

Viral Penetration ASTM Method F 1671 Final Report

Test Article: 1) Q-20290-W5G4C2 B (blue from BL-250's)
2) Q-20290-W5G4C2 W (white from either BL-250 or KH-450)
3) Q-20290-W5G4C2 P (purple from KH-450)
4) Q-20290-W5G4C2 PW (purple to white seam from KH-450)

Purchase Order: 10202014
Laboratory Number: 784948
Study Received Date: 23 Oct 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 $21 \pm 5^\circ\text{C}$ and 30-80% relative humidity (RH), and then tested for viral penetration using a Φ X174 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 Φ X174 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: 40
Number of Test Articles Passed: 40
Test Article Side Tested: Outside
Test Article Preparation: Cut from the Material at Random (1, 2, and 3)
Cut from the Purple to White Seam at Random (4)
Exposure Procedure: B (Retaining Screen: Woven Polyester Mesh, with >50% Open Area)
Compatibility Ratio: 1.1 (1, 2, and 3); 1.2 (4)
Environmental Plate Results: Acceptable


Results:

Test Article	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
1 (1-10)	3.3×10^8	3.4×10^8	$<1^a$	None Seen	Pass
3 (1-10)	3.3×10^8	3.4×10^8	$<1^a$	None Seen	Pass
4 (3-9)	3.3×10^8	3.4×10^8	$<1^a$	None Seen	Pass
Negative Control	3.3×10^8	3.4×10^8	$<1^a$	None Seen	Acceptable
Positive Control	3.3×10^8	3.4×10^8	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.




Study Director Adam Meese, B.S.

18 Nov 2014
Study Completion Date

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
2 (1-10)	2.6×10^8	2.8×10^8	<1 ^a	None Seen	Pass
4 (1-2, 10)	2.6×10^8	2.8×10^8	<1 ^a	None Seen	Pass
Negative Control	5.0×10^8	4.3×10^8	<1 ^a	None Seen	Acceptable
Positive Control	2.6×10^8	2.8×10^8	TNTC ^b	Yes	Acceptable

^a A value of <1 PFU/mL is reported for assay plates showing no plaques.

^b TNTC = PFUs were too numerous to count.