

B. Braun Medical AG  
CoE Infection Control  
Seesatz 17  
CH - 6204 Sempach

Bremen, 21. Oktober 2015

## Gutachten

Wirksamkeit von Stabimed ultra gegenüber dem MNV im quantitativen Suspensionsversuch nach der EN 14476:2013 unter hoher Belastung

Dieses Gutachten basiert auf dem Prüfbericht B15L0483M vom 21.10.2015.

Das Instrumentendesinfektionsmittel Stabimed ultra der B. Braun Medical AG wurde gemäß Auftrag auf seine virusinaktivierenden Eigenschaften gegenüber dem murinen Norovirus (MNV) im quantitativen Suspensionsversuch nach der EN 14476:2013 unter hoher Belastung untersucht.

In der EN 14476:2013 wird dann von einer Virus-Wirksamkeit eines Desinfektionsmittels ausgegangen, wenn nach einer bestimmten Einwirkzeit eine Reduktion des initialen Virustiters um  $\geq 4 \log_{10}$  Stufen (Inaktivierung  $\geq 99,99\%$ ) erfolgt ist.

Das Instrumentendesinfektionsmittel Stabimed ultra wurde als 0,1 %, 0,5 % und 1,0 % ige Lösungen bei 20 °C untersucht. Die Einwirkzeiten betrugen 5 Minuten. Nach 5 (0,5 %ige Lösung) Minuten war eine ausreichende Reduktion des Virustiters nachweisbar. Deshalb ergibt sich eine Wirksamkeit gegenüber dem MNV wie folgt:

**0,5 %            5 Minuten**

**Dr. Jochen Steinmann**

**Stabimed ultra – Gutachten nach EN 14476**

B. Braun Medical AG  
CoE Infection Control  
Seesatz 17  
CH - 6204 Sempach

Bremen, 21/10/2015

## Expert opinion

Activity of Stabimed ultra against MNV in a quantitative suspension test according to EN 14476:2013 under dirty conditons

This expert opinion is based on the test report B15L0483M dating 21.10.2015.

The virus-inactivating properties of the instrument disinfectant Stabimed ultra of B. Braun Medical AG against murine norovirus (MNV) were investigated by a quantitative suspension test according to EN 14476:2013 under dirty conditions.

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is considered as having virus-inactivating properties if within the recommended exposure period the titre is reduced by  $\geq 4 \log_{10}$  (inactivation  $\geq 99.99\%$ ).

Stabimed ultra was examined as 0.1 %, 0.5 % and 1.0 % solutions at 20 °C. 5 minutes were chosen as exposure times. After 5 (0.5 % solution) minutes the virus titre was decreased by  $\geq 4 \log_{10}$  steps. Therefore, a virucidal activity against MNV was measured as follows:

**0.5 %    5 minutes**

**Dr. Jochen Steinmann**



**DR. BRILL + DR. STEINMANN**  
INSTITUTE FOR HYGIENE AND MICROBIOLOGY



21.10.2015

## Test report B15L0483M

### Evaluation of the effectiveness of **Stabimed ultra**

Test virus: murine norovirus (as surrogate of human norovirus)

Method: EN 14476:2013

quantitative suspension test for the evaluation  
of virucidal activity of chemical disinfectants and  
antiseptics used in human medicine

#### **Sponsor:**

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## 1. Identification of test laboratory

Dr. Brill + Partner GmbH Institute for Hygiene and Microbiology, Norderoog 2, DE - 28259 Bremen

## 2. Identification of sample

Manufacturer	B. Braun Medical AG
Name of product	Stabimed ultra
Product diluent recommended by the manufacturer	-
Batch number	14263M25
Application	instrument disinfection
Production date	
Expiry date	11/2015
Active compound (s) (kg)	peracetic acid
Appearance, odour	white powder product specific
pH-values (in WSH)	1.0 %: 7.53 (20 °C) 0.5 %: 7.82 (20 °C)
Storage conditions	room temperature in the dark (area with restricted access)
Date of arrival in the laboratory	11.09.2015

## 3. Materials

### 3.1 Culture medium and reagents

- Dulbecco's Modified Eagle's Medium (DMEM, Biozym Scientific GmbH, catalogue no. 880006)
- Fetal calf serum (Thermo Fisher, article no. CH30160.02)
- 1.4 % formaldehyde solution (dilution of Roti®-Histofix 4 %, Carl Roth GmbH)
- Aqua bidest. (SG ultrapure water system, type Ultra Clear; serial no. 86996-1)
- PBS (Invitrogen, article no. 18912-014)
- BSA (Sigma-Aldrich-Chemie GmbH, article no. CA-2153)
- sheep erythrocytes (Fiebig-Nährstofftechnik).

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### 3.2 Virus and cells

Murine norovirus (MNV) was obtained from PD. Dr. E. Schreier, Head of FG15 Molecular Epidemiology of Viral Pathogens at the Robert Koch-Institute (RKI) in Berlin. Prior to inactivation, MNV was passed three times in *RAW 264.7 cells* (a macrophage-like, Abelson leukemia virus transformed cell line derived from BALB/c mice, ATCC TIB-71). RAW 264.7 cells were cultured with Dulbecco's Modified Eagle's Medium with 4.5 g/l glucose and fetal calf serum with low endotoxin.

Furthermore, cells (passage 27) were inspected regularly for morphological alterations and for contamination by mycoplasmas. No morphological alterations of cells and no contamination by mycoplasmas could be detected.

### 3.3 Apparatus, glassware and small items of equipment

- CO<sub>2</sub> incubator, Nunc GmbH & Co. KG, model QWJ 350
- Agitator (Vortex Genie Mixer, type G 560E)
- pH measurement 315i (WTW, article no. 2A10-100)
- Centrifuge (Sigma-Aldrich-Chemie GmbH, type 113)
- Microscope (Olympus, type CK 30)
- Centrifuge 5804 R (Eppendorf AG)
- Water bath (JULABO, Julabo U 3)
- Adjustable and fixed-volume pipettes (Eppendorf AG)
- Polyesterol 96-well microtitre plate (Nunc GmbH & Co. KG, Wiesbaden)
- Cell culture flask (Nunc GmbH & Co. KG, Wiesbaden)
- Sealed test tubes (Sarstedt AG & Co., Nümbrecht).

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#### 4. Experimental conditions

Test temperature	20 °C ± 1.0 °C
Concentration of test product	1.0 %, 0.5 %, 0.1 % and 0.01 % (demonstration of non-active range) solutions
Appearance of product dilutions	no precipitation
Contact times	5 minutes
Interfering substance	3.0 g/l bovine serum albumin + 3.0 g/l erythrocytes (dirty conditions, EN 14476:2013)
Procedure to stop action of disinfectant	immediate dilution
Diluent	water of standardised hardness (WSH)
Stability of product in the mix with virus and interfering substance (1.0 % solution)	no flocculation, no precipitation
Virus strain	murine norovirus (Berlin 06 / 06 / DE Isolate S99)
Date of testing	11.09.2015 – 21.10.2015
End of testing	21.10.2015

#### 5. Methods

##### 5.1 Preparation of test virus suspension

To prepare the test virus suspension, *RAW 264.7 cells* which have been cultured with Dulbecco's Modified Eagle's Medium with 4.5 g/l glucose and 10 % fetal calf serum with low endotoxin were inoculated with MNV (stock virus solution) in a 175 cm<sup>2</sup> cell culture flask. Once a cytopathic effect had been induced (approx. 1-3 days), freezing and thawing was carried out two times. The cell debris was removed by low speed centrifugation (400 g<sub>N</sub> and 15 min) and the supernatant was recovered as test viral suspension, aliquoted and stored at -80 °C.

##### 5.2 Preparation of disinfectant (dilutions)

The test product was tested as 1.0 %, 0.5 %, 0.1 % and 0.01 % solutions under dirty conditions (1 part test virus suspension + 1 part interfering substance + 8 parts disinfectant). Due to the addition of interfering substance and test virus suspension the solutions had to be prepared by the factor 1.25.

These solutions were prepared with water of standardised hardness immediately before the inactivation tests.

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### 5.3 Infectivity assay

Infectivity was determined as endpoint titration according to EN 5.5 transferring 0.1 ml of each dilution into eight wells of a microtitre plate to 0.1 ml of freshly trypsinised *RAW 264.7 cells* ( $10\text{--}15 \times 10^3$  cells per well), beginning with the highest dilution. Microtitre plates were incubated at 37 °C in a 5 % CO<sub>2</sub>-atmosphere. The cytopathic effect was read by using an inverted microscope after five days. Calculation of the infective dose TCID<sub>50</sub>/ml was calculated with the method of Spearman (2) and Kärber (3) with the following formula:

$$-\log_{10}\text{TCID}_{50} = X_0 - 0.5 + \sum r/n$$

meaning

$X_0$  = log<sub>10</sub> of the lowest dilution with 100 % positive reaction

$r$  = number of pos. determinations of lowest dilution step with 100 % positive and all higher positive dilution steps

$n$  = number of determinations for each dilution step.

### 5.4 Calculation and verification of virucidal activity

The virucidal activity of the test disinfectant was evaluated by calculating the decrease in titre in comparison with the control titration without disinfectant. The difference is given as reduction factor (RF).

According to the EN 14476:2013, a disinfectant or a disinfectant solution at a particular concentration is having virus-inactivating efficacy if the titre is reduced at least by four log<sub>10</sub> steps within the recommended exposure period. This corresponds to an inactivation of  $\geq 99.99\%$ .

### 5.5 Inactivation assay

Determination of virucidal activity has been carried out in accordance to EN 5.5. The test product was examined as 1.0 %, 0.5 %, 0.1 % and 0.01 % (demonstration of non-active range) solutions in WSH at 20 °C according to EN 14476:2013. 5 minutes were chosen as contact times.

Immediately at the end of a chosen contact time, activity of the disinfectant was stopped by dilution to 10<sup>-8</sup>.

Titration of the virus control were performed after the longest exposure time (EN 5.5.7).

Furthermore, a cell control (only addition of medium) was incorporated.

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Inactivation tests were carried out in sealed test tubes in a water bath at  $20\text{ °C} \pm 1.0\text{ °C}$ . Aliquots were retained after appropriate exposure times and residual infectivity was determined.

## 5.6 Determination of cytotoxicity

Determination of cytotoxicity was performed according to EN 5.5.4.1.

## 5.7 Cell sensitivity to virus

For the control of cell sensitivity to virus two parts by volume of water were mixed with eight parts by volume of the lowest apparently non-cytotoxic dilution of the product. This mixture or PBS as control was added to a volume of double concentrated cell suspension. After 1 h at  $37\text{ °C}$  the cells were centrifuged and re-suspended in cell culture medium (EN 5.5.4.2b).

Finally, a comparative titration of the test virus suspension was performed on the pre-treated (disinfectant) and non-pre-treated (PBS) cells as described above.

## 5.8 Control of efficacy for suppression of disinfectant's activity

Furthermore, a control of efficiency for suppression of disinfectant's activity was included (EN 5.5.5.1).

## 5.9 Reference virus inactivation test

As reference for test validation a 0.7 % formaldehyde solution according to EN 5.5.6 was included. 5, 15, 30 and 60 minutes were chosen as contact times. In addition, cytotoxicity of formaldehyde test solution was determined following EN 5.5.6.2 with dilutions up to  $10^{-5}$ .

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## 6. Verification of the methodology

The following criteria as mentioned in EN 5.7 were fulfilled:

- a) The titre of the test virus suspension allowed the determination of a  $\geq 4 \log_{10}$  reduction (maximal virus reduction  $\geq 5.50 \pm 0.27$ ).
- b) The test product (1.0 % and 0.5 %) showed cytotoxicity in the 1:10 dilutions thus allowing the detection of a  $4 \log_{10}$  reduction of virus titre.
- c) The comparative titration on pre-treated (disinfectant) and non-pre-treated (PBS) *RAW 264.7 cells* showed no significant difference ( $< 1 \log_{10}$ ; EN 5.7) of virus titre:  $7.63 \pm 0.25$  (PBS) versus  $8.00 \pm 0.38$  (1:100 dilutions of disinfectant as 1.0 % solution)  $\log_{10}\text{TCID}_{50}/\text{ml}$ .
- d) The control of efficacy for suppression of disinfectant's activity (1.0 % solution) showed a decrease ( $< 0.5 \log_{10}$ ; EN 5.5.5.1) in virus titre ( $8.00 \pm 0.38$  versus  $7.38 \pm 0.41 \log_{10}\text{TCID}_{50}/\text{ml}$ ) due to the fact that even the 0.1 % solution showed a reduction of virus titre (RF  $4.13 \pm 0.56$  after 5 minutes). In these experiments at the end of the defined exposure time the test mixture was immediately diluted and the dilutions transferred to the cell culture. Therefore, despite the insufficient control of efficacy for suppression the assay is valid.
- e) One concentration demonstrated a  $4 \log_{10}$  reduction and (at least) one concentration demonstrated a  $\log_{10}$  reduction of less than 4.

Since all criteria according EN 5.7 were fulfilled, examination with MNV according to EN 14476:2013 is valid.

## 7. Results

Results of examination are shown in tables 1 to 8. Tables 1 to 7 demonstrate the raw data, whereas table 8 (a+b) gives a summary of results.

The test product as 1.0 % solution was able to inactivate MNV after 5 minutes under dirty conditions in this quantitative suspension test (Table 1). The reduction factor was  $\geq 5.50 \pm 0.27$  at this time point.

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The test product as 0.5 % solution was also able to inactivate MNV after 5 minutes under dirty conditions in this quantitative suspension test (Table 2). The reduction factor was  $\geq 5.50 \pm 0.27$ . This corresponded to an inactivation of  $\geq 99.999$  %.

The test product as 0.1 % solution was also able to inactivate MNV after 5 minutes under dirty conditions in this quantitative suspension test (Table 3). The reduction factor was  $4.13 \pm 0.56$ .

Tested as 0.01 % solution, the test product was not active within 5 minutes of exposure time (Table 4).

## 8. Conclusion

The instrument disinfectant Stabimed ultra tested as 0.5 % solution demonstrated effectiveness against MNV after an exposure time of 5 minutes under dirty conditions.

Therefore, the instrument disinfectant Stabimed ultra can be declared as active against MNV as follows:

**0.5 %    5 minutes**

**Bremen, 21.10.2015**

**- Dr. Jochen Steinmann -**  
Scientific Director

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## 9. Quality control

The Quality Assurance of the results was maintained by performing the determination of the virus-inactivating properties of the disinfectant in accordance with Good Laboratory Practice regulations:

- 1) Chemicals Act of Germany, Appendix 1, dating of 01.08 1994 (BGBl. I, 1994, page 1703). Appendix revised at 14. 05. 1997 (BGBl. I, 1997, page 1060).
- 2) OECD Principles of Good Laboratory Practice (revised 1997); OECD Environmental Health and Safety Publications; Series on Principles of Good Laboratory Practice and Compliance Monitoring – Number 1. Environment Directorate, Organization for Economic Co-operation and Development, Paris 1998.

The plausibility of the results was additionally confirmed by controls incorporated in the inactivation assays.

## 10. Records to be maintained

All testing data, protocol, protocol modifications, the final report, and correspondence between Dr. Brill + Partner GmbH and the sponsor will be stored in the archives at Dr. Brill + Partner GmbH.

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The test results in this test report relate only to the items examined.

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## 11. Literature

1. EN 14476:2013: Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemicals disinfectants and antiseptics in human medicine test - Test method and requirements (phase 2, step 1)
2. Spearman, C.: The method of 'right or wrong cases' (constant stimuli) without Gauss's formulae.  
Brit J Psychol; 2 1908, 227-242
3. Kärber, G.: Beitrag zur kollektiven Behandlung pharmakologischer Reihenversuche.  
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## Appendix:

### Legend to the Tables

Table 1:	Raw data for Stabimed ultra (1.0 %) tested against MNV
Table 2:	Raw data for Stabimed ultra (0.5 %) tested against MNV
Table 3:	Raw data for Stabimed ultra (0.1 %) tested against MNV
Table 4:	Raw data for Stabimed ultra (0.01 %) tested against MNV
Table 5:	Raw data for formaldehyde solution (0.7 %) tested against MNV
Table 6:	Raw data for control of efficacy for suppression of disinfectant's activity (1.0 %)
Table 7:	Raw data (MNV) for cell sensitivity (1.0 %)
Table 8 (a+b):	Summary of results (end point dilution) with Stabimed ultra and MNV

### Legend to the Figures

Figure 1:	Virus-inactivating properties of Stabimed ultra (0.5 %)
Figure 2:	Virus-inactivating properties of formaldehyde (0.7 %)

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**Table 1: Raw data for Stabimed ultra (1.0 %) tested against MNV at 20 °C (quantal test; 8 wells) (4118)**

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log <sub>10</sub> )								
				1	2	3	4	5	6	7	8	9
test product	1.0%	dirty conditions	5	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	1.0%	dirty conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0044 4400	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 0044	0000 0000	0000 0000

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 2: Raw data for Stabimed ultra (0.5 %) tested against MNV at 20 °C (quantal test; 8 wells) (4118)**

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log <sub>10</sub> )								
				1	2	3	4	5	6	7	8	9
test product	0.5%	dirty conditions	5	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.5%	dirty conditions	n.a.	tttt tttt	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0044 4400	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 0044	0000 0000	0000 0000

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 3: Raw data for Stabimed ultra (0.1 %) tested against MNV at 20 °C (quantal test; 8 wells) (4118)**

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log <sub>10</sub> )								
				1	2	3	4	5	6	7	8	9
test product	0.1%	dirty conditions	5	4444 4444	4444 4444	0000 0404	0004 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.
			10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.1%	dirty conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0044 4400	0000 0000	0000 0000
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4400 0044	0000 0000	0000 0000

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 4: Raw data for Stabimed ultra (0.01 %) tested against MNV at 20 °C (quantal test; 8 wells) (4124)**

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log <sub>10</sub> )								
				1	2	3	4	5	6	7	8	9
test product	0.01%	dirty conditions	5	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4440 4444	0000 4044	0000 0000	n.d.
			10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			15	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product cytotoxicity	0.01%	dirty conditions	n.a.	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	dirty conditions	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0000 0040	0000 0040	0000 0000

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 5: Raw data for formaldehyde solution (0.7 %) tested against MNV at 20 °C (quantal test; 8 wells) (4118)**

Product	Concentration	Interfering substance	Contact time (min)	Dilutions (log <sub>10</sub> )								
				1	2	3	4	5	6	7	8	9
formaldehyde	0.7% (m/V)	PBS	5	tttt tttt	tttt tttt	tttt tttt	4444 4444	4444 4444	4444 4444	0000 0404	n.d.	n.d.
			15	tttt tttt	tttt tttt	tttt tttt	4444 4444	4444 4444	0444 0044	0004 0000	n.d.	n.d.
			30	tttt tttt	tttt tttt	tttt tttt	4444 4444	4440 4444	0400 4400	0000 0000	n.d.	n.d.
			60	tttt tttt	tttt tttt	tttt tttt	4444 4444	0040 4044	0000 0000	0000 0000	n.d.	n.d.
formaldehyde cytotoxicity	0.7% (m/V)	PBS	n.a.	tttt tttt	tttt tttt	tttt tttt	0000 0000	0000 0000	n.d.	n.d.	n.d.	n.d.
virus control	n.a.	PBS	0	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
			60	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4000 4444	0000 0000	0000 0000

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 6: Raw data for control of efficacy for suppression of disinfectant's activity (1.0 %) (4118)**

Product	Interfering substance	dilutions (log <sub>10</sub> )								
		1	2	3	4	5	6	7	8	9
test product	PBS	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	clean conditions	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	dirty conditions	tttt tttt	4444 4444	4444 4444	4444 4444	4444 4444	0440 4444	0000 0004	0000 0000	n.d.

n.a. = not applicable  
n.d. = not done

0 = no virus present; t = cytotoxic  
1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 7: Raw data (MNV) for cell sensitivity (1.0 %) (4118)**

Product	Dilution	Dilutions (log <sub>10</sub> )								
		1	2	3	4	5	6	7	8	9
PBS	-	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0400 0000	0000 0000	n.d.
test product	1:10	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.
test product	1:100	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	4444 4444	0040 0444	0000 0000	n.d.
test product	1:1,000	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.	n.d.

n.a. = not applicable

n.d. = not done

0 = no virus present; t = cytotoxic

1 to 4 = virus present (degree of CPE in 8 cell culture units) (wells of microtitre plates)

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**Table 8a: Summary of results with Stabimed ultra and MNV**

Product	Con- centration	Interfering substance	Level of cytotoxicity	log <sub>10</sub> TCID <sub>50</sub> /ml after ....min					> 4 log <sub>10</sub> reduction after ... min
				5	10	15	30	60	
test product	1.0%	dirty conditions	2.50	≤2.50±0.00	n.d.	n.d.	n.d.	n.d.	5 (RF ≥ 5.50±0.27)
test product	0.5%	dirty conditions	2.50	≤2.50±0.00	n.d.	n.d.	n.d.	n.d.	5 (RF ≥ 5.50±0.27)
test product	0.1%	dirty conditions	2.50	3.88±0.41	n.d.	n.d.	n.d.	n.d.	5 (RF = 4.13±0.56)
test product	0.01%	dirty conditions	1.50	7.75±0.44	n.d.	n.d.	n.d.	n.d.	> 5

n.a. = not applicable    n.d. = not done

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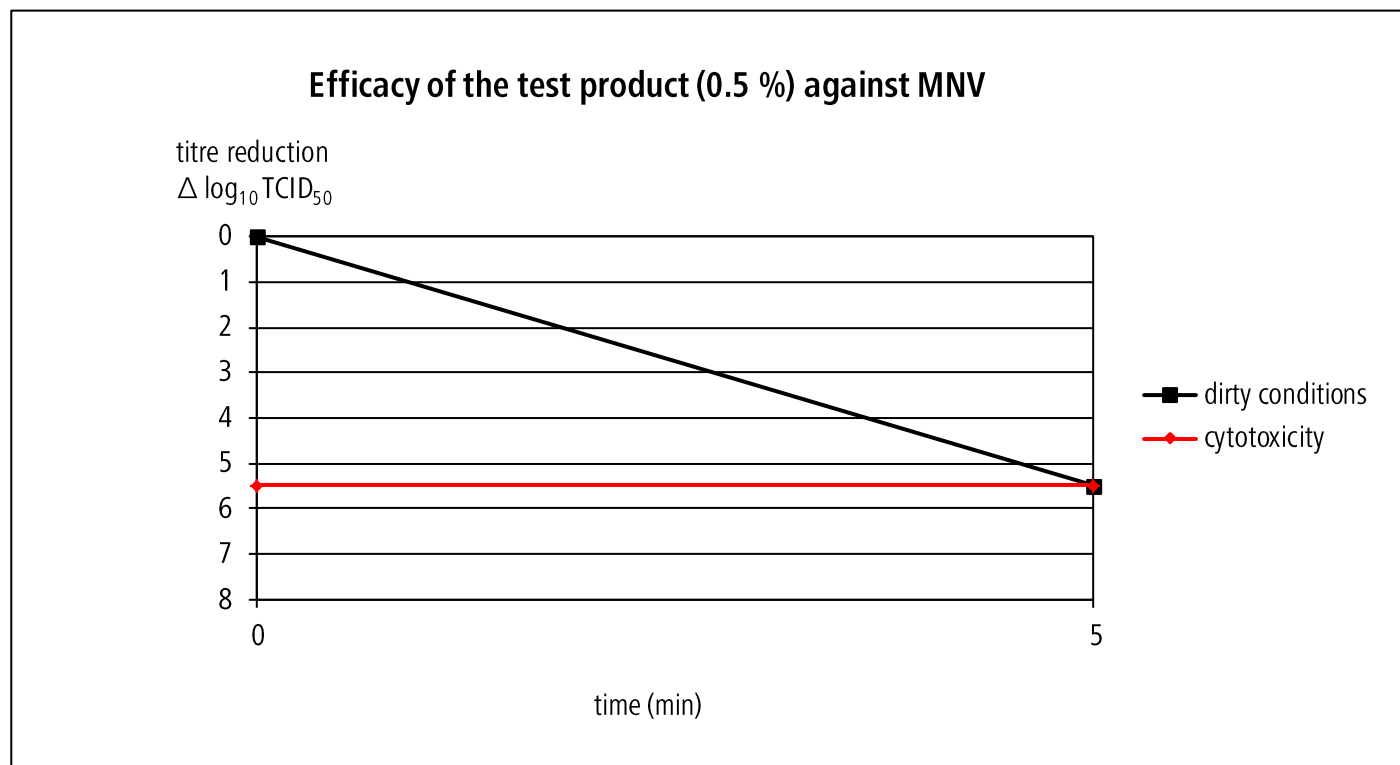
**Table 8b: Summary of results with Stabimed ultra and MNV**

Product	Con- centration	Interfering substance	Level of cytotoxicity	log <sub>10</sub> TCID <sub>50</sub> /ml after ....min					> 4 log <sub>10</sub> reduction after ... min
				0	5	15	30	60	
formaldehyde	0.7% (w/v)	PBS	4.50	n.d.	7.75±0.33	7.25±0.44	6.75±0.44	6.00±0.38	> 60
virus contr.	n.a.	PBS	n.a.	n.d.	n.d.	n.d.	n.d.	8.13±0.37	n.a.
virus control 1	n.a.	dirty conditions	n.a.	8.00±0.38	n.d.	n.d.	n.d.	8.00±0.38	n.a.
virus control 2	n.a.	dirty conditions	n.a.	n.d.	n.d.	n.d.	n.d.	7.75±0.35	n.a.
suppression control	1.0%	dirty conditions	2.50	n.d.	n.d.	n.d.	7.38±0.41	n.d.	n.a.
sens.control PBS	n.a.	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	7.63±0.25	n.a.
sens. control test product	1.0% → 1:100	n.a.	n.a.	n.d.	n.d.	n.d.	n.d.	8.00±0.38	n.a.

n.a. = not applicable    n.d. = not done    sens. = sensitivity

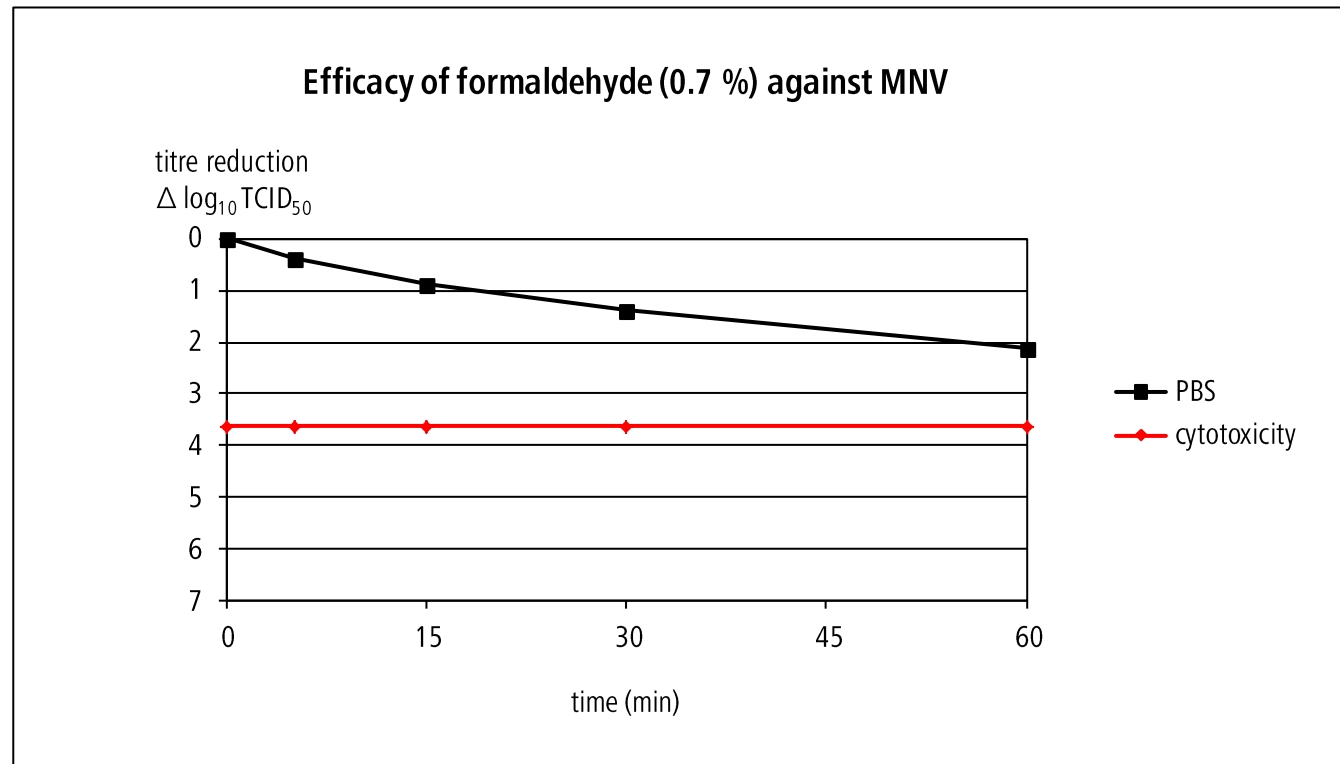
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**Figure 1: Virus-inactivating properties of Stabimed ultra (0.5 %)**



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Figure 2: Virus-inactivating properties of formaldehyde (0.7 %)



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