

NT C.1 1 // 1 1 1 1 1 1	LE LOUIS DE MADI
Name of the product/Details about the product	GEL DEZINFECTANT DE MAINI
	Lot: 72020
	Production date: 20.08.2020
	Keeping conditions – Dry, without sunlight
Expiration date	20/08/2022
The active substance	Ethanol CAS 64-17-5 and CE 200-578-6 concentration of active
D) MECH MENTOD	substance 60% (60 g active substance at 100 g product)
B) TEST METHOD	NE DN 1447 (2012 42 2010 M) 111 11 11 11 11
Performed in accredited subcontracted partner	NF EN 14476:2013+A2:2019 Virucidal quantitative suspension
laboratory: Scope of Accreditation Nr.	test for chemical disinfectants and antiseptics used in human
648/LE1286	medicine. Test method and requirements (Phase
Tanking made d	2/Step1).AFNOR
Testing method	Procedure DESIN-1078 (NF EN 14476:2013+ A2:2019
	GUIDELINE) and internal procedure DESIN-6225 based on NF
C) EVDEDIMENTAL CONDITIONS	14476:2013+A2:2019 guideline
C) EXPERIMENTAL CONDITIONS	06/10/2020 +- 22/10/2020
Assay period	06/10/2020 to 23/10/2020
Assay temperature	37°C ± 1°C (Vaccinia)
Titration method	35°C ± 1°C (Coronavirus)
Titration method	TCID50 (Tissue Culture Infective Dose 50%)
Duadret concentrations for the esser	(Tissue Culture Infective Dose 50%)
Product concentrations for the assay	80%, 50% and 0.1% Sterile distilled water
Solvent of the product used in the assay	
Product concentrations for the assay	Pure (80%), 50% and 0.1%
Contact time	60 seconds
Contact temperature	37°C ± 1°C (Vaccinia)
Procedure to stop product cytotoxicity	Molecular sieving
Procedure to stop product activity	Cooling with ice
Aspect of the dilutions of the product	Transparent
Stability of the mixture (interfering substance	
and product diluted in sterile hard	Stable
water/distilled water)	
Interfering substance	Internal control of dirty conditions in the presence of bovine
	serum albumin 3 g/L.
	Dirty conditions in the presence of bovine serum albumin 3 g/L
	plus 3mL erythrocytes 3mL/L
Identification of the origin of viral stains and	Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC
number of passes	VR-1508), aliquot 2018/01/22, passage 2.
	Coronavirus 229 E (ATCC VR-740) aliquot: 03/03/2020
	passage 2
Cell lines (name, origin, number of passes)	BHK-21, ref. FTBH, working aliquot 6, passage 20 and working
	aliquot 7, passages 10 and 13
	MRC-5 ref. FTMR, working aliquot 9, passage 21 and working
	aliquot 10, passages 10 and 13

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania

Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

^{*}Test method accredited # Test performed by subcontractor. Ø Non accredited methods.



7. Validation of assay results

Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508)

Titre of the viral suspension for the virus control (at the requested test time): • Dirty conditions
Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level): • Dirty conditions
Internal control of dirty conditions log 10 ^{-5.74}
Coronavirus 229E (ATCC VR-740)
Titre of the viral suspension for the virus control (at the requested test time): • Dirty conditions
Internal control of dirty conditions
Reference test (formaldehyde 1.4%)
Cytotoxicity level of formaldehyde 0.7%log 10 ^{-0.50}
Viral quantification in the reference test (formaldehyde) after 15 minutes and with Vaccinia virus strain modified Vaccinia Ankara (MVA)log10 ^{-2.33} Viral quantification in the reference test (formaldehyde) after 15 minutes and with Coronavirus 229E

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



ENCLOSORE NO. 1 SUBCONTRACTED TESTS TO REPORT OF ANALYSIS NO 54405/20/ROBCH Confidence interval

Titre of virus with 95% confidence interval with Vaccinia virus strain modified Vaccinia Ankara (MVA) (at the requested test time):

0	Dirty conditions	$\log 10^{-6.16 \pm 0.43}$
		_

o Internal control of dirty conditions log 10^{-6.24 ± 0.43}

Titre of virus with 95% confidence interval with Coronavirus 229E (at the requested test time):

0	Dirty conditions	log 10 ^{-6.24 ± 0.43}
---	------------------	--------------------------------

o Internal control of dirty conditions log 10^{-6.16 ± 0.29}

Sensitivity of cells to virus

- Viral quantification of Vaccinia virus (MVA) with cells not treated by the test solution with the test productlog10^{-6,32}
- Viral quantification of Vaccinia virus (MVA) with cells treated by the test solution with the test productlog10^{-5.82}
- Viral quantification of Coronavirus 229E with cells treated by the test solution with the test productlog10^{-6.07}

Note: only can be used to determine the infectivity of cells, those dilutions which: a) show a low degree of cellular destruction (< 25% of cell monolayer) and b) produce a reduction of the title of the virus <I log₁₀.

Control of the effectivity of the disinfectant detection activity

- Viral quantification of Vaccinia virus (MVA) after 30 minutes on bath ice without exposing the virus to the test productlog10^{-6.00}
- Viral quantification of Vaccinia virus (MVA) exposing the virus to the test product and incubated 30 minutes on ice bath......log10^{-5.74}
- Viral quantification of Coronavirus 229E after 30 minutes on bath ice without exposing the virus to the test productlog10^{-6.08}
- Viral quantification of Coronavirus 229E exposing the virus to the test product and incubated 30 minutes on ice bath......log10^{-5,82}

Note: The difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension should be ≤ 0.5

1

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



8. Special remarks

- The product is tested at 80%; 50% and 0.1%. The highest concentration that can be tested in the test is 80%, because of the mixtures made during the test.
- All controls and validation were between the basic limits.
- One concentration at least showed a log reduction less than 4 log.
- One concentration at least showed a log reduction higher than ≥4 log.

9. Assay results

9.1 Description

Virus of assay	reduction obtained	Test concentrations, reduction obtained with the confidence interval of 95 % and virucidal activity									
	80%	50%	0.1%								
Virus Vaccinia Ankara (MVA)	≥ 5.66 ± 0.43 TCID ₅₀ Shows	≥ 5.66 ± 0.43 TCID ₅₀ Shows	0.25 ± 0.60 TCID ₅₀ Does not show								
Coronavirus 229E	≥ 5.74 ± 0.43 TCID ₅₀ Shows	≥ 5.74 ± 0.43 TCID ₅₀ Shows	0.33 ± 0.64 TCID ₅₀ Does not show								

Virucidal activity exists when the titre of virus shows a reduction $\geq 4 \log$. TCID₅₀: Tissue Culture Infectious Dose 50%.

9.2 Tables of results and graphics

See tables 1 and 4 and figure 1 and 2.

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



The disinfectant product "GEL DEZINFECTANT DE MAINI", batch **not indicated**, under dirty conditions (bovine serum albumin 3 g/L plus 3 mL erythrocytes 3 mL/L), diluted at **80%**, requested by the customer, and during 60 seconds of exposure and 20°C temperature, **shows** virucidal activity against Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508) when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline. It also **shows** virucidal activity against Coronavirus 229E (ATCC VR-740) when the activity is assayed according with the internal procedure DESIN-6225 based on NF EN 14476: 2013 + A2: 2019 guideline.

Virucidal activity against the enveloped virus of the disinfectant "GEL DEZINFECTANT DE MAINI", batch not indicated, against Poxvirus Vaccinia (ATCC VR-1508), does not means that the product has general virucidal activity, but only that the product shows activity against Vaccinia virus, thereby showing virucidal activity against the enveloped virus presented in annex A for surfaces, when tested according to NF EN 14476: 2013 + A2: 2019 guideline. It also shows virucidal activity against Coronavirus.

Note 1: The results obtained correspond to the product received in this laboratory.

Note 2: The information that depend on the information received from the client and are not facilitated by the same one, shown as "not indicated".

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



Table 1. Results of activity of the product test product with Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508) under test conditions requested by the customer.

Assay	Concen- tration*	Interfering substance	bstance xicity level		log ₁₀ afte	Reduction wit the confidence interval of 95 %		
	-			min	seg	min	min	
	80%	3 g/L BSA	0.5	-	0.50	-	-	$\geq 5.66 \pm 0.43$
Test product	50%	+ 3 mL/L erythrocytes	0.5	-	0.50	-	-	≥ 5.66 ± 0.43
	0.1%	eryunocytes	0.5	-	5.91	-	-	0.25 ± 0.60
	80%	3 g/L BSA	0.5	-	0.50	-	-	≥ 5.74 ± 0.43
Test product	50%		0.5	-	0.50	-	-	≥ 5.74 ± 0.43
	0.1%		0.5	-	6.08	-	-	0.16 ± 0.63
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	6.24	6.16	-	-	NA
Virus control	NA	3 g/L BSA	NA	6.33	6.24	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	3.24	2.33	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	6.16	NR	NR	5.99	NA

NA: not applicable; NR: not realized

Times recommended by Guideline for surfaces: maximum 5 or 60 minutes

Times recommended by Guideline for instruments: maximum 60 minutes

Times recommended by Guideline for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.

PBS: phosphate buffered saline; BSA: bovine serum albumin.

Virucidal activity exists when the titre of virus shows a reduction ≥4 log.

*: see Special remarks to understand the values of these concentrations.

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 6 of 14



Table 2. Results of the activity of the test product, with Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508) (Assay of titration with 12 wells), under test conditions requested by the customer.

			Time of			D	ilutions	(log10)	a,b		
Assay	Concen- tration *	Interfering substance	contact (seg/min)	1	2	3	4	5	6	7	8
	80%		60 seg	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Test product	50%	3 g/L BSA + 3 mL/L erythrocytes	60 seg	0000 0000 0000	0000 0000 0000	0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	0.1%		60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0322 3403 2233	2010 2032 0030	0000 0200 0000	NR
	80%	3 g/L BSA	60 seg	0000 0000	NR						
Test product	50%		60 seg	0000 0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000 0000	0000 0000	0000 0000	NR
	0.1%		60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3223 0403 3244	2020 3020 0230	0010 0002 0002	NR
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000	NR
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0322 0303 0403	0000 2000 2000	0000
Thub comes			60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0322 3444 3244	2033 0020 0203	0000 1200 2000	0000
Virus control	NA.	2 -/T DC4	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3240 4300 2234	0000 0002 0000	000 000
virus controi	NA	3 g/L BSA	60 seg	4144 4144 4144	4444 4444 4444	4444 4444 4444	4444 4444 4444	0324 4332 4322	2203 0302 2030	0000 0210 0200	0000
Formaldehyde	0.7 (****	NA.	5	4141 4141 4141	4444 4444 4444	2303 0320 3330	0001 0000 0000	0000 0000	0000 0000	0000 0000	NR
	0.7 (w/v)	NA	15	4444 4444 4444	3003 0200 3303	0010 0001 2001	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Control of formaldehyde cytotoxicity	0.7 (w/v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000	0000 0000	0000 0000	NR
Virus control formaldehyde	0.7 (w/v)	NA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	0200 3030 2303	0001 0000 0100	NR

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 7 of 14

Date: 24.11.2020

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

^{*}Test method accredited # Test performed by subcontractor. Ø Non accredited methods.



			15	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4333 4332 3433	0230 0200 3003	0000 0000 0100	NR	
Sensitivity control of cells to virus	NA		Cells not treated	CCCC	CCCC	CCCC CCCC	CCCC		COCC OCOC	0C00 C000 0C00	0000 0000 000	
		NA	Cells treated	CCCC	CCCC	CCCC CCCC	CCCC CCCC	CCCC CCCC	0C0C 0C0C	0000 000C	0000 0000	
Effectiveness control of the disinfectant detection activity	NA		3 g/L BSA	Without	CCCC	CCCC CCCC	CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC	CCC0 CC00	0000 0000 0000	0000 0000
		+ 3 mL/L erythrocytes	With	CCCC CCCC	CCCC CCCC	CCCC CCCC	CCCC CCCC CCCC	CCCC	00C0 C0C0 C00C	0000 0000	0000 0000	

a): 1 to 4, virus present and grade of cytophatic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 8 of 14

Date: 24.11.2020

Authorized by: Mariana Ilinca, Manager of Microbiological laboratory

Aprobat de: Mihai Alina-Roxana, General manager (Approved with qualified electronic signature)

C = cytopathic effect with presence of virus (in this case and according to guideline does not take into account the degree of cytopathic effect only, the presence or absence of the same).

^{0 =} no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline. sec: seconds; min: minutes.

^{*:} see Special remarks to understand the values of these concentrations.



Table 7. Results of activity of the test product, with Coronavirus 229E (ATCC VR-740), under test conditions requested by the customer.

Assay	Concen- tration*	Interfering substance	Cytoto- xicity level	0	log ₁₀ 7 afte	Reduction with the confidence interval of		
				min	seg	5 min	15 min	95 %
	80%	2 - G DC4	0.5	-	0.50	-	-	≥5.74 ± 0.43
Test product	50%	3 g/L BSA + 3 mL/L	0.5	-	0.50	-	-	≥5.74 ± 0.43
	0.1%	erythrocytes	0.5	-	5.91	-	-	0.33 ± 0.64
	80%		0.5	-	0.50	-	-	≥5.66 ± 0.29
Test product	50%	3 g/L BSA	0.5	-	0.50	-	-	≥5.66 ± 0.29
	0.1%		0.5	-	5.99	-	-	0.17 ± 0.48
Virus control	NA	3 g/L BSA + 3 mL/L erythrocytes	NA	6.41	6.24	-	-	NA
Virus control	NA	3 g/L BSA	NA	6.24	6.16	-	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	3.32	3.49	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	6.41	NR	NR	6.24	NA

Control of the effectiveness of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension).......log10^{-0.26}

NA; not applicable; NR: not realized

Times recommended by Guideline for surfaces: maximum 5 or 60 minutes

Times recommended by Guideline for instruments: maximum 60 minutes

Times recommended by Guideline for Hygienic treatment of hands by friction and hygienic handwashing: between 30 or 120 seconds.

PBS: phosphate buffered saline; BSA: bovine serum albumin.

Virucidal activity exists when the titre of virus shows a reduction ≥4 log.

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

^{*:} see Special remarks to understand the values of these concentrations.



Table 8. Results of the activity of the test product, with Coronavirus 229E (ATCC VR-740) (Assay of titration with 12 wells), under test conditions requested by the customer.

Assay	Concen-	Interfering	Time of contact			D	ilutions	(log10)	a,b		
resuly	tration *	substance	(seg/min)	1	2	3	4	5	6	7	8
	80%		60 seg	0000 0000 0000	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000	N
Test product	50%	3 g/L BSA + 3 mL/L erythrocytes	60 seg	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000	N
	0.1%		60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3220 3443 4003	2033 0020 0020	0002 0020 0001	N
	80%		60 seg	0000 0000	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	N
Test product	50%	3 g/L BSA	60 seg	0000 0000 0000	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	N
	0.1%		60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3244 3022 3343	0020 3302 0202	0002 0000 0000	N
Cytotoxicity	80%	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	0000 0000	N
Virus control	Virus control NA	3 g/L BSA + 3 mL/L	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2303 0220 3020	0003 2000 1002	00 00 00
viius comitor	, AA	erythrocytes	60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4302 3444 3323	0120 3003 2023	0002 0200 0200	00 00
Virus control	NA		0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3220 3443 0322	0302 0020 3201	0000 2103 0020	00: 00:
v irus controi	NA	3 g/L BSA	60 seg	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	1024 3002 0232	0000 0000	00 00
Formaldehyde	0.77	NA.	5	4444 4444 4444	4444 4444 4444	3020 3034 3032	0020 0010 0000	0000 0000	0000 0000 0000	0000 0000	N
	0.7 (w/v)	NA	15	4444 4444 4444	3403 0303 0332	0120 0100 0100	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	N
Control of formaldehyde cytotoxicity	0.7 (w/v)	3 g/L BSA + 3 mL/L erythrocytes	NA	0000 0000 0000	0000 0000	0000 0000	0000 0000	0000 0000 0000	0000 0000	0000 0000	N
Virus control			0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2303 0302 3302	0002 0001 0100	N
formaldehyde	0.7 (w/v)	NA	15	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2030 3320 3030	0010 0010 0000	N

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

JS. HAMILTON ROMANIA S.R.L.

8Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

PGL 09 F 04 Ed. 1 Rev. 0

Page 10 of 14

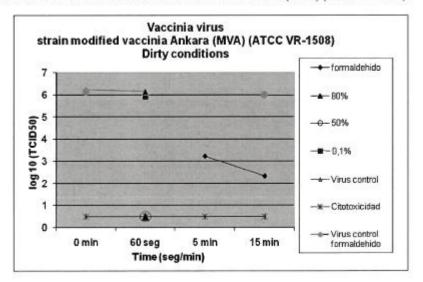
^{*}Test method accredited # Test performed by subcontractor. Ø Non accredited methods.



Sensitivity control			Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC CCCC	CCC0 CCC0	000C C00C 00C0	0000 0000
of cells to virus	NA	NA	Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC CCCC	C0C0 C0C0	0000 0C00 0C00	0000 0000 0000
Effectiveness control of the disinfectant detection activity		3 g/L BSA	Without	CCCC	CCCC	CCCC	CCCC CCCC	CCCC	0C0C C00C C0C0	0000 000C	0000 0000
	NA	+ 3 mL/L erythrocytes	With	CCCC CCCC	CCCC	145 CONTROL 15 CO.			0C00 CC0C 00C0	000C 0000 0C00	0000 0000

a): 1 to 4, virus present and grade of cytophatic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

Figure 1. Results of the activity of the test product under test conditions requested by the customer with Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508).



Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests

C = cytopathic effect with presence of virus (in this case and according to guideline does not take

into account the degree of cytopathic effect only, the presence or absence of the same).

0 = no virus present or absence of cellular lesions in the cytotoxicity assay; NA: not applicable; NR: not realized; BSA: Bovine serum albumin; PBS: phosphate buffered saline. sec: seconds; min: minutes

^{*:} see Special remarks to understand the values of these concentrations.



Figure 1.1. Results of the activity of the test product under internal control of test conditions requested by the customer with Vaccinia virus strain modified Vaccinia Ankara (MVA) (ATCC VR-1508).

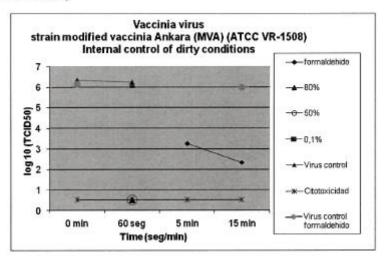
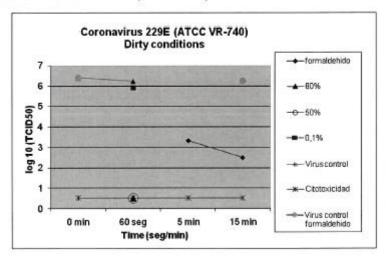


Figure 2. Results of the activity of the test product under test conditions requested by the customer with Coronavirus 229E (ATCC VR-740).



Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

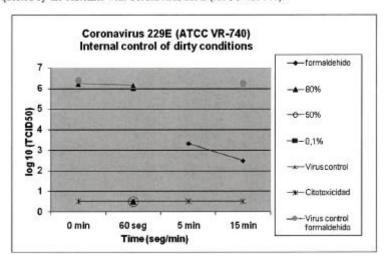
JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



Figure 2.1. Results of the activity of the test product under internal control of test conditions requested by the customer with Coronavirus 229E (ATCC VR-740).



Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests



Annex A of the guideline NF EN 14476: 2013 + A2: 2019: Examples of viruses that can contaminate medical instruments, hands or surfaces (Note 1: this list is not exhaustive; Note 2: Enveloped viruses are in bold).

Blood:

Enterovirus, Filoviridae, Flavivirus, Herpesviridae, Hepatitis A virus (HAV), Hepatitis B virus (HBV), Hepatitis C virus (HCV), Hepatitis Delta virus (HDV), Human Immunodeficiency virus (HIV), Human T-cell lymphotropic virus (HTLV), Parvovirus B19.

Respiratory tract:

Adenovirus, Coronavirus, Enterovirus, Herpesviridae, Influenza virus, Paramyxoviridae, Rhinovirus, Rubella virus.

Nervous system, ears & nose, eyes:

Adenovirus, Enterovirus, Herpesviridae, Measles virus, Human Immunodeficiency virus (HIV), Polyomavirus, Rabies virus, Rubella virus.

Gastrointestinal tract:

Adenovirus, Caliciviridae, Coronavirus, Astrovirus, Enterovirus, Hepatitis A virus (HAV), Hepatitis E virus (HEV), Rotavirus.

Skin, Breast, maternal milk:

Enterovirus, Herpeviridae, Human Immunodeficiency virus (HIV), Human T-cell lymphotropic virus (HTLV), Papillomavirus, Poxviridae.

Spleen and lymph nodes:

Human T-cell lymphotropic virus (HTLV), Human Immunodeficiency virus (HIV).

Dental procedures:

Adenovirus, Enterovirus, Herpesviridae, Hepatitis B virus (HBV), Hepatitis C virus (HCV), Hepatitis D virus (HDV), Human Immunodeficiency virus (HIV).

Urogenital tract:

Hepatitis B virus (HBV), Herpesviridae, Human Immunodeficiency virus (HIV), Human T-cell lymphotropic virus (HTLV), Papillomavirus, Polyomavirus.

Laboratory: Bucharest 041914, 8 Berceni Street.

The results relate to the analyzed samples only. The enclosore cannot be reproduced partially without a prior written consent of J.S. Hamilton Romania S.R.L. Responsibility of J.S. Hamilton Romania is restricted exclusively to the results and statements presented in original copy of the enclosore.

*Test method accredited # Test performed by subcontractor. Ø Non accredited methods.

JS. HAMILTON ROMANIA S.R.L.

8 Berceni Street, 041902 Bucharest, Romania Tel.+40 21 634 10 81 bucharest@hamilton.com.pl, www.hamilton.com.pl

Enclosore no. 1 subcontracted tests