



28.08.2012

Test report no. F12ML1412-1B

Evaluation of the effectiveness of **ProCare+Handcare**

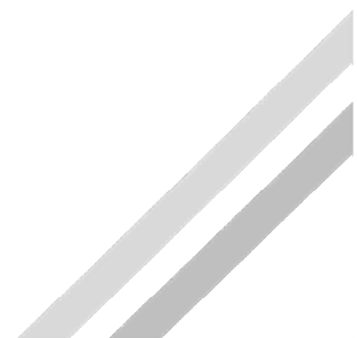
Testvirus: Bovine Viral Diarrhea Virus (BVDV) (Surrogate of HCV)

Method: according to the guideline of DVV and RKI (dating 01.08.2008)

TEST REPORT

Sponsor:

Hygicare ApS
Vesterbrogade 76
DK-1620 Cph. V
Denmark





7. 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.

8. Records to be maintained

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

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



9. Literature

1. Leitlinie der Deutschen Vereinigung zur Bekämpfung der Viruskrankheiten (DVV) e.V. und des Robert Koch-Institutes (RKI) zur Prüfung von chemischen Desinfektionsmitteln auf Wirksamkeit gegen Viren in der Humanmedizin (in der Fassung vom 1. August 2008)
Bundesgesundheitsbl., 51, 2008, 936-445
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.
Arch Exp Path Pharmac; 162, 1931, 480-487
4. Lycke, E.: Studies of the Inactivation of Poliomyelitis Virus by Formaldehyde.
Arch Ges Virusforsch; 7, 1957: 483-493



Table 1: Cytotoxicity of ProCare+HandCare and 0.7 % formaldehyde before and after the treatment with the MicroSpin™ S-400 HR columns

before treatment	conc.	soil load	dilutions				
			10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵
product	50.0%	Aqua bidest.	t	t	t	-	-
product	50.0%	10.0% FCS	t	t	t	-	-
product	10.0%	Aqua bidest.	t	t	-	-	-
product	10.0%	10.0% FCS	t	t	-	-	-
product	0.1%	Aqua bidest.	n.d.	n.d.	n.d.	n.d.	n.d.
product	0.1%	10.0% FCS	t	-	-	-	-
formaldehyde	0.7%	PBS	t	t	t	-	-
after treatment	conc.	soil load	dilutions				
			10 ⁻¹	10 ⁻²	10 ⁻³	10 ⁻⁴	10 ⁻⁵
product	50.0%	Aqua bidest.	t	-	-	-	-
product	50.0%	10.0% FCS	t	-	-	-	-
product	10.0%	Aqua bidest.	-	-	-	-	-
product	10.0%	Aqua bidest.	-	-	-	-	-

t = cytotoxic n.d. = not done



Table 2: Inactivation of BVDV by ProCare+HandCare (50.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	50.0%	Aqua bid.	≤4.50±0.00	≤4.50±0.00	n.d.	n.d.	≥0.88±0.35	≥0.88±0.35	n.a.	n.a.	≥ 30 s
test product	50.0%	10.0% FCS	≤4.50±0.00	≤4.50±0.00	n.d.	n.d.	≥1.13±0.18	≥1.13±0.18	n.a.	n.a.	≥ 30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	5.38±0.49	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.63±0.25	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 3: Inactivation of BVDV by ProCare+HandCare (50.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C (with columns)

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	50.0%	Aqua bid.	≤2.50±0.00	n.d.	n.d.	n.d.	≥2.75±0.23	n.a.	n.a.	n.a.	≥ 30 s
test product	50.0%	10.0% FCS	≤2.50±0.00	n.d.	n.d.	n.d.	≥3.00±0.25	n.a.	n.a.	n.a.	≥ 30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	5.25±0.33	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.50±0.35	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 4: Inactivation of BVDV by ProCare+HandCare (10.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C (1st assay)

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	10.0%	Aqua bid.	≤3.50±0.00	≤3.50±0.00	n.d.	n.d.	≥1.88±0.35	≥1.88±0.35	n.a.	n.a.	≥ 30 s
test product	10.0%	10.0% FCS	≤3.50±0.00	≤3.50±0.00	n.d.	n.d.	≥2.13±0.18	≥2.13±0.18	n.a.	n.a.	≥ 30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	5.38±0.49	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.63±0.25	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 5: Inactivation of BVDV by ProCare+HandCare (10.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C (2nd assay)

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	10.0%	Aqua bid.	≤3.50±0.00	n.d.	n.d.	n.d.	≥1.88±0.35	n.a.	n.a.	n.a.	≥ 30 s
test product	10.0%	10.0% FCS	≤3.50±0.00	n.d.	n.d.	n.d.	≥2.00±0.39	n.a.	n.a.	n.a.	≥ 30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	≤4.50±0.00	≤4.50±0.00	≤4.50±0.00	≤4.50±0.00	≥0.88±0.35	≥0.88±0.35	≥0.88±0.35	≥0.88±0.35	≥ 5 min
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	5.38±0.49	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.50±0.55	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 6: Inactivation of BVDV by ProCare+HandCare (10.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C (with columns) (1st assay)

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	10.0%	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
test product	10.0%	10.0% FCS	≤1.50±0.00	n.d.	n.d.	n.d.	≥4.00±0.25	n.a.	n.a.	n.a.	30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.50±0.35	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 7: Inactivation of BVDV by ProCare+HandCare (10.0 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C (with columns) (2nd assay)

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	10.0%	Aqua bid.	≤1.50±0.00	n.d.	n.d.	n.d.	≥3.50±0.27	n.a.	n.a.	n.a.	≥ 30 s
test product	10.0%	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	5.00±0.38	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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



Table 8: Inactivation of BVDV by ProCare+HandCare (0.1 %) and formaldehyde (0.7 %) in a quantitative suspension test at 20 °C

Product	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			30 s	60 s	120 s	240 s	30 s	60 s	120 s	240 s	
test product	0.1%	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
test product	0.1%	10.0% FCS	5.38±0.41	5.75±0.44	n.d.	n.d.	0.13±0.69	0.00±0.71	n.a.	n.a.	> 30 s
Controls	Conc.	Interfering substance	Log ₁₀ TCID ₅₀ /ml with 95% level of confidence after				Reduction factor with 95% level of confidence after				≥ 4 log ₁₀ reduction after
			5 min	15 min	30 min	60 min	5 min	15 min	30 min	60 min	
formaldehyde	0.7%	PBS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
virus control	n.a.	FCS	n.d.	n.d.	n.d.	5.50±0.55	n.a.	n.a.	n.a.	n.a.	n.a.
interference control PBS	n.a.	-	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	Aqua bid.	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.
interference control disinf.	n.a.	10.0% FCS	n.d.	n.d.	n.d.	n.d.	n.a.	n.a.	n.a.	n.a.	n.a.

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