ordering parties) to submit orders directly to the laboratory or via an access gateway or EHR repository
- Capacity of laboratories (authors of lab results) to receive orders directly or to access orders via gateways/nodes or a common EHR repository
- Agreed metadata set for laboratory orders to facilitate query/filtering/selection
- Capacity of laboratories to apply query/select/retrieve function
- Equivalent information: The information exchanged must be equivalent in their meaning, i.e., a unified meaning of the information must be coherent with that system (e.g., laboratory order content and metadata is interpreted equally by querying laboratory and ordering party).
- Information understandability: The information exchange must be fully understandable to human actors as well as to the information systems to facilitate correct interpretation (e.g., use of standard metadata set, test codes test names, etc.)

6.1.5.2 Non-functional requirements

- Authentication and authorisation mechanisms for healthcare providers (laboratories) and professionals eligible to perform queries
- Appropriate auditing mechanisms, including logging of query attributes, query results (list of laboratory results) and retrievals of laboratory results
- Cybersecurity and data protection mechanisms to ensure secure end-to-end data exchange

7 Annex 1: Proposed EU value sets for laboratory domain

7.1 Specimen types

Several EU countries are using SNOMED CT terminology to share information about specimen for laboratory and non-laboratory observations in their national system. This value set proposal has been created as a merge of value sets provided by Austria, Estonia, Netherlands, and Sweden. We excluded terms that were not from the SNOMED CT Specimen hierarchy, but we decided to include few national extensions provided by Estonia and Netherlands. We recommended to both countries to initiate a process of inclusion of these national extensions to the SNOMED CT International release. These extensions are marked with a * symbol.

Code	Concept
119376003	Tissue specimen
119359002	Bone marrow specimen
122571007	Pericardial fluid
119297000	Blood specimen
418564007	Pleural fluid
119303007	Microbial isolate
122554006	Capillary blood specimen
119326000	Hair specimen
258450006	CSF specimen
119327009	Nail specimen
119361006	Plasma specimen
119334006	Sputum specimen
119373006	Amniotic fluid
119339001	Faeces specimen
122552005	Arterial blood specimen
119341000	Bile specimen
122555007	Venous blood specimen
119342007	Saliva specimen
122575003	Urine specimen
119347001	Seminal fluid
309051001	Body fluid
119351004	Erythrocyte specimen
119364003	Serum specimen
119312009	Catheter tip submitted as specimen
258566005	Deoxyribonucleic acid specimen
258529004	Throat swab
119323008	Pus specimen
258607008	Bronchoalveolar lavage fluid
122556008	Cord blood specimen
258470000	Prostatic fluid specimen
122569007	Sweat specimen

Code	Concept
258530009	Urethral swab
440500007	Dried blood spot specimen
258574006	Mid-stream urine specimen
119340004	Meconium specimen
119360007	Dialysis fluid
119332005	Synovial fluid
258455001	Drainage fluid
119371008	Specimen from abscess
168139001	Peritoneal fluid
258565009	Chorionic villi specimen
442173007	Urine specimen from nephrostomy tube
309128003	Eye fluid
119348006	Seminal plasma specimen
258528007	Rectal swab
122594008	Tears specimen
258591005	White blood cell specimen
127479004	Specimen from uterus
432825001	Body secretion specimen
446952006	Specimen from skin obtained by scraping
258503004	Skin swab
447103002	Foreign body submitted as specimen
119318008	Water specimen
699287008	Urine specimen obtained via suprapubic indwelling urinary catheter
119298005	Mixed venous blood specimen
703431007	Venous cord blood specimen
122565001	Urinary catheter specimen
705054005	Muscle specimen
309210009	Oesophageal brushings specimen
708049000	Plasma specimen with ethylenediamine tetraacetic acid
440473005	Contact lens submitted as specimen
733056005	Fluid specimen from ear
446846006	Urine specimen obtained via indwelling urinary catheter
258428005	Products of conception tissue specimen
258508008	Genital swab
258441009	Exudate specimen
119338009	Dentin specimen
119350003	Calculus specimen
258564008	Buccal smear specimen
119399004	Specimen from eye
119329007	Colostrum specimen
258458004	Fistula fluid
258589002	Lymph node specimen

Code	Concept
258459007	Gastric fluid
258603007	Respiratory specimen
258465007	Lacrimonal fluid
122567009	Urine sediment specimen
258466008	Middle ear fluid
309176002	Bronchial brushings specimen
258469001	Pharyngeal washings
119300005	Specimen from blood product
119403008	Specimen from placenta
439961009	Implant submitted as specimen
258479004	Interstitial fluid
119336008	Exhaled air specimen
258482009	Vesicle fluid
445160003	Swab of eye
258498002	Conjunctival swab
122572000	Vomitus specimen
258500001	Nasopharyngeal swab
472929000	Central venous catheter tip submitted as specimen
168141000	Nasal fluid
703430008	Arterial cord blood specimen
257261003	Swab
703432000	Venous plasma specimen
258411007	Nasopharyngeal aspirate
708048008	Plasma specimen with citrate
258415003	Biopsy specimen
732976006	Fluid specimen from external auditory canal
258417006	Bone tissue specimen
898201001	Specimen from device
258424007	Heart valve tissue
1003705007	Drain tip submitted as specimen
698276005	First pass urine specimen
119316007	Non-biological fluid
119358005	Platelet specimen
258461003	Hydrocele fluid
309146009	Thyroid fine needle aspirate specimen
258462005	Ileostomy fluid
258577004	Vaginal secretion specimen
119328004	Mother's milk specimen
258587000	Buffy coat
122550002	Specimen obtained by fine needle aspiration procedure
119301009	Plant specimen
258467004	Nasopharyngeal washings

Code	Concept
472923004	Peripheral vascular catheter tip submitted as specimen
258468009	Oedema fluid
708317005	Pooled specimen from vaginal introitus and rectal swab
16216171000119108	Specimen from liver obtained by aspiration
119389009	Specimen from throat
16221491000119104	Voided urine specimen
119383005	Specimen from liver
258471001	Prostatic massage fluid
119367005	Specimen from burn injury
258475005	Sinus washings
119321005	Milk specimen
168136008	Colostomy fluid
434406008	Specimen from salivary gland obtained by fine needle aspiration biopsy
119294007	Dried blood specimen
122614000	Specimen from lung obtained by fine needle aspiration procedure
258483004	Mucus specimen
57741000052105	Tracheal secretion specimen (specimen)
258484005	Postmortem tissue specimen
119305000	Specimen from plasma bag
258487003	Faecal smear
734379005	Specimen from periodontal tissue
258488008	Lymph node smear
119344008	Specimen from genital system
258492001	Gallstone specimen
119391001	Specimen from bronchus
258493006	Bladder stone specimen
119337004	Inhaled gas specimen
258494000	Pancreatic stone specimen
703691002	Spun CSF
258495004	Renal stone specimen
430268003	Specimen from bone
258497007	Abscess swab
122574004	Duodenal fluid
119331003	Skeletal muscle specimen
127462005	Specimen from heart
258499005	Cough swab
431406009	Specimen from pancreas obtained by fine needle aspiration biopsy
2421000181104*	Capillary serum specimen
309479002	Artery specimen
258502009	Pus swab
119379005	Specimen from stomach
2431000181102*	Arterial plasma specimen

Code	Concept
472942000	Ventriculoperitoneal shunt submitted as specimen
258505006	Skin ulcer swab
472886009	Swab from gastrostomy stoma
2441000181109*	Capillary plasma specimen
473415003	Intrauterine contraceptive device submitted as specimen
258513007	Prepuce swab
57931000052101	Combined cervical mucus and urine specimen (specimen)
258520000	Vaginal swab
258446004	Bronchial fluid
258521001	High vaginal swab
258453008	Cyst fluid
258522008	Low vaginal swab
119349003	Spermatozoa specimen
258524009	Cervical swab
123038009	Specimen
258527002	Anal swab
122592007	Acellular blood (serum or plasma) specimen
2451000181107*	Mixed venous plasma specimen
119362004	Platelet poor plasma specimen
2501000181105*	Biopsy sample in tissue fixative
119393003	Specimen from urethra
2511000181107*	Exfoliative cytologic material
119333000	Fibroblast specimen
258531008	Wound swab
122558009	Blood specimen from blood product
258538002	Transudate specimen
702701006	Specimen from cervix or vagina
258559009	Gingivocrevicular fluid
608969007	Specimen from skin
258562007	Genetic specimen
446302006	Air sample
2521000181103*	Specimen from root canal
122560006	Blood specimen from blood donor
2531000181101*	Prostatic massage urine specimen
127456000	Specimen from breast
2541000181108*	Leukopheresis product specimen
119400006	Specimen from cornea
1003706008	Specimen from drain tip
119396006	Specimen from endometrium
258575007	Early morning urine specimen
122579009	Genital lochia specimen
258576008	Suprapubic aspirate

Code	Concept
399492000	Tissue specimen from lung
258580003	Whole blood specimen
128155007	Specimen from ovary
258581004	Clotted blood specimen
119397002	Specimen from penis
258582006	Blood clot specimen
119386002	Specimen from prostate
258583001	Bone marrow clot specimen
258606004	Lower respiratory specimen
258588005	Haematoma specimen
433308004	Specimen from spleen
258407001	Abscess tissue
128154006	Specimen from testis
119345009	Menstrual blood specimen
399411006	Specimen from trophoblast
258599007	Contact lens solution specimen
725946000	Reticulocyte specimen
119368000	Specimen from cyst
16214171000119101	Genital fluid
122566000	Fluid specimen from wound
472919007	Device submitted as specimen
258627009	Cannula tip submitted as specimen
119325001	Tissue specimen from skin
276833005	24 hour urine specimen
57711000052109	Specimen obtained by puncture procedure (specimen)
302795002	Lymph node aspirate
57921000052103	Whole blood specimen with edetic acid (specimen)
258418001	Burn tissue
697989009	Anterior nares swab
309072003	Soft tissue specimen
258442002	Fluid sample
309078004	Lymph node tissue specimen
258448003	Bursa fluid
309101008	Cartilage specimen
258452003	Chylous fluid
16211051000119109	Specimen from deep wound
258454002	Dialysate specimen
309110000	Bursa tissue specimen
710069003	Tick specimen
309114009	Ligament specimen
258456000	Empyema fluid
309117002	Fascia specimen

Code	Concept
110913002	Pleural cytologic material
309121009	Synovial tissue specimen
119295008	Specimen obtained by aspiration
309123007	Synovial specimen
258664003	Scotch tape slide
258419009	Curettings
119395005	Specimen from uterine cervix
309129006	Nerve tissue specimen
430248009	Specimen from nasopharyngeal structure
309131002	Neuroma specimen
119363009	Platelet-rich plasma specimen
309171007	Lower respiratory fluid
441810001	Specimen from soft tissue obtained by fine needle aspiration biopsy
258420003	Cyst tissue
119394009	Specimen from vagina
309199003	Gastrointestinal fluid
122586001	Peritoneal dialysis fluid
309201001	Ascitic fluid
142261000146106*	Lymphoblast specimen (specimen)
119369008	Specimen from ulcer
122638001	Tissue specimen from small intestine
309213006	Gastric brushings specimen
122562003	Blood specimen from newborn
309261004	Sigmoid colon brushings specimen
122589008	Serum specimen from blood donor
309481000	Temporal artery specimen
127473003	Specimen from kidney
309502007	Fetus specimen
447154002	Specimen from nose
373826004	Surgical excision specimen
119365002	Specimen from wound
122568004	Exudate specimen from wound
309141004	Adrenal gland specimen
418932006	Oral swab
119392008	Specimen from anus
430304001	Specimen from unspecified body site
122551003	Peripheral blood specimen
432657002	Ganglion cyst specimen
122559001	Blood specimen from control
258431006	Scrapings
119398007	Specimen from brain
433324003	Specimen from eye region

Code	Concept
309061008	Breast fine needle aspirate specimen
433799002	Nerve ganglion specimen
119308003	Cannula submitted as specimen
433861002	Specimen from nasal sinus obtained by fine needle aspiration biopsy
122577006	Cervical mucus specimen
438805006	Whole tooth specimen
119346005	Egg yolk specimen
439580004	Urine collection pad submitted as specimen
440229008	Specimen from environment
439628000	Urinary collection bag submitted as specimen
119320006	Food specimen
258432004	Sebum specimen
122576002	Genital mucus specimen
440468004	Tampon submitted as specimen
127458004	Specimen from lung
258433009	Smear specimen
432382007	Specimen from lymph node obtained by fine needle aspiration biopsy
440493002	Graft specimen from patient
309503002	Breast nipple discharge specimen
258434003	Spun urinary sediment
127469001	Specimen from pancreas
441479001	Fresh tissue specimen
441695007	Specimen from parotid gland obtained by fine needle aspiration biopsy
441903006	Specimen obtained by bronchial aspiration
430250001	Specimen from peritoneum
258435002	Tumour tissue specimen
127459007	Specimen from pleura
258436001	Umbilical cord tissue specimen
384819001	Specimen from prostate obtained by needle biopsy
445295009	Blood specimen with EDTA
122582004	Erythrocyte specimen from blood product
445297001	Swab of internal nose
258604001	Upper respiratory specimen
445367006	Swab of umbilicus
309508006	Soft tissue lesion fine needle aspirate specimen
445447003	Specimen from trachea obtained by aspiration
258609006	Sputum specimen obtained by aspiration from trachea
445744006	Fluid specimen from seroma
441749007	Specimen from submandibular gland obtained by fine needle aspiration biopsy
446306009	Urine specimen obtained from urinary collection bag
399680007	Specimen from thyroid

Code	Concept
446676001	Expressed breast milk specimen
119390000	Specimen from trachea
258437005	Vegetation from heart valve
450872001	Specimen from urinary bladder
258439008	Discharge specimen
258438000	Vitreous humour specimen
258440005	Effusion specimen
433116003	Specimen from liver obtained by fine needle aspiration biopsy
447488002	Suprapubic urine specimen
1003708009	Specimen from drain device
447589008	Urine specimen obtained by single catheterisation of bladder
122580007	Cerumen specimen
472871003	Swab from ulcer
309107007	Tendon specimen

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