

ISO 16604 Viral Penetration Final Report

Test Article: Product Name: Disposable Medical Protective Gown
Model: ZKF-01
Lot No: 2020080503
Purchase Order: QHT20080426
Study Number: 1340491-S01.1 Amended
Study Received Date: 11 Sep 2020
Study Completion Date: 09 Oct 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: STP0174 Rev 04
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 $60 \pm 10\%$ 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 ISO 16604. 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 (3 per area)
Number of Test Articles Passed: 3
Test Article Side Tested: Outside
Test Article Preparation: Cut from the Critical Area of the Chest Material and Sleeve Seam Areas at Random
Test Article Sealed: Paraffin Wax
Exposure Procedure: C (no retaining screen; 3.5 kPa)
Compatibility Ratio: 1.3 (Chest Material)
2.0 (Sleeve Seam)
Settle Plate Results: Acceptable



Robert Dieker electronically approved for
Study Director

Jennifer Jorgenson

19 Oct 2020 20:01 (+00:00)
Amended Report Date and Time

Results:

Test Article Number	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result
Chest Material (3)	2.6×10^5	3.2×10^8	$<1^a$	None Seen	Pass
Chest Material (1)	2.6×10^5	3.2×10^8	TNTC ^b	None Seen	Fail
Chest Material (2)	2.6×10^5	3.2×10^8	2.3×10^2	None Seen	Fail
Sleeve Seam (1, 3)	5.3×10^8	5.7×10^8	$<1^a$	None Seen	Pass
Sleeve Seam (2)	5.3×10^8	5.7×10^8	2.2×10^1	None Seen	Fail
Negative Control	2.6×10^5	3.2×10^8	$<1^a$	None Seen	Acceptable
Positive Control	2.6×10^5	3.2×10^8	TNTC ^b	Yes	Acceptable

^a A value of <1 plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

^b TNTC = PFU were too numerous to count.

Amendment Justification: At the request of the sponsor, the post code was changed in the sponsor address.