

Synthetic Blood Penetration Resistance Final Report

Test Article: WLM2002
Purchase Order: WL201906-0920
Study Number: 1225963-S01
Study Received Date: 26 Sep 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: STP0012 Rev 09
Deviation(s): None

Summary: This procedure was performed to evaluate surgical facemasks and other types of protective clothing materials designed to protect against fluid penetration. The purpose of this procedure is to simulate an arterial spray and evaluate the effectiveness of the test article in protecting the user from possible exposure to blood and other body fluids. The distance from the target area surface to the tip of the cannula is 30.5 cm. A test volume of 2 mL of synthetic blood was employed using the targeting plate method.

This test method was designed to comply with ASTM F1862 and ISO 22609 (as referenced in EN 14683:2019 and AS4381:2015) with the following exception: ISO 22609 requires testing to be performed in an environment with a temperature of $21 \pm 5^{\circ}\text{C}$ and a relative humidity of $85 \pm 10\%$. Instead, testing was performed at ambient conditions within one minute of removal from the environmental chamber held at those parameters.

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: 32
Number of Test Articles Passed: 30
Test Side: Outside
Pre-Conditioning: Minimum of 4 hours at $21 \pm 5^{\circ}\text{C}$ and $85 \pm 5\%$ relative humidity (RH)
Test Conditions: 20.6°C and 23% RH (Units 1-16)
 22.1°C and 21% RH (Units 17-32)


Study Director

For
Janelle R. Bentz, M.S.

11 Nov 2019
Study Completion Date



1225963-S01

Results: Per ASTM F1862 and ISO 22609, an acceptable quality limit of 4.0% is met for a normal single sampling plan when ≥ 29 of 32 test articles show passing results.

Test Pressure: 120 mmHg (16.0 kPa)
Test Date: 03 Oct 2019

Test Article Number	Synthetic Blood Penetration
1-3, 5-16	None Seen
4	Yes

Test Pressure: 120 mmHg (16.0 kPa)
Test Date: 07 Nov 2019

Test Article Number	Synthetic Blood Penetration	Test Article Number	Synthetic Blood Penetration
17-27, 29-32	None Seen		
28	Yes		