

Test report n°: 20LA05102 of 29/05/2020

Dear Parx Plastics Europe BV Westblaak 189 3012KJ Rotterdam ()

Acceptance Data

Subject of the test: Polymers

Date of arrival: 09/04/2020 Time of arrival: 15.54

Acceptance date: 09/04/2020

Sample data

Description: PE0018/M18120301/10137/NICEXX

Sampling data

Sampling by: Customer Place: Customer location

The analytical results are exclusively referred to the sample.

Representation of a Test Report signed electronically in accordance with current legislation.

This document can not be reproduced in part without the written permission of the laboratory.

Laboratory management system certified UNI EN ISO 9001: 2015 by CSQA with the No. 14270. Recommended by AIC for the analysis of quantification of gluten in food matrices. Registrated laboratory for the analysis of food contact materials intended for export to Japan.

Laboratory registered in the list of regional laboratories carrying out analysis in the context of self-control procedures for Food Industries No. 52. It is the responsibility of the OSA to communicate the warnings to the bodies in charge

Mod.PT01.01 Rev.9



Test report n°: 20LA05102 of 29/05/2020

Parameter - Specification	M.U.	Results	LoQ	LoD	Test start
Method - Notes		Notes			Test end

Virucidal activity (le) ISO 21702:2019

See the attached report

10/04/2020 29/05/2020

If the sampling is not the responsibility of 3ALaboratori srl, the latter declines all responsibility with regard to sampling information as provided by the Customer; the test results refer only to the sample as received. When these data include measurements that affect the measurement unit, the results expressed are obtained by processing them. The Acceptance Data is the responsibility of the Laboratory while the sample data are the responsibility of the Customer. If the sample is not suitable but the Customer chooses to continue anyway, the laboratory declines all responsibility for the results that could be influenced by the deviation

LEGEND: **U.M.** = Unit of measurement; **(Sup)** = upper limit; **(Inf)** = Lower Limit; **LoQ** = limit of quantification, it is the lower limit of concentration above which it is possible to obtain a quantitative measurement instrumentally; in microbiology the LoQ is of a theoretical nature; **LoD** = limit of detectability, is the lower limit of concentration below which the sample cannot be detected; in qualitative analyzes it represents the minimum concentration at which an analyte can be determined or not; **NQ** = unquantifiable, indicates a value less than LoQ; **NR** = not detectable, indicates a value lower than LoD;"<x" or ">x" respectively indicate a value lower or higher than the measuring range of the test, where x is the result

(§): Indicates a change from the previous version of the Test Report.

(le): Indicates that the parameters/activities are performed in subcontracting.

UNLESS OTHERWISE SPECIFIED: Quantitative microbiological tests are performed on single replica and two consecutive dilutions in accordance with UNI EN ISO 7218: 2013 (with the exception of the analysis of water and MPN); the results of this test report are not corrected for recovery factors (R) as the values of recovery are in the tolerance specified in the test method; summations are calculated using the criterion of the lower bound (LB)

Technical Director

Dr. Giovanni Mitaritonna Chemist Ordine Interprov. Chimici del Veneto - Padova n° 910 SEZ. A

 End of Test Report	

The analytical results are exclusively referred to the sample.

Representation of a Test Report signed electronically in accordance with current legislation.

This document can not be reproduced in part without the written permission of the laboratory.

Laboratory management system certified UNI EN ISO 9001: 2015 by CSQA with the No. 14270. Recommended by AIC for the analysis of quantification of gluten in food matrices. Registrated laboratory for the analysis of food contact materials intended for export to Japan.

Laboratory registered in the list of regional laboratories carrying out analysis in the context of self-control procedures for Food Industries No. 52. It is the responsibility of the OSA to communicate the warnings to the bodies in charge

Mod.PT01.01 Rev.9

Instituto Valenciano de Microbiología

Masía El Romeral Ctra. Bétera - San Antonio de Benagéber, Km 0,3 46117 Bétera (Valencia) Tel. 96 169 17 02

Fax 96 169 16 37

e-mail: ivami@ivami.com

www.ivami.com CIF B-96337217

Virucidal activity on plastics and other Non-porous surfaces with the product "PE0018/M18120301/10137/NICEXX" against Coronavirus 229E (ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 standard guidelines)

Report

Registration No.: D/20/416.

1. Laboratory identification Instituto Valenciano de Microbiología.

2. Client identification 3A Laboratori. Address Via A. Volta, 1/d

Maserà di Padova, 35020 Italy.

3. Sample identification (information provided by the customer)

• Product name PE0018/M18120301/10137/NICEXX.

 Batch number... Not indicated.

• Expiration date None.

• Manufacturer (supplier) Parx.

• Storing conditions Not indicated.

• Active substance(s) and its concentration(s)...... Not indicated.

• Time(s) of exposure ordered 24 hours.

IVAMI is not responsible for customer-supplied information.

4. Information about sample reception

• Date of reception of order with test conditions...

2020/04/15. • Date of reception of the product..... 2020/04/21.

 Aspect of the received product...... Control samples: non-treated polymeric film.

Test samples: treated polymeric film.

DESIN-5510-b// ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 Registration No.: D/20/416

Version 1 (2020-03-10)

Page 1 of 10

5. Testing method

Procedure DESIN-5510 (based on ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 standard guidelines).

6. Experimental conditions

 Assay period Assay incubation temperature Titration method Virus detection method Time of contact Temperature of contact Relative humidity Procedure to stop product activity Virus used: 	 35°C ± 1°C. TCID₅₀ (Tissue Culture Infective Dose 50%). Cytopathic effect. 24 hours. 25°C ± 1°C. > 90%
o Coronavirus 229E (ATCC VR-740)	
 Identification of the origin of viral strains and number of passages Cell lines (name, origin and number of passages) 	Coronavirus 229E (ATCC VR-740) aliquot: 2019/03/04, passage 2. MRC-5, ref: FTMR, working aliquot 4, passages 16 and 18 and working aliquot 5, passage 12.
• Description of test surfaces	50 mm square pieces and ≤ 10 mm
Description of control test surfaces	thickness. 50 mm square pieces and ≤ 10 mm
Description of covering film	thickness
Number of pieces used in the assay	
• Control of product and the	
• Control of Call 1	1
• Control of Cellular susceptibility to virus	3 treated pieces and 3 control pieces.
• Control of effectivity of product inactivation	3 treated pieces and 3 control pieces.
• Control of inoculation at time "0"	3 non-treated pieces.
• Control of virus survival after the time of assay	3 non-treated pieces.
Assay of antiviral efficacy	3treated pieces.

DESIN-5510-b// ISO 21702: 2019 and FEN 14476: 2013 + A2: 2019 Registration No.: D/20/416

Version 1 (2020-03-10)

Page 2 of 10 Instituto Valenciano de Microbiología

7. Validation of assay results

Coronavirus	229E	(ATCC	VR-740)
-------------	------	-------	---------

()
 Titre of the viral suspension for the virus control in one piece without treatment, after inoculation (0 hours) – Piece No. 1
Mean titre of viral suspension for the virus control in one piece without treatment, after inoculation (0 hours)
 Titre of the viral suspension for the virus control in one piece without treatment, after inoculation (24 hours) – Piece No. 1
Reference test (formaldehyde 0.7%)
Cytotoxicity level of formaldehyde 0.7%log 10 ^{-0.5}
Viral quantification in the reference test (formaldehyde) after 15 minutes and with Coronavirus 229Elog10 ^{-2.66}
Confidence interval
• Titre of virus with 95% confidence interval with Coronavirus 229E (24 hours)
Reduction with the confidence interval of 95 %

Control of Sensitivity of cells to virus

Mean titre of virus infectivity for Coronavirus 229E with cells treated with the negative control, the virus diluted in culture medium (Sn) $\log 10^{-5.41}$

DESIN-5510-6// ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 Registration No.: D/20/416

Version 1 (2020-03-10)

- Mean titre of virus infectivity for Coronavirus 229E with cells treated with the virus diluted in the washing solution recovered from the control non-treated samples (Su)..... $\log 10^{-5.41}$
- Mean titre of virus infectivity for Coronavirus 229E with cells treated with the virus the washing solution recovered from the test

Note: The difference between \log_{10} of Sn and Su, and between Sn and St, must be

Control of the effectivity of suppression of the product activity:

- Mean titre of virus infectivity for Coronavirus 229E with cells treated with the negative control, the virus diluted in the culture medium, after incubation for 30 minutes on ice $bath \, (Sn) \, ... \, log 10^{\text{-5.55}}$
- Mean titre of virus infectivity for Coronavirus 229E with cells treated with the virus diluted in the washing solution recovered from the control non-treated samples, after incubation for 30 minutes on ice bath (Su) log10^{-5.44}
- Mean titre of virus infectivity for Coronavirus 229E with cells treated with the virus diluted in the washing solution recovered from the "PE0018/M18120301/10137/NICEXX" and incubation for 30 minutes on ice bath (St)...... log10^{-5.27}

Note: The difference between log10 of Sn and Su, and between Sn and St, must be

8. Special remarks

- All controls and validation were between the basic limits.
- The ISO 21702: 2019 standard guideline describes the procedure to calculate the value of the antiviral activity (R) mentioning that it can be used to characterize the effectivity of an antiviral agent in any treated material, with respect to a non-treated material, but do not indicate an specific criteria to evaluate the effectivity of the treated product to assign a significance, leaving it to the discretion of implicated parts. The percentages of reduction obtained for the virus of assay with respect to the non-treated pieces of the control are shown in the conclusion paragraph.

DESIN-5510-b// ISO 21702: 2019 and NH EN 14476: 2013 + A2: 2019

Registration No.: D/20/416

Version 1 (2020-03-10)

9. Assay results

9.1.-Description

The product "PE0018/M18120301/10137/NICEXX", batch not indicated, after 24 hours of incubation, shows an antiviral activity (R) against Coronavirus 229E of 1.00 \pm 0.21, for the 3 assayed pieces, when compared with the virus obtained from the control pieces without antiviral product after 24 hours of incubation (5.61 \pm 0.38 TCID₅₀) and it is evaluated the activity according with the procedure DESIN-5510, based on the ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 guidelines.

9.2. Tables of results and figures

See tables 1 to 2 and figure 1.

10. Conclusion

The product "PE0018/M18120301/10137/NICEXX", batch not indicated, against Coronavirus 229E, after a time of contact of 24 hours, ordered by the customer, shows an antiviral activity (R) of $R = 1.00 \pm 0.21$, with a percentage of reduction of 20.76% with respect to the non-treated pieces, when the activity is evaluated according with the internal procedure DESIN-5510, based on the ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 standard guidelines.

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), May 25, 2020.

Signed. Miguel Ángel Fernández Responsible technician

Signed. Encarnación Esteba

Technical Director

References:

ISO 21702: 2019. Measurement of antiviral activity on plastics and other non-porous

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.

N-5510-b// ISO 21702: 2019 and NF IN 14476: 2013 + A2: 2019 gistration No.: D/20/416

Version 1 (2020-03-10)

Page 5 of 10 Instituto Valenciano de Microbiología

Table 1. Results of activity of the product "PE0018/M18120301/10137/NICEXX", batch not indicated, with Coronavirus 229E (ATCC VR-740), during 24 hours of contact.

Product	Carriers	Cytotox ity leve		log ₁₀ TCID ₅₀				
			0 min	5 mi	1 .		and 24	
Virus control	Piece No.1	NA	5.66	-	-	-	NA	
after inoculation	Piece No.2	NA	5.58	-	-	-	NA	
	Piece No.3	NA	5.58	-	-	-	NA	
Virus control after incubation	Piece No.1	NA	-	-	-	5.32		
PE0018/M181203 01/10137/ NICEXX	Piece No.1	0,5	-	-	_	5.16	0.17 ± 0.54	
	Piece No.2	0,5	-	-	-	5.16	0.17 ± 0.50	
	Piece No.3	0,5	-	-	-	5.24	0.09 ± 0.54	
Virus control after incubation	Piece No.2	NA	-	-	-	5.25	NA	
PE0018/M181203	Piece No.1	0,5	-	-	-	5.16	0.17 ± 0.54	
01/10137/ NICEXX	Piece No.2	0,5	-	-	_	5.16	0.17 ± 0.50	
	Piece No.3	0,5	-		-	5.24	0.09 ± 0.54	
Virus control after incubation	Piece No.3	NA	-	-	-	5.33	NA	
PE0018/M181203	Piece No.1	0,5	-	-	-	5.16	0.25 ± 0.56	
01/10137/ NICEXX	Piece No.2	0,5	-	-	-	5.16	0.25 ± 0.56	
NICLAX	Piece No.3	0,5	-	-	-	5.24	0.17 ± 0.43	
Formaldehyde	0.7% (p:v)	0,5	NR	3.74	2.66	NR NR	NA NA	
irus control of formaldehyde	0.7% (p:v)	NA	5.74	NR	5.66	NR	NA	

DESIN 5510-b// ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 Registration No.: D/20/416 Version 1 (2020-03-10)

$U_0 =$	$5.08 \pm 0.05 \text{ TCID}_{50}/\text{ cm}^2$	_
$U_t =$	$4.82 \pm 0.17 \text{ TCID}_{50}/\text{ cm}^2$	_
$A_t =$	$3.82 \pm 0.17 \text{ TCID}_{50}/\text{ cm}^2$	
Antiviral activity (R)	$1.00 \pm 0.21 \text{ TCID}_{50}/\text{ cm}^2$	
Control of cellular susceptibil	ity (Sn-Su)	0.0

of cellular susceptibility (Sn-Su) log10^{-0.00} Control of cellular susceptibility (Sn-St) log10^{-0.13}

Control of the efficacy of the suppression of the product activity (Sn-Su) log10^{-0.11} Control of the efficacy of the suppression of the activity of the product (Sn-St)...... log10^{-0.28}

NA: not applicable; NR: not realized.

PBS: Buffered phosphate saline; BSA: Bovine serum albumin.

U₀: Mean of the infectivity titre of the solutions recovered from the three non-treated samples of assay recovered from the sample immediately after the inoculation, in

Ut: Mean of the infectivity titre of the solutions recovered from the 3 non-treated samples after the incubation of the pieces for 24 hours, in TCID₅₀/ cm².

At: Mean of the infectivity titre of the solutions recovered from the 3 treated samples after the incubation of the pieces for 24 hours, in $TCID_{50}/cm^2$.

R: Antiviral activity. ($R = U_{t-} A_{t}$)

Values of U₀, Ut, At and R, are expressed as the mean value with the corresponding

Sn: Mean of the log of the infectivity titre in $TCID_{50}$ of the 3 replicates of the negative control with culture medium.

Su: Mean of the log of the infectivity titre in $TCID_{50}$ of the 3 replicates of the solution recovered from the 3 non-treated test samples.

St: Mean of the log of the infectivity titre in TCID₅₀ of the 3 replicates of the solution recovered from the 3 treated test samples.

ESIN 5510-b// ISO 21702: 2019 and NHEN 14476: 2013 + A2: 2019 sistration No.: D/20/416

Version 1 (2020-03-10)

Page 7 of 10

Table 2. Results of activity of the product "PE0018/M18120301/10137/NICEXX", batch not indicated, with Coronavirus 229E (ATCC VR-740), during 24 hours of contact (titration assay with 12 wells).

Product	Replica	-	ime of ontact Dilutions (log10)										
	tes	Comac	1	2	3	4	5	6	7	8			
PE0018/M181 20301/10137/	Piece No	.1	4444				1	03 010	2 0000				
			4444	444	1		. -03		1				
NICEXX	Piece No.	2 24 hour	S 4444	1		4 444	4 230						
(pieces with	1000 110.	2	4444			''''	1 0-0	0000	0000	NF			
antiviral)	D: N		4444										
	Piece No.	3	4444		1	4 444				NR			
			0000					0 0000		ININ			
	Piece No.	1	0000			000	1 000.		1				
			0000	0000	0000	1			1	NR			
Cytotoxicity	Diago NI (0000	0000	0000								
Cytotoxicity	Piece No.2	2 NA	0000	0000	0000	0000				NR			
		-	0000	0000	0000				0000	IVIC			
	Piece No.3		0000	0000	0000	1			0000				
			0000	0000	0000				0000	NR			
	Piece No.1	D' N		4444	4444	4444	4444	2323		0000			
Virus control			4444	4444	4444	4444	0220		0000	NR			
(pieces		-	4444	4444	4444	4444	3220		0000	TVIC			
without	Piece No.2	0 hours	4444	4444	4444 4444	4444 4444	2320	0100	0000	NR NR			
antiviral)			4444	4444	4444	4444	2320 2322	0210 0000	0000				
	Piece No.3		4444	4444	4444	4444	2302	0220	0000				
	1 1000 1 (0.5		4444 4444	4444 4444	4444 4444	4444	3023	0200	0000				
	D:		4444	4444	4444	4444	2022	1000	0000				
Virus control	Piece No.1		4444	4444	4444	4444	0302 3020	0010 1200	0000	NR			
(pieces			4444	4444	4444	4444	0232	0000	0000				
without	Piece No.2	24 hours	4444 4444	4444 4444	4444	4444	0203	1000	0000				
antiviral)			4444	4444	4444 4444	4444 4444	2030	0002	0000	NR			
ŕ	´		4444	4444	4444	4444	2320	1020	0000				
1	Piece No.3		4444	4444	4444	4444	0002	0000	0000	NR			
			4444	4444	4444	4444	3202	0020	0000	IVIX			
Cytotoxicity	NA	NA	0000	0000	0000	0000	0000	0000	0000				
Formaldehyde	de 1111	INA	0000	0000 0000	0000 0000	0000	0000	0000	0000	NR			
			4444			0000	0000	0000	0000				
	NA	5 min	4444	4444 4444	3222 3022	0200 0001	0000	0000	0000				
Formaldehyde –			4444	4444	3232	2020	0000	0000	0000	NR			
	NIA	1.5	4444	3232	0100	0000	0000	0000	0000				
	NA	15 min	4444	0320	0021	0000	0000	0000	0000	NR			
			4444	2223	0200	0000	0000	0000	0000	1417			
	NA	0 min	4444 4444	4444 4444	4444	4444	3323	0100	0000				
irus control of		> ********	4444	4444	4444 4444	4444 4444	0232 2203	0121	0000	NR			
ormaldehyde	D.T.A		4444	4444	4444	4444	3023	0002	0000				
1	NA		4444	4444	4444	4444	2233	2001 0000	0000	NR			
			4444	4444	4444	4444	2022	0120	0000	INK			

DESIN-5510-b// ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 Registration No.: D/20/416 Version 1 (2020-03-10)

Page 8 of 10
Instituto Valenciano de Microbiología

			CCC	C CCC	C CCC	000	10 00	- 1		
	Piece No.1	NA	CCC					1		
Sensitivity		- 1.2.2	CCC						1	
control of cells			CCC							
to virus:	Piece No.2	NA NA	CCC			1		1		
1		1111	CCC							
Sn			CCCC							
	Piece No.3	NA	CCCC					1	1	
			CCCC			_	1			NR
			CCCC							
	Piece No.1	NA	CCCC					1	1 0000	
Sensitivity			CCCC					4		NR
control of cells			CCCC							
to virus:	Piece No.2	NA	CCCC							
		1 171	CCCC							NR
Su			CCCC						0000	
	Piece No.3	NA	CCCC					0C00	0000	
		1 172 1	CCCC			1		0C00	0000	NR
			CCCC					0000	0000	
	Piece No.1	NA	CCCC					0C00	0000	
Sensitivity	1 1000 1 (0.1	11/7		1				00CC	0000	NR
control of cells			CCCC					0000	0000	1
	Piece No.2	NA	CCCC	CCCC				0C0C	0000	
to virus:	1 1000 140.2	NA	CCCC	CCCC				0000	0000	NR
St			CCCC	CCCC				0000	0000	1110
	Piece No.3	NIA	CCCC	CCCC				0000	0000	NR
	1 1000 140.5	NA	CCCC	CCCC		: cccc	0CCC	0C00	0000	
			CCCC	CCCC	CCCC	CCCC	0CC0	0C00	0000	1
Effectiveness	Piece No.1	N.T.A	CCCC	CCCC	CCCC		C0CC	0CC0	0000	NR
control of the	riece No.1	NA	CCCC	CCCC	CCCC	CCCC	C0C0	C000	0000	
			CCCC	CCCC	CCCC	CCCC	CC0C	0CC0	0000	
disinfectant	Piece No.2	374	CCCC	CCCC	CCCC	CCCC	CCC0	0C00	0000	NR
detection	Fiece No.2	NA	CCCC	CCCC	CCCC	CCCC	CC0C	C000	0000	
activity:			CCCC	CCCC	CCCC	CCCC	0CCC	CC00	0000	
Sn	Pioco No 2	NA	CCCC	CCCC	CCCC	CCCC	0CCC	COCO	0000	
511	Piece No.3		CCCC	CCCC	CCCC	CCCC	COCC	0000	0000	NR
			CCCC	CCCC	CCCC	CCCC	0CCC	00C0	0000	
Effectiveness	D'. N		CCCC	CCCC	CCCC	CCCC	CC0C	0C00		
	Piece No.1	NA	CCCC	CCCC	CCCC	CCCC	C0C0	0C00	0000	ND
control of the			CCCC	CCCC	CCCC	CCCC	CCC0	C000		NR
disinfectant	D: 37 a		CCCC	CCCC	CCCC	CCCC	C0C0	0CC0	0000	
detection	Piece No.2	NA	CCCC	CCCC	CCCC	CCCC	0CC0	000C	0000	
activity:			CCCC	CCCC	cccc	CCCC	CC0C	0C00	0000	NR
. *	D:		CCCC	CCCC	CCCC	CCCC	COCC		0000	
Su	Piece No.3	NA	CCCC	CCCC	CCCC	CCCC	OCCC	0CC0	0000	
			CCCC	CCCC	CCCC	CCCC	0C0C	00C0	0000	NR
control of the disinfectant			CCCC	CCCC	CCCC	CCCC		0000	0000	
	Piece No.1	NA	CCCC	CCCC	CCCC	CCCC	C0C0 0CCC	000C	0000	
			CCCC	CCCC	CCCC	CCCC		00C0	0000	NR
		- 140	CCCC	CCCC	CCCC		0CCC	0000	0000	
	Piece No.2	NA	CCCC	CCCC	CCCC	CCCC	CCCC	0000	0000	
			CCCC	CCCC	CCCC	CCCC	0CC0	0000	0000	NR
activity:			CCCC	CCCC		CCCC	CCC0	0000	0000	
St F	Piece No.3	NA	1	cccc	CCCC	CCCC	CC0C	0C00	0000	
		1		CCCC	CCCC	CCCC	00CC	000C	0000	NR
): 1 to 4. virus			3000	CCCC	CCCC	CCCC	C0C0	0000	0000	1

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.

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

DESIN 5510-b// ISO 21702: 2019 and NF EN 14476: 2013 + A2: 2019 egistration No.: D/20/416

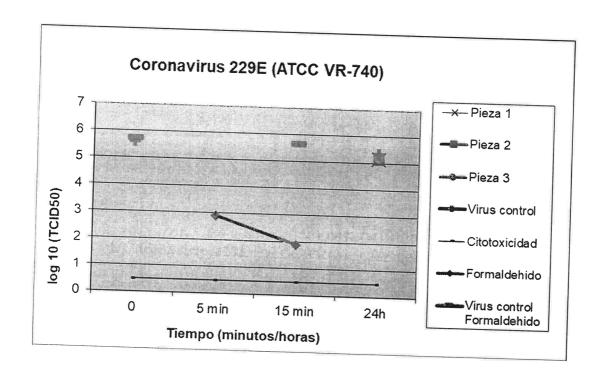
Version 1 (2020-03-10)

Page 9 of 10

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 cytopathic effect).

^{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.

Figure 1. Results of activity of the product "PE0018/M18120301/10137/NICEXX", batch not indicated, with Coronavirus 229E (ATCC VR-740), for the times of contact indicated.



DESIN 5510-b// ISO 21702: 2019 and NEW 14476: 2013 + A2: 2019 Registration No.: D/20/416

Version 1 (2020-03-10)

Page 10 of 10
Instituto Valenciano de Microbiología