Nelson Labs
A Sotera Health company

Sponsor:
Preechaya Insuwan
SRI Trang Gloves (Thailand) Public Company Limited
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Viral Penetration ASTM Method F 1671 Final Report

Test Article:	Latex Powder Free Gloves (401200347)
Study Number:	1156409-S01.1 Amended
Study Received Date:	27 Feb 2019
Study Completion Date:	06 Mar 2019
Testing Facility:	Nelson Laboratories, LLC 6280 S. Redwood Rd. Salt Lake City, UT 84123 U.S.A.
Test Procedure(s):	Standard Test Protocol (STP) Number: STP0062 Rev 16
Deviation(s):	None

Summary: This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at 21 ± 5°C and 30-80% relative humidity (RH), and then tested for viral penetration using a ΦX174 bacteriophage suspension. At the conclusion of the test, the observed side of the test article was rinsed with a sterile medium and assayed for the presence of ΦX174 bacteriophage. The viral penetration method complies with ASTM F1671; sampling was at the discretion of the sponsor. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Number of Test Articles Tested:	3
Number of Test Articles Passed:	3
Test Article Side Tested:	Outside
Test Article Preparation:	Cut from the Palm of Glove at Random
Exposure Procedure:	B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio:	1.2, per sponsor
Environmental Plate Results:	Acceptable

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1-3	1.6×10^8	2.4×10^8	<1[a]	None Seen	Pass
Negative Control	1.6×10^8	2.4×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.6×10^8	2.4×10^8	TNTC[b]	Yes	Acceptable

[a] A value of <1 plaque forming unit (PFU)/mL is reported for assay plates showing no plaques.
[b] TNTC = PFUs were too numerous to count.

Amendment Justification: The sponsor's address was corrected to accurately reflect the sample submission form

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Study Director — FOR Jennifer Jorgenson, B.S., RM(NRCM) — 08 MAR 2019 Amended Report Date

1156409-S01