

## Viral Penetration ASTM Method F 1671 Final Report

Test Article: Demron-C  
 Study Number: 1289030-S01  
 Study Received Date: 15 Apr 2020  
 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 17  
 Deviation(s): None

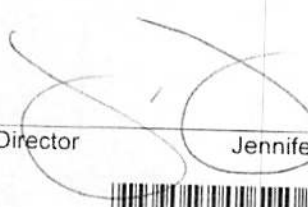
**Summary:** This test method was performed to evaluate the barrier performance of protective materials which are intended to protect against blood borne pathogen hazards. Test articles were conditioned for a minimum of 24 hours at  $21 \pm 5^{\circ}\text{C}$  and 30-80% relative humidity (RH), and then tested for viral penetration using a  $\Phi\text{X174}$  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  $\Phi\text{X174}$  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: 3  
 Number of Test Articles Passed: 3  
 Test Article Side Tested: Grey Side  
 Test Article Preparation: Received Pre-Cut  
 Test Article Sealed: Paraffin Wax  
 Exposure Procedure: A (No retaining screen)  
 Compatibility Ratio: 1.4  
 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	$2.0 \times 10^8$	$2.4 \times 10^8$	$<1^a$	None Seen	Pass
Negative Control	$2.0 \times 10^8$	$2.4 \times 10^8$	$<1^a$	None Seen	Acceptable
Positive Control	$2.0 \times 10^8$	$2.4 \times 10^8$	TNTC <sup>b</sup>	Yes	Acceptable

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

Study Director:  Jennifer Jorgenson, B.S., RM(NRCM)

29 Apr 2020  
 Study Completion Date



1289030-S01