

## Synthetic Blood Penetration Resistance GLP Report

Test Article: BH MEDICAL 3-Ply Medical Mask  
Study Number: 1321731-S01  
Study Received Date: 17 Jul 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: 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.

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:  $23.3^{\circ}\text{C}$  and 21% RH

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

Test Pressure: 160 mmHg (21.3 kPa)

Test Article Number	Synthetic Blood Penetration
2-13, 15-32	None Seen
1, 14	Yes



Trang Truong electronically approved  
Study Director

Trang Truong

18 Aug 2020 02:15 (+00:00)  
Study Completion Date and Time

**Test Method Acceptance Criteria:** The output of synthetic blood passing through the targeting hole before and after every set of test articles must be  $\leq 5\%$  ( $\pm 0.10$  g) in difference from the theoretical output of 2 mL.

**Procedure:** A clean cannula was fixed onto the front of the valve and the reservoir was filled with synthetic blood. The reservoir pressure and timer were set to allow a differential weight of 95-102%. This was achieved by setting the valve timer to 0.5 seconds and 1.5 seconds, collecting and weighing the amount of fluid before and after the targeting hole, and then calculating the weight differences for the deliveries. After the reservoir pressure and timer duration had been adjusted, the 2 mL spray was verified by dispensing three spurts in a row through the targeting hole into a graduated cylinder and weighing. After every 16 test articles, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood.

Each test article was tested within one minute of removal from the conditioning chamber. The facemask was mounted on the test article(s) holding fixture and positioned 305 mm (12 in) from the cannula. The mask was then subjected to the 2 mL volume spray, which moved from the cannula in a horizontal path perpendicular to the facemask. This procedure used a targeting hole that blocked the initial, high-pressure portion of the synthetic blood stream and allowed only the fluid traveling at the target velocity to hit the center of the mask. Each test article was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

## Quality Assurance Statement

**Compliance Statement:** The test was conducted in accordance with the USFDA (21 CFR Parts 58, 210, 211, and 820) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	04 Aug 2020
Phase Inspected by Quality Assurance: Sample Preparation/Conditioning	07 Aug 2020
Audit Results Reported to Study Director	11 Aug 2020
Audit Results Reported to Management	13 Aug 2020

Scientists	Title
Adrianne Sandall	Supervisor
Trang Truong	Study Director

**Data Disposition:** The study plan, raw data and final report from this study are archived at Nelson Laboratories, LLC or an approved off-site location.

Robert De Vargas electronically approved  
Quality Assurance

17 Aug 2020 20:52 (+00:00)  
Date and Time