NELSON LABORATORIES

Sponsor:
Andrew McCleister
Radiation Shield Technologies
P.O. Box 14-4254
Coral Gables FL 33114

Viral Penetration ASTM Method F 1671 Final Report

Test Article: ICE Lot #RSC01141006-20-26
Purchase Order: ICE1103
Laboratory Number: 787155
Study Received Date: 05 Nov 2014
Test Procedure(s): Standard Test Protocol (STP) Number: STP0062 Rev 13

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: 6
Number of Test Articles Passed: 6
Test Article Side Tested: Outside
Test Article Preparation: Cut from the Chest and Sleeve Seam at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: A (No retaining screen)
Compatibility Ratio: 1.4 (Chest), 1.5 (Sleeve Seam)
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
Chest (1-3)	3.1×10^8	3.3×10^8	<1[a]	None Seen	Pass
Sleeve Seam (1-3)	3.1×10^8	3.3×10^8	<1[a]	None Seen	Pass
Negative Control	3.1×10^8	3.3×10^8	<1[a]	None Seen	Acceptable
Positive Control	1.5×10^8	2.2×10^8	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.

ACLASS ACCREDITED TESTING

JDM for

Study Director Adam Meese, B.S.

20 Nov 2014
Study Completion Date