

## Synthetic Blood Penetration Resistance Final Report

Test Article: Company Name: Xinxiang Tianhong Medical Device Co., LTD  
Product Name: Disposable Medical Face Mask  
Type: Flat Earloop Type  
Lot #20200207  
Study Number: 1279074-S01  
Study Received Date: 20 Mar 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. 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: 29  
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:  $22.1^\circ\text{C}$  and 22% RH



*James W. Lusk*  
Study Director

James W. Lusk

*26 Mar 2020*  
Study Completion Date



1279074-S01

**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: 120 mmHg (16.0 kPa)

Test Article Number	Synthetic Blood Penetration
1-8, 10-20, 22-26, 28-32	None Seen
9, 21, 27	Yes