

Test Report

JOB REF NO. : 2020-08-18-021
DATE RECEIVED : 18th Aug 2020
DATE REPORTED : 24th Nov 2020
PAGE : 1 of 10

Test Report No. : CRSSA/201150576-CA44476
Company :

The following merchandise was (were) submitted and identified by the client as:

Sample Description : (Electrolyzed Water pH12.5)
Sample Appearance : Clear, colourless solution
Sample Receiving Date : 18th Aug 2020
Storage Conditions : Room temperature
Product Diluent : Distilled water
Testing Period : 18th Aug 2020 – 24th Nov 2020
Test Requested : Determination of the Virucidal Activity
Test Method : EN 14476:2013 + A1: 2015 (E)
Chemical disinfectants and antiseptics – Quantitative suspension test for the evaluation of virucidal activity in the medical area – Test method and requirements (phase 2, step 1)

Test Result : Please see the next page(s)
Tested by : The test was externally provided.

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LOW ZHEN HUI
MULTI-BUSINESS LABORATORY MANAGER
FOOD ANALYST NO. MJMM 0178

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Experimental Conditions

Test Organism(s) : *Human coronavirus*, strain 229E, ATCC VR-740
Concentration/ Contact Time : 100.00%* / 30 seconds
Loading : 0.30 g/L bovine albumin solution
Test Temperature : 20 ± 1°C
Incubation Period : 5 days, 36 ± 1°C

Test Method and Its Validation

Testing Method : Quantal test
Inactivation Method : Immediate dilution
Molecular sieving using MicroSpin™ S 400 HR

The results of validation test A, B, and C proved the viability of the method in all cases.

Test Results

The results are stated in Tables A and B.

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Conclusion

..... (Electrolyzed Water pH12.5) showed the required virus reduction of $\geq 4.0 \log_{10}$ against test strain *Human coronavirus* ATCC VR-740 in accordance with EN 14476:2013+A1:2015 (E) at 100.00%* concentration after 30 seconds under the stated condition. According to the simple acceptance decision rule[†], there is a minimal risk of false acceptance.

Note

Virucidal Activity : The capability of a product to produce a reduction in the number of viable viruses belonging to reference strains under defined conditions by at least 4 orders (10^4).

$R = V_c/N_a$ = the reduction in viability, or $\lg R = \lg V_c - \lg N_a$

*The product can only be tested at 80.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

†The decision rule applied is simple acceptance rule with no guard band and up to 50% risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

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Table A: Evaluation of the virucidal activity of [Electrolyzed Water pH12.5] (Electrolyzed Water pH12.5) on test strains according to EN 14476

Product : (Electrolyzed Water pH12.5)
 Loading : 0.30 g/L bovine albumin solution
 Test Strain : *Human coronavirus* ATCC VR-740

Virus control, V _C	Cytotoxicity effect, CE
V _{C1} : 5.75 ± 0.33 V _{C2} : 6.13 ± 0.37	CE ₁ : 1.50 ± 0.00 CE ₂ : 1.50 ± 0.00

Test concentration (%) / contact time (sec)	First assay, N _{a1}	Second assay, N _{a2}	Average reduction
100.00* / 30	N _{a1} : ≤1.50 ± 0.00 lg R ₁ : ≥4.25 ± 0.33	N _{a2} : ≤1.50 ± 0.00 lg R ₂ : ≥4.63 ± 0.37	lg R: ≥4.44 ± 0.35

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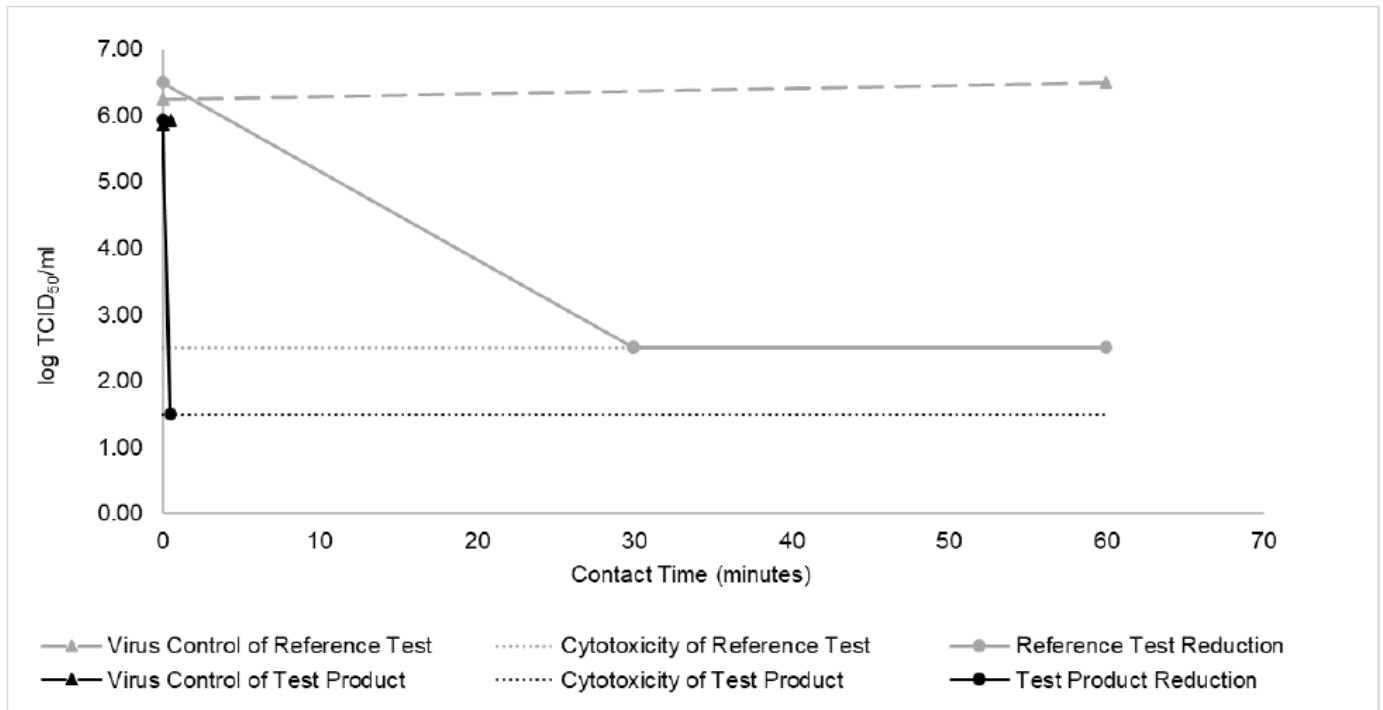
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*The product can only be tested at 97.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

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Table B: Control tests and method validation for Table A

Test strain	Cell susceptibility control	Suppression efficiency control	Reference test for virus inactivation
<i>Human coronavirus ATCC VR-740</i>	A: 6.25 ± 0.33 A _{PBS} : 6.50 ± 0.00	B: 5.63 ± 0.25 V _c : 5.75 ± 0.33	C ₃₀ : ≥4.00 ± 0.00 C ₆₀ : ≥4.00 ± 0.00

Note

- TCID₅₀ : The dilution of the virus suspension that induces a cytopathic effect (CPE) in 50% of cell culture units.
- CPE : The morphological alteration of cells and/or their destruction caused by the cytopathic effect of virus multiplication.
- V_c : log₁₀ TCID₅₀ per ml in the viral test suspension at the beginning and at the maximum contact time.
- N_a : log₁₀ TCID₅₀ per ml in the test mixture at the end of the contact time.
- CE : The morphological alteration of cells caused by the cytotoxicity effect of the product test solution.
- A : log₁₀ TCID₅₀ per ml in the cell susceptibility control as compared to PBS.
- B : log₁₀ TCID₅₀ per ml in the suppression efficiency control as compared to the virus control.
- C : log₁₀ TCID₅₀ per ml in the reference test for virus inactivation after 30 and 60 minutes (5 and 15 minutes for vaccinia virus).

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Table C: Summary of the log reductions of the quantitative suspension test according to EN 14476

Test strain	Test concentration (%) / contact time (sec)	Log reduction (TCID ₅₀ /ml)	Associated risk [†]
<i>Human coronavirus ATCC VR-740</i>	100.00* / 30	≥4.44 ± 0.35	Minimal risk of false acceptance

*The product can only be tested at 97.00% concentration or less, as some dilution always occurs when test organisms and interfering substance are added.

†The decision rule applied is simple acceptance rule with no guard band and up to 50% risk of false acceptance or rejection. This rule has been determined by the laboratory and agreed with the client prior to testing.

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Efficacy of Electrolyzed Water pH12.5 against *Human coronavirus*, strain 229E, ATCC VR-740, in a quantitative suspension test at 20°C according to EN 14476:2013+A1:2015 (E) under clean condition

Expert Opinion*

This expert opinion is based on the test report CRSSA/201150576-CA44476 dated 24th Nov 2020.

The virucidal activity of the disinfectant Electrolyzed Water pH12.5 of *Human coronavirus* ATCC VR-740 was investigated by a quantitative suspension test according to EN 14476:2013+A1:2015 (E) under clean condition (0.30 g/L bovine albumin solution).

According to this suspension test, a disinfectant or a disinfectant solution at a particular concentration is considered as having virucidal activity if the virus titre is reduced by $\geq 4 \log_{10}$ (inactivation $\geq 99.99\%$) within the recommended exposure period.

Electrolyzed Water pH12.5 was examined at 20°C at the concentration of 100.00%** for the exposure time of 30 seconds. After the exposure time, the viral reduction exceeded 4 \log_{10} -steps in all assays. According to the simple acceptance decision rule[†], there is a minimal risk of false acceptance. Therefore, a virucidal activity against for *Human coronavirus* ATCC VR-740 was measured as follows:

Clean condition 100.00%** 30 seconds

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*Opinions and interpretations expressed here are outside the scope of SAMM (Laboratory Accreditation Scheme of Malaysia) accreditation.

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Test Part Description

Sample Description : (Electrolyzed Water pH12.5)



SGS authenticate the photo on original report only
****End of Test Report****

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