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FINAL REPORT

EN 14683:2005
SYNTHETIC BLOOD PENETRATION RESISTANCE

PROCEDURE NO. STP0012 REV 03

LABORATORY NO. 513443

PREPARED FOR:

[redacted]

SUBMITTED BY:

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EN 14683:2005
SYNTHETIC BLOOD PENETRATION RESISTANCE

LABORATORY NUMBER:	513443
PROCEDURE NUMBER:	STP0012 REV 03
SAMPLE SOURCE:	[redacted]
SAMPLE IDENTIFICATION:	Refer to Table 1
DEVIATIONS:	None
STUDY RECEIVED DATE:	08 Feb 2010
LAB PHASE START DATE:	10 Feb 2010
LAB PHASE COMPLETION DATE:	11 Feb 2010
REPORT ISSUE DATE:	12 Feb 2010

INTRODUCTION:

This report describes details for testing surgical face masks and other types of protective clothing materials designed to protect against fluid penetration. The purposes of this procedure are to simulate an arterial spray and then evaluate the effectiveness of the material in protecting the healthcare worker from possible exposure to blood and other body fluids. This test method was designed to comply with ASTM F 1862 and EN 14683:2005. This test method does not address the possible biological exposure to blood borne pathogen hazards such as Hepatitis B virus (HBV), Hepatitis C virus (HCV), or Human Immunodeficiency Virus (HIV) which may be present in blood and body fluids. This test method attempts to determine visually whether synthetic blood penetration occurs during exposure.

ACCEPTANCE CRITERIA:

The output of synthetic blood through the targeting hole before and after every sixteen test specimens is within 2% (± 0.04 g) of the theoretical output of 2 mL.

TEST SPECIMEN PREPARATION:

Samples were conditioned for a minimum of 4 hours at a temperature of 21 ± 5°C and a relative humidity of 85 ± 5%.

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TEST PROCEDURE:

A clean canula 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 sixteen specimens, synthetic blood was delivered into a graduated cylinder and weighed to ensure the test apparatus was still delivering 2 mL of synthetic blood. Each sample was tested within one minute of removing it from conditioning. The face mask was mounted on the specimen holding fixture and positioned 305 mm (12 in.) from the canula. The mask was then subjected to the 2 mL volume spray which moved from the canula in a horizontal path perpendicular to the face mask. This procedure used a targeting hole, which 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 sample was observed for penetration within 10 seconds of dispensing the synthetic blood against the target area.

The lab conditions during testing were a temperature of 22°C and a relative humidity of 29%.

RESULTS:

Refer to Table 1 for a summary of the test results. To meet an Acceptable Quality Level of 4.0%, it is required that 29 of the 32 specimens pass the test. Testing met the acceptance criteria previously stated in this report. The BFE and Delta P results are required to determine if the samples met the performance requirements of EN 14683:2005 as Type IR or IIR, as listed in Table 1, Section 5.2.3 of the standard.

STATEMENT OF UNCERTAINTY:

If applicable, the statement of uncertainty is available to sponsors upon request.

Technical Reviewer

Hilda M. Fontanet, B.S.
Study Director

13 Feb 2010
Study Completion Date

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TABLE 1. Synthetic Blood Penetration Resistance
Sample Identification: flat face mask
Test Pressure: 120 mm Hg
Test Date: 11 Feb 2010

SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION	SAMPLE NUMBER	SYNTHETIC BLOOD PENETRATION
1	None Seen	17	None Seen
2	None Seen	18	None Seen
3	None Seen	19	None Seen
4	None Seen	20	None Seen
5	None Seen	21	None Seen
6	None Seen	22	None Seen
7	None Seen	23	None Seen
8	None Seen	24	None Seen
9	None Seen	25	None Seen
10	None Seen	26	None Seen
11	None Seen	27	None Seen
12	None Seen	28	None Seen
13	None Seen	29	None Seen
14	None Seen	30	None Seen
15	None Seen	31	None Seen
16	Yes	32	None Seen