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FINAL REPORT
BACTERIAL FILTRATION EFFICIENCY (BFE)
PROCEDURE NO. SOP/KEN/J.10
LABORATORY NO. JP005

Kenrico

SUBMITTED BY:

JAPAN ASSOCIATION STANDARD
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BACTERIAL FILTRATION EFFICIENCY (BFE)

LABORATORY NUMBER: JP005
PROCEDURE NUMBER: SOP/KEN/J.10
SAMPLE SOURCE: Kenrico
SAMPLE IDENTIFICATION: Kenrico Facial Disposal Mask
DEVIATIONS: None
DATA ARCHIVE LOCATION: Sequentially by lab number
SAMPLE RECEIVED DATE: 10 June 2009
LAB START DATE: 15 June 2009
LAB COMPLETION DATE: 26 June 2009

REFERENCES:

ASTM F2101-01. 2001. Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using 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 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.

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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 $3.0 \pm 0.3 \mu\text{m}$.

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

SAMPLE PREPARATION:

BFE test samples were conditioned for a minimum of 4 hours at $21 \pm 5^\circ\text{C}$ 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 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 $3.0 \mu\text{m}$. 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 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 $37 \pm 2^\circ\text{C}$ for 48 ± 4 hours and the colonies formed were counted and converted to probable hit values using the hole conversion chart provided by Andersen.

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RESULTS:

The results are summarized in Table 1.

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

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

Where: C = Average of control values.
T = Count total for test material.

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.

TABLE 1. Results

UNIT NUMBER	SAMPLE IDENTIFICATION	PERCENT BFE
1	KENRICO FACIAL DISPOSAL MASK	>99.9%
2	KENRICO FACIAL DISPOSAL MASK	>99.9%
3	KENRICO FACIAL DISPOSAL MASK	>99.9%
4	KENRICO FACIAL DISPOSAL MASK	>99.9%
5	KENRICO FACIAL DISPOSAL MASK	>99.9%

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Kenrico