

## Synthetic Blood Penetration Resistance Final Report

Test Article: 15061729, 15061730, 15061731, 15061732, 15061733, 15061734, 15061735,  
15061736, 15061737, 15061738, 15061739, 15061740, 15061741, 15061742,  
15061743, 15061744, 15061745, 15061746, 15061747, 15061748, 15061749,  
15061750, 15061751, 15061752, 15061753, 15061754, 15061755, 15061756,  
15061757, 15061758, 15061759, 15061760

Purchase Order: NA2410  
Laboratory Number: 831879  
Study Received Date: 06 Jul 2015  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0012 Rev 06

**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 14683:2014) 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: 31  
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:  $21.0^\circ\text{C}$  and 32% RH

  
Study Director

Brandon L. Williams

16 Jul 2015  
Study Completion Date

**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 mm Hg

Test Article	Synthetic Blood Penetration	Test Article	Synthetic Blood Penetration
15061729	None Seen	15061745	None Seen
15061730	None Seen	15061746	None Seen
15061731	None Seen	15061747	None Seen
15061732	None Seen	15061748	None Seen
15061733	None Seen	15061749	None Seen
15061734	None Seen	15061750	None Seen
15061735	None Seen	15061751	None Seen
15061736	None Seen	15061752	None Seen
15061737	Yes	15061753	None Seen
15061738	None Seen	15061754	None Seen
15061739	None Seen	15061755	None Seen
15061740	None Seen	15061756	None Seen
15061741	None Seen	15061757	None Seen
15061742	None Seen	15061758	None Seen
15061743	None Seen	15061759	None Seen
15061744	None Seen	15061760	None Seen

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