



Instituto Valenciano de Microbiología

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Test with the certificate of GLPs
(Good Laboratory Practices)
No. 2/19-C.VAL. General Directorate of
Pharmacy and Medical Devices of the Health
Department of the Valencian Region. Spain

Virucidal test with the product “Iza Effect Silver Line 3” against Poliovirus type 1, Adenovirus type 5 and Murine Norovirus (NF EN 14476 : 2013 + A2 : 2019 Guideline)

Report

Registration No.: D/20/455

1. **Laboratory identification** Instituto Valenciano de Microbiología.
2. **Client identification** Iza d.o.o.
Address Podgorje 27A
1241 Kamnik.
3. **Sample identification** (information provided by the customer)
 - Product name..... **Iza Effect Silver Line 3.**
 - Batch number..... Not indicated.
 - Expiration date..... Not indicated.
 - Manufacturer (supplier)..... Iza d.o.o.
 - Date of manufacturer..... Not indicated.
 - Store conditions..... Room temperature.
 - Active(s) Substance(s) and its concentration (s)..... 3% H₂O₂.
 - Conditions of use..... Hand disinfection.
 - Concentrations ordered for the assay.... 80%

IVAMI is not responsible for customer-supplied information.

4. Information about sample reception.

- Date of reception of order with test conditions 2020/04/17.
- Date of reception of the product..... 2020/04/24.
- Aspect of the received product..... Colourless liquid in a plastic bottle.

5. Testing method

Procedure **DESIN-1078** (NF EN 14476: 2013 + A2: 2019 guideline).

6. Experimental conditions

- Assay period..... May 12 to May 28, 2020
- Assay temperature..... $37^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Titration method TCID₅₀ (Tissue Culture Infective Dose 50%).
- Product concentrations for the assay.... 80%, 50% and 0.1%.
- Contact time..... 120 seconds.
- Contact temperature..... $20^{\circ}\text{C} \pm 1^{\circ}\text{C}$.
- Procedure to stop product cytotoxicity.. Molecular sieving.
- Procedure to stop product activity Cooling with ice.
- Solvent of the product used in the assay..... Sterile destiled water.
- Aspect of the dilutions of the product... Transparent dilutions.
- Stability of the mixture (interfering substance and product diluted in sterile hard water)..... Stable.
- Interfering substance:
 - Clean conditions in the presence of bovine serum albumin 0.3 g/L.
- Identification of the origin of viral strains and number of passes..... Poliovirus aliquot: 14/03/2018 passage 2.
Adenovirus aliquot: 23/05/2019 passage 2.
Norovirus aliquot: 01/08/2019 passage 2.
- Cell lines (name, origin, number of passes and culture medium)..... Vero, ref: FTVE, working aliquot 2, passages 10, 13 and 17.

Raw 264.7, Public health England, working aliquot 2, passages 10, 13 and 16.

7. Validation of assay results

Poliovirus type 1 (ATCC VR-192)

Titre of the viral suspension for the virus control (120 seconds):

- Clean conditions..... $\log 10^{-6.74}$
- Cytotoxicity level (80%)..... $\log 10^{-0.5}$

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

- Clean conditions..... $\log 10^{-6.24}$

Adenovirus type 5 (ATCC VR-5)

Titre of the viral suspension for the virus control (120 seconds):

- Clean conditions..... $\log 10^{-5.66}$
- Cytotoxicity level (80%)..... $\log 10^{-0.5}$

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

- Clean conditions..... $\log 10^{-5.16}$

Murine norovirus (strain S99 Berlin)

Titre of the viral suspension for the virus control (120 seconds):

- Clean conditions..... $\log 10^{-5.66}$
- Cytotoxicity level (80%)..... $\log 10^{-0.5}$

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

- Clean conditions..... $\log 10^{-5.16}$

Reference test (formaldehyde 1.4%)

Cytotoxicity level of formaldehyde 0.7%..... $\log 10^{-0.5}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Poliovirus Type 1..... $\log 10^{-2.66}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Adenovirus Type 5 $\log 10^{-1.32}$

Viral quantification in the reference test (formaldehyde) after 60 minutes and with Murine Norovirus $\log 10^{-1.58}$

Confidence interval

Titre of virus with 95% confidence interval with Poliovirus Type 1 (120 seconds):

- Clean conditionslog 10^{-6.74 ± 0.33}

Titre of virus with 95% confidence interval with Adenovirus Type 5 (120 seconds):

- Clean conditionslog 10^{-5.66 ± 0.40}

Titre of virus with 95% confidence interval with Murine Norovirus (120 seconds):

- Clean conditionslog 10^{-5.66 ± 0.36}

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

Sensitivity of cells to virus

- Viral quantification of Poliovirus type 1 with cells not treated with “Iza Effect Silver Line 3” disinfectantlog10^{-6.91}
- Viral quantification of Poliovirus type 1 with cells treated with the “Iza Effect Silver Line 3” disinfectant.....log10^{-6.57}
- Viral quantification of Adenovirus type 5 with cells not treated with “Iza Effect Silver Line 3” disinfectantlog10^{-5.83}
- Viral quantification of Adenovirus type 5 with cells treated with the “Iza Effect Silver Line 3” disinfectant.....log10^{-5.50}
- Viral quantification of Murine Norovirus with cells not treated with “Iza Effect Silver Line 3” disinfectantlog10^{-5.74}
- Viral quantification of Murine Norovirus with cells treated with the “Iza Effect Silver Line 3” disinfectant.....log10^{-5.58}

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 <1log₁₀.

Control of the effectivity of the disinfectant detection activity

- Viral quantification of Poliovirus type 1 after 30 minutes on bath ice without exposing the virus to the “Iza Effect Silver Line 3” disinfectantlog10^{-6.82}
- Viral quantification of Poliovirus type 1 exposing the virus to “Iza Effect Silver Line 3” disinfectant and incubated 30 minutes on ice bath.....log10^{-6.58}
- Viral quantification of Adenovirus type 5 after 30 minutes on bath ice without exposing the virus to the “Iza Effect Silver Line 3” disinfectantlog10^{-6.08}
- Viral quantification of Adenovirus type 5 exposing the virus to “Iza Effect Silver Line 3” disinfectant and incubated 30 minutes on ice bath.....log10^{-5.74}

- Viral quantification of Murine Norovirus after 30 minutes on bath ice without exposing the virus to the “Iza Effect Silver Line 3” disinfectantlog10^{-5.75}
- Viral quantification of Murine Norovirus exposing the virus to “Iza Effect Silver Line 3” disinfectant and incubated 30 minutes on ice bath.....log10^{-5.57}

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

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

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 80%, and 50% and during 120 seconds of exposure, **shows** virucidal activity against Poliovirus type 1, with a reduction 5.50 ± 0.50 TCID₅₀ when tested 80% and with a reduction 4.83 ± 0.45 TCID₅₀ when tested 50%, when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 0.1%, and during 120 seconds of exposure, **does not show** virucidal activity against Poliovirus type 1, with a reduction 0.16 ± 0.51 TCID₅₀, when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 80% and 50% and during 120 seconds of exposure, **shows** virucidal activity against Adenovirus type 5, with a reduction $\geq 5.16 \pm 0.40$ TCID₅₀ when tested 80% and with a reduction 4.50 ± 0.49 when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 0.1% and during 120 seconds of exposure, **does not show** virucidal activity against Adenovirus type 5, with a reduction 3.41 ± 0.52 TCID₅₀ when tested 4% and with a reduction 0.25 ± 0.52 TCID₅₀ when tested 0.1% when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 80% and 50% and during 120 seconds of exposure, **shows** virucidal activity against Murine Norovirus with a reduction $\geq 5.16 \pm 0.36$ TCID₅₀, for both concentrations, when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline.

The disinfectant product, “**Iza Effect Silver Line 3**”, batch not indicated, under clean conditions, diluted at 0.1% and during 120 seconds of exposure, **does not show** virucidal activity against Murine Norovirus, with a reduction 0.41 ± 0.45 TCID₅₀, when the activity is assayed according with the NF EN 14476: 2013 + A2: 2019 guideline.

9.2 Tables of results and graphics

See tables 1 to 6 and figure 1 to 3.

10. Conclusion

The disinfectant product “**Iza Effect Silver Line 3**”, batch not indicated under clean conditions, diluted at **80%**, requested by the customer, and during 120 seconds of exposure, **shows** virucidal activity against the three mandatory viruses, Poliovirus type 1 and Adenovirus type 5 and Murine Norovirus, when the activity is evaluated according to the NF EN 14476: 2013 + A2: 2019 guideline.

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".

Bétera (Valencia), June 2, 2020

Signed. Miguel Ángel Fernández
Responsible Technician
(Investigator)

Quality Assurance Review:

The assay development and the results obtained have been supervised by the Director of the study.

The Quality Assurance Director has inspected the development of the assay, proving that has been realized following the proper procedure and using the adequate media, materials and reagents, following as well the Good Laboratory Practices (GLPs) and the final report contains the primary data obtained.

Signed. Ruth Novella
Responsible for the Laboratory Area
(Study Director)

Signed. Encarna Esteban
Technical Director
(Quality Assurance Director)

Reference:

- 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). AFNOR.

Table 1. Results of activity of the product “**Iza Effect Silver Line 3**”, batch not indicated with Poliovirus type 1 (ATCC VR-192) under clean conditions.

Product	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 % after 120 seconds
				0 min	120 sec	30 min	60 min	
Iza Effect Silver Line 3	80%	0.3 g/L BSA	0.5	-	1.24	-	-	5.50 ± 0.50
	50%		0.5	-	1.91	-	-	4.83 ± 0.45
	0.1%		0.5	-	6.58	-	-	0.16 ± 0.51
Virus control	NA	0.3 g/L BSA	NA	6.82	6.74	-	-	NA
Formaldehyde	0.7% (p:v)	NA	0.5	NR	NR	4.66	2.66	NA
Virus control Formaldehyde	0.7% (p:v)	NA	0.5	6.83	NR	NR	6.74	NA
<p>Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log₁₀^{-0.34}</p> <p>Control of the effectivity of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension)..... log₁₀^{-0.24}</p>								
<p>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 titer of virus shows a reduction ≥4 log. *: see Special remarks to understand the values of these concentrations.</p>								

Table 2. Results of the activity of the product “**Iza Effect Silver Line 3**”, batch not indicated, with Poliovirus type 1 (ATCC VR-192) (Assay of titration with 12 wells), under clean conditions.

Product	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}									
				1	2	3	4	5	6	7	8		
Iza Effect Silver Line 3	80 %	0.3 g/L BSA	120 sec	2023	0000	0000	0000	0000	0000	0000	0000	NR	
				0202	2020	0000	0000	0000	0000	0000			
				3200	0000	0000	0000	0000	0000	0000			
	50 %		120 sec	3344	0020	0000	0000	0000	0000	0000	0000	0000	NR
				3324	2102	0000	0000	0000	0000	0000			
				4322	0200	0000	0000	0000	0000	0000			
0.1 %	120 sec	4444	4444	4444	4444	4444	4444	3223	0020	0000	0000		
		4444	4444	4444	4444	4444	4444	0223	0000	0000			
		4444	4444	4444	4444	4444	4444	2200	2102	0000			
Cytotoxicity	80 %	NA	NA	0000	0000	0000	0000	0000	0000	0000	0000	0000	
				0000	0000	0000	0000	0000	0000	0000			
				0000	0000	0000	0000	0000	0000	0000			
Virus control	NA	0.3 g/L BSA	0	4444	4444	4444	4444	4444	2323	0202	0000	0000	
				4444	4444	4444	4444	4444	0232	0021	0000		
				4444	4444	4444	4444	4444	2322	2000	0000		
			120 sec	4444	4444	4444	4444	4444	3223	0202	0000	0000	
				4444	4444	4444	4444	4444	2230	2000	0200		
				4444	4444	4444	4444	4444	2223	0002	0000		
Formaldehyde	0.7 (p/v)	NA	30 min	4444	4444	4444	3203	0210	0000	0000	NR		
				4444	4444	4444	2220	1022	0000	0000			
				4444	4444	4444	2032	0000	0000	0000			
			60 min	4444	2322	0020	0000	0000	0000	0000	NR		
				4444	3022	1200	0000	0000	0000	0000			
				4444	0322	0002	0000	0000	0000	0000			
Control of folmaldehyde cytotoxicity	0.7 (p/v)	NA	NA	0000	0000	0000	0000	0000	0000	0000	NR		
				0000	0000	0000	0000	0000	0000	0000			
				0000	0000	0000	0000	0000	0000	0000			
Virus control folmaldehyde	0.7 (p/v)	NA	0 min	4444	4444	4444	4444	4444	2230	1012	0000	0000	
				4444	4444	4444	4444	4444	3230	0100	0000		
				4444	4444	4444	4444	4444	3233	0202	0000		
			60 min	4444	4444	4444	4444	4444	3023	0220	0000	0000	
				4444	4444	4444	4444	4444	2322	0010	0000		
				4444	4444	4444	4444	4444	0323	2200	0000		
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C00	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000		
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0CC0	0000		
			Cells treated	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	00C0	0000	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C00	0000		
				CCCC	CCCC	CCCC	CCCC	CCCC	0CCC	0000	0000		
Effectivity control of the disinfectant detection activity	NA	0.3 g/L BSA	Without PRODUCT	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	0C0C	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C0CC	C00C	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C000	C000	0000	
			With PRODUCT	CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	C0CC	000C	0000	0000
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CC0C	00CC	0000	
				CCCC	CCCC	CCCC	CCCC	CCCC	CCCC	CCC0	00C0	0000	

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.

Table 3. Results of activity of the product “**Iza Effect Silver Line 3**”, batch not indicated, with Adenovirus type 5 (ATCC VR-5), under clean conditions:

Product	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 % after 120 seconds
				0 min	120 sec	30 min	60 min	
Iza Effect Silver Line 3	80%	0.3 g/L BSA	0.5	-	0.50	-	-	≥5.16 ± 0.40
	50 %		0.5	-	1.16	-	-	4.50 ± 0.49
	0.1%		0.5	-	5.33	-	-	0.33 ± 0.50
Virus control	NA	0.3 g/L BSA	NA	5.75	5.66	-	-	NA
Formaldehyde	0.7% (p:v)	NA	0.5	NR	NR	1.74	1.32	NA
Virus control Formaldehyde	0.7% (p:v)	NA	0.5	5.91	NR	NR	5.74	NA
<p>Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log₁₀^{-0.33}</p> <p>Control of the effectivity of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension)..... log₁₀^{-0.34}</p>								
<p>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 titer of virus shows a reduction ≥4 log. *: see Special remarks to understand the values of these concentrations.</p>								

Table 4. Results of the activity of the product “**Iza Effect Silver Line 3**”, batch not indicated, with Adenovirus type 5 (ATCC VR-5) (Assay of titration with 12 wells), under clean conditions:

Product	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}							
				1	2	3	4	5	6	7	8
Iza Effect Silver Line 3	80 %	0.3 g/L BSA	120 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	50 %		120 sec	0222 0302 2033	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	0.1 %		120 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2323 0223 0220	0020 0000 0000	0000 0000 0000	NR
Cytotoxicity	80 %	NA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
Virus control	NA	0.3 g/L BSA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3230 2303 2302	0022 1010 0012	0000 0000 0000	0000 0000 0000
			120 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2303 3223 2300	0000 1021 0102	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7 (p/v)	NA	30 min	3230 2233 2332	1000 1002 1000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
			60 min	2033 2020 3202	0002 0100 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000
Control of folmaldehyde cytotoxicity	0.7 (p/v)	NA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Virus control folmaldehyde	0.7 (p/v)	NA	0 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3220 3233 2323	2022 0101 2000	0000 0000 0000	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3233 2323 0222	0100 0000 2102	0000 0000 0000	NR
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC 0CCC 0CCC	0C0C CC0C 000C	0000 0000 0000	0000 0000 0000
			Cells treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0CC CCCC 0CCC	00C0 000C 0C00	0000 0000 0000	0000 0000 0000
Effectivity control of the disinfectant detection activity	NA	0.3 g/L BSA	Without PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	C0CC CC00 CCC0	0000 0000 0000	0000 0000 0000
			With PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC C0CC	0CC0 0C0C 0000	0000 0000 0000	0000 0000 0000

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.

Table 5. Results of activity of the product “**Iza Effect Silver Line 3**”, batch not indicated, with Murine Norovirus, strain S99 Berlin, under clean conditions:

Product	Concentration*	Interfering substance	Cytotoxicity level	log ₁₀ TCID ₅₀ after.....				Reduction with the confidence interval of 95 % after 120 sec
				0 min	120 sec	30 min	60 min	
Iza Effect Silver Line 3	80%	0.3 g/L BSA	0.5	-	0.50	-	-	≥ 5.16 ± 0.36
	50 %		0.5	-	0.50	-	-	≥ 5.16 ± 0.36
	0.1%		0.5	-	5.25	-	-	0.41 ± 0.45
Virus control	NA	0.3 g/L BSA	NA	5.83	5.66	-	-	NA
Formaldehyde	0.7% (p:v)	NA	0.5	NR	NR	3.00	1.58	NA
Virus control Formaldehyde	0.7% (p:v)	NA	0.5	5.74	NR	NR	5.58	NA
<p>Control of sensitivity of cells to virus (difference between decimal logarithm of titre using treated and untreated cells)log10^{-0.16}</p> <p>Control of the effectivity of the disinfectant detection activity (difference between decimal logarithm of titre without exposing the virus to the product and of the test suspension)..... log10^{-0.17}</p>								
<p>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 titer of virus shows a reduction ≥4 log. *: see Special remarks to understand the values of these concentrations.</p>								

Table 6. Results of the activity of the product “**Iza Effect Silver Line 3**”, batch not indicated with Murine Norovirus strain S99 Berlin (Assay of titration with 12 wells), under clean conditions:

Product	Concentration *	Interfering substance	Time of contact (sec/min)	Dilutions (log10) ^{a,b}							
				1	2	3	4	5	6	7	8
Iza Effect Silver Line 3	80 %	0.3 g/L BSA	120 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	50 %		120 sec	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
	0.1 %		120 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	4333 4443 4444	2012 0202 1222	0000 0000 0000	NR
Cytotoxicity	80 %	NA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR	NR
Virus control	NA	0.3 g/L BSA	0	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2230 2323 2202	2201 0020 0012	0000 0000 0000	0000 0000 0000
			120 sec	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2023 2230 2232	0100 1102 0000	0000 0000 0000	0000 0000 0000
Formaldehyde	0.7 (p/v)	NA	30 min	4444 4444 4444	4334 4434 2244	0220 1020 2020	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
			60 min	3220 3233 2220	0000 2000 2100	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Control of folmaldehyde cytotoxicity	0.7 (p/v)	NA	NA	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	0000 0000 0000	NR
Virus control folmaldehyde	0.7 (p/v)	NA	0 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	2320 3302 3332	0201 1020 0020	0000 0000 0000	NR
			60 min	4444 4444 4444	4444 4444 4444	4444 4444 4444	4444 4444 4444	3223 3230 3202	0202 0000 1000	0000 0000 0000	NR
Sensitivity control of cells to virus	NA	NA	Cells not treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC 0CCC CC0C	CC0C 000C 00C0	0000 0000 0000	0000 0000 0000
			Cells Treated	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0CC 0C0C	0CC0 0C00 000C	0000 0000 0000	0000 0000 0000
Effectivity control of the disinfectant detection activity	NA	0.3 g/L BSA	Without PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC C0CC 0CC0	0C00 CC0C 0C0C	0000 0000 0000	0000 0000 0000
			With PRODUCT	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CCCC CCCC CCCC	CC0C 00CC C0CC	00C0 CC0C 0C00	0000 0000 0000	0000 0000 0000

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 “Iza Effect Silver Line 3”, batch not indicated, at 80%, 50% and 0.1% concentration under clean conditions with Poliovirus type 1 (ATCC VR-192).

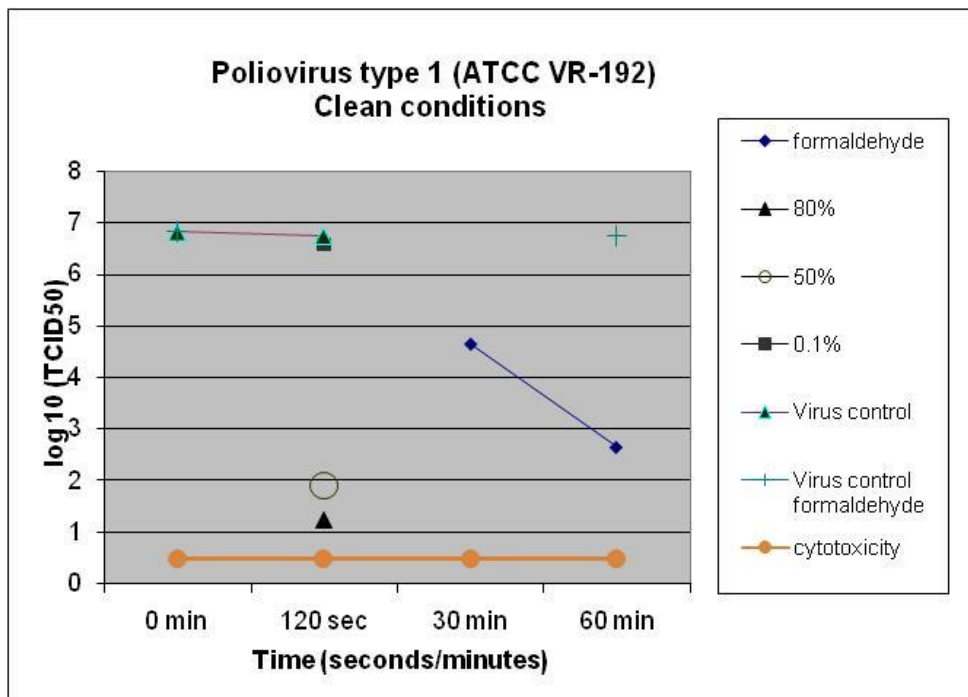


Figure 2. Results of the activity of the product “Iza Effect Silver Line 3”, batch not indicated, at 80%, 50% and 0.1% concentration under clean conditions with Adenovirus type 5 (ATCC VR-5).

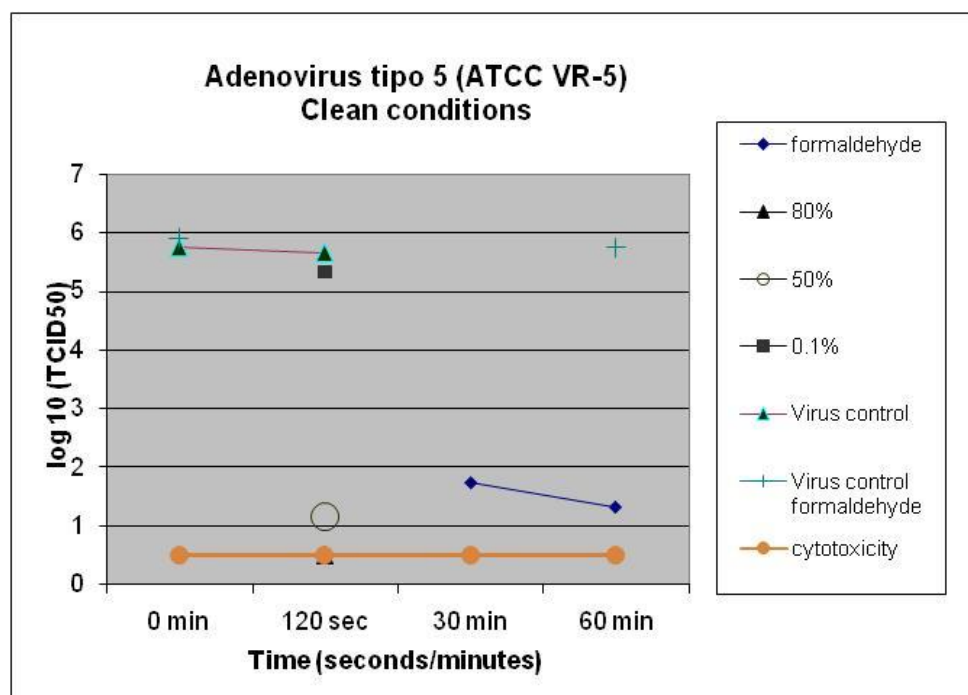


Figure 3. Results of the activity of the product “Iza Effect Silver Line 3”, batch not indicated, at 80%, 50% and 0.1% concentration under clean conditions with Murine Norovirus strain S99 Berlin.

