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FINAL REPORT

BACTERIAL FILTRATION EFFICIENCY (BFE)

PROCEDURE NO. SOP/ARO/007J.1

LABORATORY NO. 270137

SUBMITTED BY:

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BACTERIAL FILTRATION EFFICIENCY (BFE)

LABORATORY NUMBER:	270137
PROCEDURE NUMBER:	SOP/ARO/007J.1
SAMPLE SOURCE:	Refil
SAMPLE IDENTIFICATION:	Half Mask REFIL 651
DEVIATIONS:	None
DATA ARCHIVE LOCATION:	Sequentially by lab number
SAMPLE RECEIVED DATE:	09 Aug 2004
LAB PHASE START DATE:	16 Aug 2004
LAB PHASE COMPLETION DATE:	19 Aug 2004
REPORT ISSUE DATE:	23 Aug 2004
TOTAL NUMBER OF PAGES:	7

REFERENCES:

MIL-M-36954C. 1975. Headquarters, Defense Personnel Support Center, Philadelphia, PA.

ASTM F2101-01. 2001. Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of *Staphylococcus aureus.* American Society for Testing and Materials, West Conshohocken, PA.

ASTM F2100-04. 2004. Standard Specification for Performance of Materials Used in Medical Face Masks. American Society for Testing and Materials, West Conshohocken, PA.

Andersen 2000 Inc. 1976. Viable (Microbial) Particle Sizing Samplers Operating Manual. Andersen 2000 Inc., Atlanta, GA.

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 provided 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 procedure has been used with little or no modifications and provides a standard procedure for comparison of filtration materials.

ACCEPTANCE CRITERIA:

The BFE control average must be 2200 ± 500 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 sponsor's approval.

The mean particle size (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.

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at 21 ± 5°C and 85 ± 5% relative humidity prior to testing.

TEST PROCEDURE:

A culture of *Staphylococcus aureus* ATCC #6538 was diluted in 1.5% peptone water to a precise concentration to yield challenge level counts of 2200 ± 500 colony forming units (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 mean particle size (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. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 Lpm (1 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 ± 500 CFU on the test control plates. A test control (no filter medium in the airstream) and reference material are included after 5-10 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 ± 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 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.

RESULTS:

The results are summarized in Table 1.

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.

This test procedure produces a more severe challenge to most filtration materials than would be expected in normal use. The purpose of this procedure is not to optimize the filtration efficiency, but to consistently measure as accurately as possible the differences between materials, or differences in the same material over time, thereby alerting the manufacturer to significant trends or changes which can then be dealt with promptly.

Several quality control steps have been taken to insure and monitor our own ability to consistently perform the bacterial filtration efficiency procedure:

1 - The test control average, determined from control runs where no filter medium is in the airstream, must be maintained at 2200 ± 500 CFU for the test to be valid, unless the sponsor approves another control average.

2 - We include at least one reference material with every 5-10 samples tested. Statistical evaluation of these reference material data are recorded on control charts. The reference material must be within the upper and lower control limits (±3 standard deviations) established for the test.

3 - The test sample results are statistically analyzed to alert us to unusual variations which may indicate a need for retesting before data are reported.

STATEMENT OF UNCERTAINTY:

Due to the large number of data points available for the standard reference material used in the BFE test, the Type B uncertainty factors have been determined to be incorporated into the Type A uncertainty.

Statistical analysis of the BFE data resulted in the following:

Bacterial Filtration Efficiency (BFE) Mean = 99.3%
Standard Deviation = 0.29%

The combined standard uncertainty for the BFE test is 0.027% Bacterial Filtration Efficiency and the expanded uncertainty at a 95% confidence level is 0.055% Bacterial Filtration Efficiency.

It should be noted that the statistical analysis was conducted on data from Nelson Laboratories' standard reference material with a mean of 99.3%. It is expected that materials submitted for BFE testing which have a BFE lower than 99.3% would have a combined uncertainty and an expanded uncertainty greater than the uncertainty values reported here. Conversely, test materials with BFE values greater than 99.3% would be expected to yield a combined uncertainty and an expanded uncertainty less than the uncertainty values reported here.

Test samples were not collected by the laboratory and therefore the representative nature of the samples is not included in the uncertainty statement.

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21 Aug 2004

Study Completion Date

jtp

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TABLE 1. Results

UNIT NUMBER	SAMPLE IDENTIFICATION	PERCENT BFE
1	Half Mask REFIL 651	>99.9%
2	Half Mask REFIL 651	>99.9%*
3	Half Mask REFIL 651	>99.9%
4	Half Mask REFIL 651	>99.9%*
5	Half Mask REFIL 651	>99.9%*

CONTROL AVERAGE: 2227 CFU

MEAN PARTICLE SIZE: 3.0 μm

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