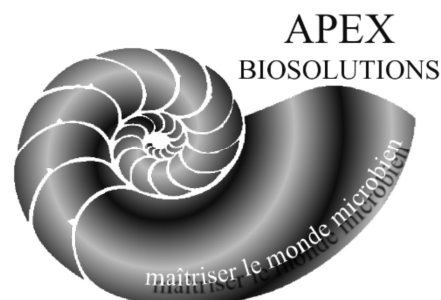


## TEST REPORT

### DETERMINATION OF VIRUCIDAL ACTIVITY OF THE SOLUTION DESINFECTANTE CLEANEA PRODUCT AGAINST THE HUMAN CORONAVIRUS ACCORDING TO THE EN 14476 :2019 STANDARD

Delivered to: **M PRUVOST**

For: **CLEANEA**  
**18 RUE DE PRESSENSE**  
**92 800 PUTEAUX**  
**FRANCE**



Date of request: 03/20/2020

Study # n°083D27-2020

#### VIRUCIDAL TESTS:

According to the NF EN 14476 standard (July 2019) – chemical antiseptics and disinfectants – virucidal quantitative suspension tests for chemical disinfectants and antiseptics used in medical area.

Tests using the SOLUTION DESINFECTANTE CLEANEA product against the *Human Coronavirus 229E* strain as surrogate of the *SARS-CoV2*.

This test report included 14 pages.



Study completion date: 04/15/2020

Stephanie MOROT-BIZOT  
PhD in microbiology  
Study director



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Ms Emilie CANTREL, laboratory technician	Ms Stephanie MOROT-BIZOT, director
	

## 1. PERFORMING LABORATORY

APEX BIOSOLUTIONS  
4, rue des Grandes Pièces  
Zone EURESPACE  
25 770 SERRE LES SAPINS  
FRANCE

## 2. PRODUCT IDENTITY

Reference	Batch n°
<b>SOLUTION DESINFECTANTE CLEANEA</b>	TEST 303



- Manufacturer : CLEANEA
- Date of manufacture : 03/20/2020
- Expiration date : 04/20/2020
- Storage conditions: room temperature
- Active substances: hypochlorous acid
- Appearance of the product: clear, colorless, pH 6,1 to 6,4 at 17°C
- Product diluent recommended by the manufacturer for use: none, ready-to-use product
- Date of delivery of the product: 03/26/2020
- Date of tests: from 03/20/2020 to 04/15/2020

## 3. EXPERIMENTAL CONDITIONS

- Temperature used during the assays: 20°C ± 1°C
- Titration unit: log TCID<sub>50</sub>
- Exposure Time: 30 s
- Tested concentrations (free chlorine): 96 ppm – 120 ppm – 149 ppm
- Diluent used for the product: sterile distilled water
- Viral strain: *human coronavirus* 229 E strain, grown on MRC5 cells, at 37°C, under 5% CO<sub>2</sub> atmosphere
- Organic soil load: BSA 0,3 g/L (clean conditions)
- Product stability: stable
- Stop solution: cold shock

### Viral titer:

Viral titer of the *human coronavirus*, expressed in TCID<sub>50</sub>, according to the Spearman-Kärber method= 6,000 log TCID<sub>50</sub>.

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#### 4. VALIDATIONS

##### a) Cytotoxicity

The solution désinfectante CLEANEA product has been tested on the MRC5 cells and a weak toxicity was observed (up to dilution  $10^{-1}$ ).

##### b) Cells sensitivity to the virus

For each viral suspension, comparative titers of the virus were performed on cells treated or untreated with the product.

Product dilution	Viral titer (log TCID <sub>50</sub> )		
	Viral suspension on untreated cells	Viral suspension on treated cells	Viral titer difference (log TCID <sub>50</sub> )
<b>SOLUTION DESINFECTANTE CLEANEA</b> $10^{-2}$	6,000	5,750	<b>0,250</b>

The SOLUTION DESINFECTANTE CLEANEA product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on MRC5 cells and the virus inoculated on the MRC5 cells treated with the SOLUTION DESINFECTANTE CLEANEA product was  $\leq 1,0$  log.

##### c) Validations of stop solution :



Concentration of the product	Organic soil load	Viral titer (log TCID <sub>50</sub> )	Viral titer difference
<b>SOLUTION DESINFECTANTE CLEANEA</b> <b>149 ppm</b>	0,3 g/L BSA	TRIAL 1: 6,000	0,000
		TRIAL 2: 6,000	0,000

The stop solution is valid if  $\leq 0,5$  log.

##### d) Inactivation of the virus

	Viral titer (log TCID <sub>50</sub> )	Reduction of the viral titer (log TCID <sub>50</sub> )
Viral suspension (control)	6,000	
formaldehyde 0,7%		
Inactivation 5 min	5,625	0,375
Inactivation 15 min	5,125	0,875
<b>Inactivation 30 min</b>	4,500	<b>1,500</b>

The virus is inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure if the reduction is comprised between  $[-0,5]$  and  $[-2,5]$  log. The reduction observed was of 1,500 log for the *human coronavirus*.

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## 5. VIRUCIDAL ASSAYS

### TRIAL 1

Viral suspension: **6,000 log TCID<sub>50</sub>**

PRODUCT	Concentration (ppm)	Exposure time	Temperature	Titer after trial (log TCID <sub>50</sub> )	Viral titer reduction
<b>SOLUTION DESINFECTANTE CLEANEA</b>	149	30 s	20°C	1,625	<b>4,375</b>
	120			2,000	<b>4,000</b>
	96			3,000	3,000

### TRIAL 2

Viral suspension: **6,000 log TCID<sub>50</sub>**



PRODUCT	Concentration (ppm)	Exposure time	Temperature	Titer after trial (log TCID <sub>50</sub> )	Viral titer reduction
<b>SOLUTION DESINFECTANTE CLEANEA</b>	149	30 s	20°C	1,750	<b>4,250</b>
	120			1,875	<b>4,125</b>
	96			2,750	3,250

*The product has a virucidal effect if the viral titer reduction is  $\geq 4,0$  log.*

## 6. VALIDATION OF THE METHODOLOGY

The assays were validated as required by the European standard EN 14476:2019:

- The viral titers of the suspension tests were sufficient in order to observe a reduction of 4 log after time exposure with the product. The viral titer of the *human coronavirus* was 6,000 log TCID<sub>50</sub>.
- The virus was inactivated with the control solution of 0,7 % formaldehyde after 30 min of exposure: the reduction observed was of 1,500 log for the *human coronavirus*.
- The Solution désinfectante CLEANEA product has a weak cytotoxic effect on the MRC5 cells.
- The Solution désinfectante CLEANEA product do not affect the infectious capacity of the virus: the differences in viral titers between the virus inoculated on MRC5 cells and the virus inoculated on the MRC5 cells treated with the Solution désinfectante CLEANEA product was  $\leq 1,0$  log (0,250 log).

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## 7. CONCLUSION

**The assays performed with the SOLUTION DESINFECTANTE CLEANEA product demonstrated that:**

- The SOLUTION DESINFECTANTE CLEANEA product demonstrated a virucidal activity against the *human coronavirus* strain 229E (surrogate virus for the SARS-CoV2) from the concentration 120 ppm, as required by the European standard EN 14476:2019, following a 30 s exposure period, at 20°C, in clean conditions.
- And by extension the SOLUTION DESINFECTANTE CLEANEA product is also virucide on the SARS-CoV-2 because this coronavirus strain is genetically close to the *human coronavirus* strain 229E.

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