STUDY REPORT

Study Title
Non-GLP Custom Virucidal Efficacy of a Device

Product Identity
UV Max
(Serial Number: 2145A0620)

Test Microorganism
Human coronavirus, Strain 229E, ATCC VR-740

Study Identification Number
NG16128

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Study Completion Date
18SEP2020

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Study Sponsor
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STUDY REPORT SUMMARY

General Study Information

Study Title:	Non-GLP Custom Virucidal Efficacy of a Device
Study Identification Number:	NG16128

Test System

Test Microorganism:	Human coronavirus, Strain 229E, ATCC VR-740
Host Cell:	MRC-5 (ATCC CCL-171)
Test Device:	UV Max
Lot Number:	Serial Number: 2145A0620
Test Device Receipt Date:	10JUN2020

Test Parameters

Test Device Preparation:	Arrived ready to use
Test Device Application:	6' distance
Organic Soil Load:	No supplementation of organic soil load incorporated into the test inoculum; virus used as propagated
Number of Replicates Per Lot:	Single
Contact Time:	30 minutes
Exposure Temperature:	Ambient room temperature
Neutralization Method:	Dilution method: Harvested with 2% fetal bovine serum EMEM (test media) 2.0 ml volume

Study Dates

Experimental Start Date/Time:	24AUG2020 / 1443
Experimental Termination Date/Time:	31AUG2020 / 1207
Study Completion Date:	18SEP2020

SUMMARY OF THE TEST PROCEDURE

- Stock virus was thawed and was not supplemented with an organic soil load.
- Sterile glass slides (1 x 3 inch) were used as the test carrier. For each device assayed, one carrier was inoculated with a 0.020 ml volume of virus suspension. The appropriate number of recovery control carriers were also prepared.
- The inoculated carriers were dried at the appropriate temperature and relative humidity to lessen the level of virus inactivation due to drying.
- The test device was prepared according to the Study Sponsor's instructions as requested and applied to the test carriers.
- The treated carriers were held for the Study Sponsor specified contact time at the Study Sponsor specified exposure temperature.
- The recovery control carrier was held covered for the contact time then harvested.
- The viral suspensions were quantified to determine the levels of infectious virus using standard cell culture techniques (e.g. $TCID_{50}$).
- The inoculated cell culture plates were incubated for the period most suitable for the virus-host cell system (e.g.~ 7 days).
- Following the incubation period, the assay was microscopically scored for the presence/absence of test virus and cytotoxic effects. The appropriate calculations were performed (e.g. Spearman-Karber) to determine viral titers and levels of test device cytotoxicity, where applicable.
- The log_{10} and percent reductions in viral titer were calculated for viral films exposed to the test product relative to the titer obtained for the study control carrier(s).

SUCCESS CRITERIA

The following measures are met to ensure the acceptability of virucidal efficacy data:

- The virus titer control demonstrate obvious and or typical cytopathic effects on the monolayers unless a detection method other than cytopathic effect is used.
- Quantification of the test and control parameters are conducted at a minimum of four determinations per dilution.

The product performance criteria follows:

- The log and percent reduction of the test virus following exposure to the test substance are calculated however, there is no minimum reduction level to qualify as “passing” or an “efficacious” product.

CALCULATIONS AND STATISTICAL ANALYSIS

The $TCID_{50}$ (Tissue Culture Infectivity Dose) represents the endpoint dilution where 50% of the cell cultures exhibit cytopathic effects due to infection by the test virus. The endpoint dilution at which 50% of the host cell monolayers exhibit cytotoxicity is termed the Tissue Culture Dose (TCD_{50}). The $TCID_{50}$, and TCD_{50} was determined using the Spearman-Kärber method and calculated as follows:

Negative logarithm of endpoint titer =

[– Log of first dilution inoculated] – [((sum of % mortality at each dilution/100) – 0.5) x Logarithm of dilution]

The result of this calculation is expressed as $TCID_{50}$/0.1 ml (or volume of dilution inoculated) for the test, virus control, and neutralization control and TCD_{50}/0.1 ml (or volume of dilution inoculated) for the cytotoxicity control.

Calculation of the Log Reduction

The log reduction in viral titer was calculated as follows:

Recovery Control Log_{10} $TCID_{50}$ – Virus-Test Device Log_{10} $TCID_{50}$

Calculation of the Percent Reduction

The percent reduction in viral titer was calculated as follows:

Percent Reduction = 1- (C/B) x 100, where:
B = Average $TCID_{50}$ of virus in control suspensions.
C = Average $TCID_{50}$ of virus in virus-test suspensions.

The presence of any test device cytotoxicity were taken into account when calculating the log and percent reductions in viral titer.

If multiple virus control and test replicates were performed, the average $TCID_{50}$ of each parameter was calculated and the average result used to calculate the log reductions in viral titer.

RESULTS

Table 1: Virus Titer Results

		Virus Titer
Cell Control		0 0 0 0
Dilution	10^{-1}	+ + + +
	10^{-2}	+ + + +
	10^{-3}	+ + + +
	10^{-4}	+ + + +
	10^{-5}	+ + + +
	10^{-6}	0 + + 0
	10^{-7}	0 0 0 0
	10^{-8}	0 0 0 0
$TCID_{50}$ per 0.1 ml		6.00 Log_{10}

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed; N/A = not applicable

Table 2: Time Zero, Virus Recovery Control, and Test Results

		Time Zero	Virus Plate Recovery Control	Test Results
Cell Control		0 0 0 0	0 0 0 00 0 0 0	0 0 0 0
Dilution	10^{-2}	+ + + +	+ + + +	0 0 0 0
	10^{-3}	+ + + +	+ + + +	0 0 0 0
	10^{-4}	+ + + +	+ + + +	0 0 0 0
	10^{-5}	+ + + +	+ + + +	0 0 0 0
	10^{-6}	0 0 + 0	0 0 0 0	0 0 0 0
	10^{-7}	0 0 0 0	0 0 0 0	0 0 0 0
$TCID_{50}$ per 0.1 ml		5.75 Log_{10}	5.50 Log_{10}	≤1.50 Log_{10}
Average Log_{10} Reduction		N/A	N/A	≥4.00 Log_{10}
Percent Reduction		N/A	N/A	≥99.990%

Key: + = Virus recovered; 0 = Virus not recovered and/or no cytotoxicity observed; T = Cytotoxicity observed; N/A = not applicable

STUDY CONCLUSION

The purpose of the study was to determine the virucidal efficacy of UV Max (Serial Number: 2145A0620) against Human coronavirus Strain 229E, ATCC VR-740 with no supplementation of organic soil load incorporated into the test inoculum, at a contact time of 30 minutes, and at an exposure temperature of ambient room temperature.

The Recovery Control demonstrated a viral titer of 5.50 Log_{10} $TCID_{50}$ per 0.1 ml.

The evaluated test device, UV Max (Serial Number: 2145A0620) demonstrated a ≥4.00 Log_{10} reduction in viral titer (≥99.990%) as compared to the titer of the corresponding Recovery Control.

The test device will be disposed of 30 days after the completion of this study, unless otherwise requested by the Study Sponsor.

The results of this study apply to the tested devicess) only. Extrapolation of findings to related materials is the responsibility of the Sponsor.