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Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) GLP Report

Test Article: Visor Masks Nautilus Safety NTLS EVM01-B
Laboratory Number: 810641
Study Received Date: 19 Mar 2015
Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 11
Protocol Detail Sheet (PDS) Number: 201501132 Rev 01

Summary: The BFE test is performed to determine the filtration efficiency by comparing the upstream bacterial control counts to downstream test article counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and challenge delivery. The challenge delivery is maintained at 2,200 ± 500 colony forming units (CFU) with a mean particle size (MPS) at 3.0 µm ± 0.3 µm. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. This test method complies with ASTM F2101-07 and EN 14683:2014, Annex B.

The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C.

All test method acceptance criteria were met.

Test Side: Inside
BFE Area Tested: ~45.6 cm^2
BFE Flow Rate: 28.3 Liters per minute (L/min)
Delta P Flow Rate: 8 L/min
Conditioning Parameters: 85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours.

Results:

Test Article Number	Percent BFE (%)	Delta P (mm H_2O/cm^2)	Delta P (Pa/cm^2)
1	99.7	4.0	38.8
2	99.4	4.1	40.5
3	99.3	4.5	43.9
4	99.2	4.0	39.3
5	99.5	3.9	37.8

Positive Control Average: 2,099 CFU
Negative Monitor Count: <1 CFU
MPS: 3.1 µm
Test Article Dimensions: ~165 mm x ~154 mm

Stacey Cushing
Technical Reviewer

Janelle Bentz
Study Director — Janelle R. Bentz, M.S.

08 Apr 2015
Study Completion Date

The filtration efficiency percentages were calculated using the following equation:

$$\% BFE = \frac{C - T}{C} x\ 100$$

C = Positive control average
T = Plate count total recovered downstream of the test article
Note: The plate count total is available upon request

Test Article Preparation: The test articles were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% RH, prior to BFE and Delta P testing.

Test Method Acceptance Criteria: The BFE positive control average must be 2,200 ± 500 CFU. Other positive control averages may be used as approved by the sponsor.

The average MPS of the challenge aerosol must be maintained at 3.0 ± 0.3 µm.

The average % BFE for the reference material must be within the upper and lower control limits established for the BFE test.

The Delta P result for each reference material must be within the upper and lower control limits established for the Delta P test.

Procedure:
BFE: A culture of *S. aureus*, ATCC #6538, was diluted in peptone water (PEPW) to a precise concentration to yield challenge level counts of 2,200 ± 500 CFU per test article. The bacterial culture suspension was pumped through a nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery, at a fixed air pressure, formed aerosol droplets with a MPS of approximately 3.0 µm. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. Test articles, positive controls, and reference material received a one minute challenge followed by a one minute vacuum cycle.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six soybean casein digest agar (SCDA) plates based on the size of each droplet. The agar plates were incubated at 37 ± 2°C for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the positive hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test articles. The distribution ratio of colonies for each of the six agar plates was used to calculate the MPS of the challenge aerosol.

Delta P: The Delta P test simply measured the differential air pressure on either side of the test article using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 L/min (volumetric). At least one reference material is included with each set of test articles.

The Delta P values were reported in mm water/cm^2 of test area and calculated using the following equation:

$$Delta\ P = \frac{\bar{M}}{Test\ Area}$$

Where: $\bar{M}$ = Average mm water or Pa of test replicates.

The test article holder used in the Delta P test has a test area of 4.9 cm^2.

Quality Assurance Statement

Compliance Statement: The test was conducted in accordance with the USFDA (21 CFR Part 58) Regulations. This final report reflects the raw data.

Activity	Date
Study Initiation	25 Mar 2015
Phase Inspected by Quality Assurance: Delta P Measurements	31 Mar 2015
Audit Results Reported to Study Director	07 Apr 2015
Audit Results Reported to Management	07 Apr 2015

Scientists	Title
Adam Meese	Supervisor
Janelle Bentz	Study Director

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

Laura Sayalchammy
Quality Assurance

09 Apr 2015
Date

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FINAL REPORT

EN 14683:2005
SYNTHETIC BLOOD PENETRATION RESISTANCE

PROCEDURE NO. STP0012 REV 03

LABORATORY NO. 526418.1 AMENDED

PREPARED FOR:

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EN 14683:2005
SYNTHETIC BLOOD PENETRATION RESISTANCE

LABORATORY NUMBER:	526418.1 Amended
PROCEDURE NUMBER:	STP0012 REV 03
SAMPLE IDENTIFICATION:	Refer to Tables 1-2
DEVIATIONS:	None
STUDY RECEIVED DATE:	03 May 2010
LAB PHASE START DATE:	13 May 2010
LAB PHASE COMPLETION DATE:	14 May 2010
REPORT ISSUE DATE:	14 May 2010
STUDY COMPLETION DATE:	14 May 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%.