

ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 208706/20/CGDA

A) IDENTIFICATION OF THE SAMPLE:	
Name of the product	SILVER FLASH
Expiration date	2 years from the date of production Batch number: 02025050 Production date: 05-05-2020
The active substance	12% Hydrogen peroxide, 0,005% Silver
B) TEST METHOD :	
Performed in accredited subcontracted partner laboratory: Scope of Accreditation Nr 648/LE1286	NF- EN-14476:2013+A2:2019 Guideline- Virucidal quantitative suspension test for chemical disinfectants and antiseptics used in human medicine. Test method and requirements (phase 2, step 1)
Testing method	Procedure DESIN-6225
C) EXPERIMENTAL CONDITIONS:	
Assay period	12/05/2020 – 01/06/2020
Product test concentrations (%V/V)	50%, 25%, 0,1%
Contact time	5 minutes
Assay temperature	35°C ± 1°C
Titration method	TCID ₅₀ (Tissue culture infective dose 50%)
Solvent of the product used in the assay	Sterile distilled water
Aspect of the dilutions of the product	Transparent
Contact temperature	20°C ± 1°C
Procedure to stop product cytotoxicity	Molecular sieving
Procedure to stop product activity	Cooling with ice
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 3 mL erythrocytes 3 mL/L.
Identification of the origin of viral strains and number of passes	Coronavirus 229E (ATCC VR-740) aliquot: 2019/03/04 passage 2
Cell lines (name, origin, number of passes and culture medium)	MRC-5 ref. FTMR, working aliquot 5, passage 10 and 13 and 15

Date: 13.07.2020

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 Approved by: Hanna Wachowska, Laboratory Director (*Approved with qualified electronic signature*)

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 208706/20/CGDA**Validation of assay results****Coronavirus 229E (ATCC VR-740)**

Titre of the viral suspension for the virus control (5 minutes):

- Dirty conditions.....log 10^{-6.16}
 - Internal control of dirty conditions.....log 10^{-5.99}
- Cytotoxicity level (50%).....log 10
- ^{-0.5}

Maximum level of virus inactivation detectable (difference between the titre of the viral suspension and the cytotoxicity level):

- Dirty conditions.....log 10^{-5.41}
- Internal control of dirty conditions.....log 10^{-5.41}

Reference test (formaldehyde 1.4%)Cytotoxicity level of formaldehyde 0.7%.....log 10^{-0.5}Viral quantification in the reference test (formaldehyde) after 15 minutes and with Coronavirus 229E.....log 10^{-2.58}**Confidence interval**

Title of virus with 95% confidence interval with Coronavirus 229E (5 minutes)

- Dirty conditionslog 10^{-6.16 ± 0.46}
- Internal control of dirty conditionslog 10^{-5.99 ± 0.46}

Reduction with the confidence interval of 95 %See table 1.

Sensitivity of cells to virus

- Viral quantification of Coronavirus 229E with cells not treated with "SILVER FLASH" disinfectantlog 10^{-6.23}
- Viral quantification of Coronavirus 229E with cells treated with the "SILVER FLASH" disinfectant.....log 10^{-5.99}

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 titre of the virus < 1 log₁₀.

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 208706/20/CGDA**Control of the effectivity of the disinfectant detection activity**

- Viral quantification of Coronavirus 229E after 30 minutes on bath ice without exposing the virus to the "SILVER FLASH" disinfectantlog10^{-6.07}
- Viral quantification of Coronavirus 229E exposing the virus to "SILVER FLASH" disinfectant 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

Special remarks

- 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.

Assay results**Description**

The disinfectant product, **SILVER FLASH**, batch 02025050, under dirty conditions, diluted at 50% and 25% and during 5 minutes of exposure, **shows** virucidal activity against Coronavirus 229E (ATCC VR-740), with a reduction $\geq 5.66 \pm 0.46$ TCID₅₀ for both concentrations, when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, **SILVER FLASH**, batch 02025050, under dirty conditions, diluted at 0.01% and during 5 minute of exposure, **does not show** virucidal activity against Coronavirus 229E (ATCC VR-740), with a reduction 0.26 ± 0.59 TCID₅₀, when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

Tables of results and graphics

See tables 1 and 2 and figure 1.

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 208706/20/CGDA**Conclusion**

The disinfectant product **SILVER FLASH**, batch 02025050, under dirty conditions (bovine serum albumin 3 g/L plus 3 mL erythrocytes 3 mL/L), diluted at **25%**, requested by the customer, and during 5 minutes of exposure, **shows virucidal activity against Coronavirus 229E (ATCC VR-740)**, when the activity is assayed according with the internal procedure DESIN-6255 based on the NF EN 14476: 2013 + A2: 2019 guideline.

Tests performed only with Coronavirus strain 229E, **does not allow to conclude that the product tested shows a general virucidal activity**, but only that it shows activity against Coronaviruses.

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 provided".

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ENCLOSURE No. 1 TO REPORT OF ANALYSIS NO. 208706/20/CGDA
Table 1. Results of activity of the product **SILVER FLASH**, batch 02025050 with Coronavirus 229E (ATCC VR-740) under dirty conditions.

Product	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 % after 5 minutes
				0 min	1 min	5 min	15 min	
SILVER FLASH	50%	3 g/L BSA + 3 mL/L erythrocytes	0.5	-	-	0.50	-	≥ 5.66 ± 0.46
	25%		0.5	-	-	0.50	-	≥ 5.66 ± 0.46
	0.1%		0.5	-	-	5.90	-	0.26 ± 0.59
SILVER FLASH	50%	3 g/L BSA	0.5	-	-	0.50	-	≥ 5.49 ± 0.46
	25%		0.5	-	-	0.50	-	≥ 5.49 ± 0.46
	0.1%		0.5	-	-	5.66	-	0.83 ± 0.58
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	6.07	-	5.99	-	NA
Formaldehyde	0.7% (w:v)	NA	0.5	NR	NR	3.66	2.58	NA
Virus control Formaldehyde	0.7% (w:v)	NA	0.5	5.74	NR	NR	5.66	NA
Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log ₁₀ ^{-0.24}								
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).....log ₁₀ ^{-0.25}								

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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.

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Table 2. Results of the activity of the product **SILVER FLASH**, batch 02025050, with Coronavirus 229E (ATCC VR-740) (Assay of titration with 12 wells), under dirty conditions.

Product	Concentration *	Interfering substance	Time of contact (min)	Dilutions (log10) ^{a,b}								
				1	2	3	4	5	6	7	8	
SILVER FLASH	50%	3 g/L BSA + 3 mL/L erythrocytes	5	0000	0000	0000	0000	0000	0000	0000	0000	NR
	25%			0000	0000	0000	0000	0000	0000	0000	0000	
	0.1%			4444	4444	4444	4444	3202	0210	0000	0000	
SILVER FLASH	50%	3 g/L BSA	5	0000	0000	0000	0000	0000	0000	0000	NR	
	25%			0000	0000	0000	0000	0000	0000	0000		
	0.1%			4444	4444	4444	4444	2332	0000	0000		0000
Cytotoxicity	50%	3 g/L BSA + 3 mL/L erythrocytes	NA	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	3022	0200	0000	
				4444	4444	4444	4444	4444	4000	0030	0000	
Virus control	NA	3 g/L BSA	5	4444	4444	4444	4444	3223	2003	0220	0000	
				4444	4444	4444	4444	4403	0220	0000	0000	
Virus control	NA	3 g/L BSA	0	4444	4444	4444	4444	3443	0220	0002	0000	
				4444	4444	4444	4444	2304	0030	0200	0000	
Formaldehyde	0.7 (w/v)	NA	5	4444	4444	3033	0220	0000	0000	0000	NR	
				4444	4444	2330	0202	0000	0000	0000		
Formaldehyde	0.7 (w/v)	NA	15	4444	3233	2000	0000	0000	0000	0000	NR	
				4444	2230	0202	0000	0000	0000	0000		
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	NR
Virus control formaldehyde	0.7 (w/v)	NA	0	4444	4444	4444	4444	2302	0210	0000	NR	
				4444	4444	4444	4444	3332	0100	0000		
Virus control formaldehyde	0.7 (w/v)	NA	15	4444	4444	4444	4444	0322	2020	0000	NR	
				4444	4444	4444	4444	3233	0200	0000		

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Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC
Effectiveness control of the disinfectant detection activity	NA	3 g/L BSA + 3 mL/L erythrocytes	Without PRODUCT	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC
			With PRODUCT	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC

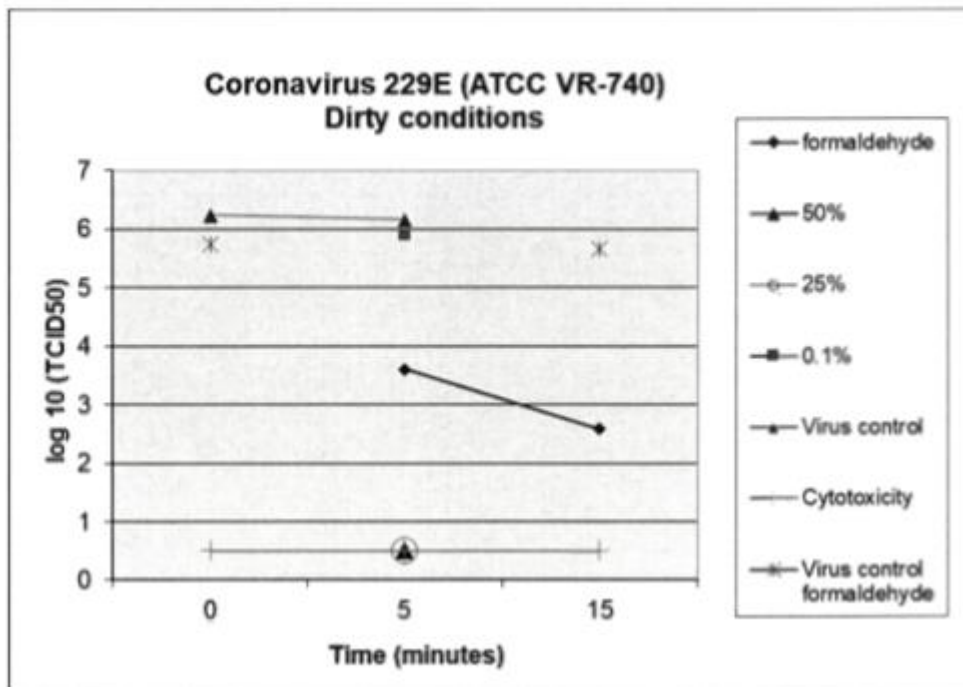
a): 1 to 4, virus present and grade of cytopathic effect in 12 units of cellular culture, or grade of cellular lesions in the cytotoxicity assay.

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. Results of the activity of the product **SILVER FLASH**, batch 02025050, at 50%, 25% and 0.1% concentration under dirty conditions with Coronavirus 229E (ATCC VR-740).



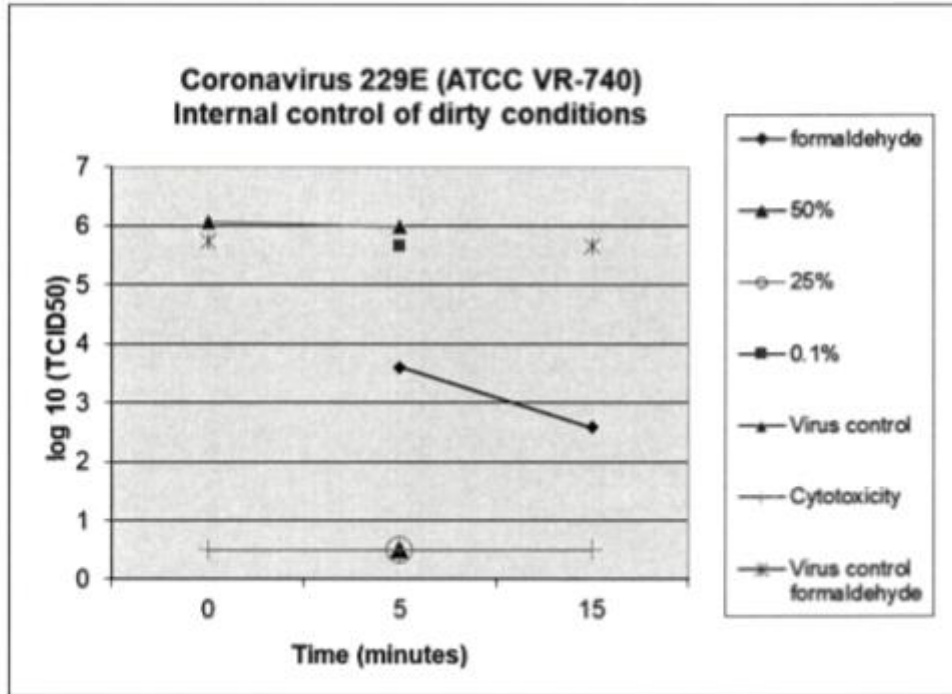
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Figure 1.1 Results of the activity of the product **SILVER FLASH**, batch 02025050, at 50%, 25% and 0.1% concentration under internal control of dirty conditions with Coronavirus 229E (ATCC VR-740).



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