

FINAL REPORT

Sponsor:
(4026)



R-573523-R0

Attn: [Redacted]
PO # 2000245
Sample ID #: 608257/1-5.33

Date Received: 04/03/2020
Date Tested: 04/07/2020
Date Completed: 04/14/2020

Virucidal Screening Test on Various Textile Swatches Woven and Non-woven Articles

Description

Five clear plastic bags, each containing one textile swatch.

Purpose

To determine the virucidal effectiveness of textile swatches against human corona virus.

Method

See page 2-3

Results

See attached tables.

Conclusion

Each textile swatch was tested in the presence of 5% organic load, according to modified ASTM E1053 method for a five [5] minutes contact time against human corona virus. The samples tested demonstrated between 1.2 and 2.8 log₁₀ reduction of the virus. Lot DP1 showed ≥ 3 log virus reduction, however, it also showed toxicity of ≤ 2.5 Log TCLD₅₀. The samples lots DP1 and DP2 were non-absorptive (not capable of soaking up liquids), thus the virus on these swatches was gently vortexed.



Respectfully Submitted,
NELSON LABORATORIES FAIRFIELD, INC.

Approved By: 
Jozef Mastej, Study Director

1. Test Conditions

- 1.1. Contact Time: 5-minute
- 1.2. Organic Load: 5% FBS in the inoculum
- 1.3. Test Temperature: Room temperature

2. Test Material

- 2.1. Gaston Knitted Sleeve. Act material CottonX fiber (Paste application trial) Yarn 30/1, 50%COX/50%CO; Lot# DP1; Other ID: C7.0-50
- 2.2. 13.5 GSM PP Non-Woven Spun bond. Act material: White copper; Lot# DP2; Other ID: FAB-013NW001-NT
- 2.3. 65 GSM Needle Punch Non-Woven. Act material: CottonX fiber; Lot# DP3; Other ID: FAB-065NW007-NT
- 2.4. Woven Fabric, Act material: A3 (into PES), Yarn: 24/1, 50%PES/50%CO; Lot# DP4; Other ID: FHB-154W001-PRP
- 2.5. 30 GSM PP Non-Woven Spun bond. Act material: Copper; Lot# DP5; Other ID: FAB-030NW003-CP

3. Equipment and Reagents

- 3.1.1. Host cell growth medium: MEM with 10% FBS, 1X P/S
- 3.1.2. Dilution medium: MEM with 5% FBS
- 3.1.3. Neutralizer medium: MEM supplemented with 5% FBS
- 3.1.4. Recovery host cell: MRC-5 ATCC CCL-171
- 3.1.5. Host cell incubation: 37± 1°C, 5% CO₂, 95 % RH
- 3.1.6. Virus incubation in host cells: 35± 1°C, 5% CO₂, 95% RH
- 3.1.7. Virus: Human Corona Virus 229E, ATCC VR-740
- 3.1.8. 96-well plates
- 3.1.9. Biosafety cabinet
- 3.1.10. Humidified Incubator
- 3.1.11. Microscope

4. Method

4.1. Fabric Swatches (with disinfectant) and Preparation of Virus Challenge

- 4.1.1. Circular swatches (2 cm²) of each fabric material were analyzed for absorbency test. Plain medium (100µl) added on the center of swatches to observe if inoculum was completely absorbed on fabric and held.
- 4.1.2. In case of swatches that failed to hold the required amount of inoculum, more than one swatch was used.

Sample Lot#	Number of Swatch	Absorbency
DP1	1	Poor*
DP2	1	Poor*
DP3	2	Good
DP4	2	Good
DP5	3	Good

*Mixed by vortexing of virus or media with swatches

- 4.1.3. For test, fresh circular swatches were placed in sterile petri dishes.

4.1.4. Virus or plain media (100µl) inoculated on the center of swatches for required contact time (5 min).

4.1.5. Proceed to the neutralization step.

4.2. Neutralization

4.2.1. Added 1 ml medium with 5% FBS (neutralizer), mixed by pipetting and transferred to a sterile tube.

4.2.2. Prepared serial 10-fold dilutions with the dilution medium (media with 5% FBS).

4.3. *In vitro* Infectivity Assay of Recovered Virus

4.3.1. Host cells were plated in 96 well plates at suitable density 1 day prior to the test.

4.3.2. Inoculated the host cells with an appropriate volume of test and controls in quadruplicate.

4.3.3. Incubated plates at 35±1 °C, 5% CO₂, 90% RH and monitor for CPE for 2-7 days.

Plate Conditions	
Cell Source	MRC-5 ATCC CCL-171
Cell Passage	28
Passage Date	04/06/2020
Seeding Density	2 x 10 ⁵ cells/mL
Medium Volume	100 µL/well

4.3.4. Presence or absence of viral infection was monitored and recorded based on the viral cytopathic effect (CPE) on the host cells, which were distinguishable from the cytotoxic effect induced by the test article.

4.4. Controls

4.4.1. Cell Viability Control

This control demonstrates that the host cells remain viable throughout the assay. Four wells will receive culture media only.

4.4.2. Virus Control

Determine the positive control virus titer that recovered from a plate at the same time of test sample. Recovered virus titer must be at least four logs.

4.4.3. Cytotoxicity Control

The extent of cytotoxicity, if any, will be determined for a proper range of 10-fold serial dilutions of the test material. Process exactly as the test procedure with one exception that no virus is inoculated, substituting virus with cell culture media. Prepare serial 10-fold dilutions and inoculate four wells per dilution. Incubate under the same conditions as the test sample.

4.4.4. Neutralization Control

Process exactly as the test procedure, substituting virus with cell culture media. Prepare serial 10-fold dilutions. Mix diluted samples with approximately 100 TCID₅₀ of test virus and inoculate four wells per dilution. Incubate under the same conditions as the test sample.

5. Results

5.1. Control and Neutralization Results

- 5.1.1.1. Virus Control met the requirements with minimum 10^4 TCID₅₀ recovered.
- 5.1.1.2. Cell Viability control met the requirements and no contamination occurred.
- 5.1.1.3. Neutralization control demonstrated that there was no carry-over virucide in the dilutions relied upon to assess whether or not virus survived treatment with the disinfectant.

Table 1: Human Corona Virus

Dilution	Virus Control (Recovered Virus)			
10 ⁻²	+	+	+	+
10 ⁻³	+	+	+	+
10 ⁻⁴	+	+	+	+
10 ⁻⁵	0	0	0	0
10 ⁻⁶	0	0	0	0
10 ⁻⁷	0	0	0	0
TCID ₅₀ (0.1mL)	4.5			
TCID ₅₀ (1mL) (Log ₁₀ TCID ₅₀)	5.5			
Cell Viability	0	0	0	0

Note: + = presence of virus, 0 = unaltered morphology, T= cytotoxicity

Table 2: Study on Test Substance (Textile Swatches)

Dilution	Lot- DP1 Replicate 1 (Sample +Virus)				Lot- DP1 Replicate 2 (Sample +Virus)				Lot- DP1 Cytotoxicity Control				Neutralization Control			
10 ⁻²	0	0	0	0	0	0	0	0	T	T	T	T	+	+	+	+
10 ⁻³	0	0	0	0	0	0	0	0	0	0	0	0	+	+	+	+
10 ⁻⁴	0	0	0	0	0	0	0	0	0	0	0	0	+	+	+	+
Log ₁₀ TCID ₅₀	≤ 1.5				≤ 1.5				N/A				N/A			
Log ₁₀ TCID ₅₀ (Average)	≤ 1.5															
Log ₁₀ TCLD ₅₀	N/A								≤ 2.5				N/A			
Log Reduction	≥ 3				≥ 3				N/A				N/A			
Log Reduction (Average)	≥ 3															

N/A= Not applicable

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Table 3: Study on Test Substance (Textile Swatches)

Dilution	Lot- DP2 Replicate 1 (Sample +Virus)				Lot- DP2 Replicate 2 (Sample +Virus)				Lot- DP2 Cytotoxicity Control			
	10 ⁻²	+	+	+	+	+	+	+	+	0	0	0
10 ⁻³	+	0	+	0	+	+	0	0	0	0	0	0
10 ⁻⁴	0	0	0	0	0	0	0	0	0	0	0	0
Log ₁₀ TCID ₅₀	3.0				3.0				N/A			
Log ₁₀ TCID ₅₀ (Average)	3.0											
Log ₁₀ TCLD ₅₀	N/A								0			
Log Reduction	1.5				1.5				N/A			
Log Reduction (Average)	1.5											

Table 4: Study on Test Substance (Textile Swatches)

Dilution	Lot- DP3 Replicate 1 (Sample +Virus)				Lot- DP3 Replicate 2 (Sample +Virus)				Lot- DP3 Cytotoxicity Control			
	10 ⁻²	+	+	+	+	+	+	+	+	0	0	0
10 ⁻³	0	+	0	0	+	+	0	0	0	0	0	0
10 ⁻⁴	0	0	0	0	0	0	0	0	0	0	0	0
Log ₁₀ TCID ₅₀	2.7				3.0				N/A			
Log ₁₀ TCID ₅₀ (Average)	2.85											
Log ₁₀ TCLD ₅₀	N/A								0			
Log Reduction	1.8				1.5				N/A			
Log Reduction (Average)	1.65											

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Table 5: Study on Test Substance (Textile Swatches)

Dilution	Lot- DP4 Replicate 1 (Sample +Virus)				Lot- DP4 Replicate 2 (Sample +Virus)				Lot- DP4 Cytotoxicity Control			
	10 ⁻²	0	0	0	+	+	+	0	0	0	0	0
10 ⁻³	0	0	0	0	0	0	0	0	0	0	0	0
10 ⁻⁴	0	0	0	0	0	0	0	0	0	0	0	0
Log ₁₀ TCID ₅₀	1.7				2.0				N/A			
Log ₁₀ TCID ₅₀ (Average)	1.85											
Log ₁₀ TCLD ₅₀	N/A								0			
Log Reduction	2.8				2.5				N/A			
Log Reduction (Average)	2.65											

Table 6: Study on Test Substance (Textile Swatches)

Dilution	Lot- DP5 Replicate 1 (Sample +Virus)				Lot- DP5 Replicate 2 (Sample +Virus)				Lot- DP5 Cytotoxicity Control			
	10 ⁻²	+	+	+	+	+	+	+	+	0	0	0
10 ⁻³	+	0	+	+	0	0	0	+	0	0	0	0
10 ⁻⁴	0	0	0	0	0	0	0	0	0	0	0	0
Log ₁₀ TCID ₅₀	3.3				2.7				N/A			
Log ₁₀ TCID ₅₀ (Average)	3.0											
Log ₁₀ TCLD ₅₀	N/A								0			
Log Reduction	1.2				1.8				N/A			
Log Reduction (Average)	1.5											