

BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

LABORATORY NUMBER:

422104

PROCEDURE NUMBER:

STP0004 REV 02

SAMPLE IDENTIFICATION:

Refer to Tables 1-2

DEVIATIONS:

None

SAMPLE RECEIVED DATE:

11 Apr 2008

LAB PHASE START DATE:

15 Apr 2008 24 Apr 2008

LAB PHASE COMPLETION DATE: REPORT ISSUE DATE:

25 Apr 2008

INTRODUCTION:

This test procedure was performed to determine the bacterial filtration efficiency (BFE) of various filtration materials, employing a ratio of the bacterial challenge counts to sample effluent counts, to determine percent bacterial filtration efficiency (%BFE). This procedure provides a more severe challenge to most filtration materials than would be expected in normal use. This test procedure allowed a reproducible bacterial challenge to be delivered to test materials. This method complies with ASTM F2101.

The differential pressure (ΔP or Delta P) test determined the air exchange differential of the porous materials. The technique involved a simple application of a basic physical principle employing a water manometer differential upstream and downstream of the test material, at a constant flow rate. A digital manometer may be used in place of a water manometer

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 colony forming units (CFU). A BFE run with a control average of less than 1700 shall be unacceptable. Challenges greater than 2700, but less than 3000, are, in our experience, valid. Acceptance of runs with control averages exceeding 2700 shall be at the sponsor's approval.

The mean particle size (MPS) of the challenge aerosol must be maintained at $3.0 \pm 0.3 \,\mu\text{m}$.

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



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

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at $21 \pm 5^{\circ}$ C and $85 \pm 5\%$ relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus*, ATCC #6538, was diluted in 1.5% peptone water (PEPW) to a precise concentration to yield challenge level counts of 2200 \pm 500 CFU per test sample. The bacterial culture suspension was pumped through a 'Chicago' 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 μ m. The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler for collection. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Liters per minute (Lpm) (1 cubic foot per minute (CFM)). Test controls and test samples were challenged for a two minute interval.

The delivery rate of the challenge also produced a consistent challenge level of 2200 \pm 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-11 test samples. The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto six agar plates based on the size of each droplet. The agar medium used was soybean casein digest agar (SCDA). The agar plates were incubated at 37 \pm 2°C for 48 \pm 4 hours and the colonies formed by each bacteria laden aerosol droplet were counted and converted to probable hit values using the hole conversion chart provided by Andersen. These converted counts were used to determine the average challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the MPS of the challenge aerosol.

The ΔP test simply measured the differential air pressure on either side of the test sample using an incline, "U" tube, or digital manometer. Testing was conducted at a flow rate of 8 Lpm (volumetric).

RESULTS:

The results are summarized in Tables 1-2.



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The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

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

Where:

C = Average of control values.

T = Count total for test material.

The ΔP values were reported in mm water/cm² of test area and calculated using the following equation:

Delta P (
$$\Delta$$
P)= $\frac{\overline{M}}{\text{Test Area}}$

Where: \overline{M} = Average mm water of test replicates.

The sample holder used in the ΔP test has a test area of 4.9 cm².

At least one reference material is included with each set of test samples. The ΔP values for the reference material are also recorded on control charts. The individual ΔP values must be within the upper and lower control limits (±3 standard deviations) for the test.

STATEMENT OF UNCERTAINTY:

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

Technical Reviewer

Stacey Cushing,

Study Director

Study Completion Date

jyr



Bacterial Filtration Efficiency and Differential Pressure

TABLE 1. Results
Sample Identification: SH302RB (3-Ply Blue Pleated Mask)
Lot #0803

SAMPLE IDENTIFICATION	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
1	2.5	99.9%
2	2.5	>99.9%ª
3	2.6	>99.9%ª

CONTROL AVERAGE: 2479 CFU

MEAN PARTICLE SIZE: 3.3 µm

^a There were no detected colonies on any of the Andersen sampler plates for this sample.



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TABLE 2. Results
Sample Identification: SH306R (4-Ply Active Carbon Pleated Mask)
Lot #0804

UNIT NUMBER	ΔP (mm H ₂ O/cm ²)	PERCENT BFE
1	3.1	>99.9%
2	3.0	>99.9%
3	3.3	99.9%

CONTROL AVERAGE: 2479 CFU

MEAN PARTICLE SIZE: 3.3 μm



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