



FINAL REPORT

EN 14683:2005

BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

PROCEDURE NO. STP0004 REV 02

LABORATORY NO. 498015.1 AMENDED

PREPARED FOR:

SUBMITTED BY:

NELSON LABORATORIES, INC.
6280 S. REDWOOD RD.
SALT LAKE CITY UT 84123-6600
801-290-7500



EN 14683:2005
BACTERIAL FILTRATION EFFICIENCY AND DIFFERENTIAL PRESSURE

LABORATORY NUMBER:	498015.1 Amended
PROCEDURE NUMBER:	STP0004 REV 02
SAMPLE SOURCE:	
SAMPLE IDENTIFICATION:	Refer to Table 1
DEVIATIONS:	None
SAMPLE RECEIVED DATE:	19 Oct 2009
LAB PHASE START DATE:	02 Nov 2009
LAB PHASE COMPLETION DATE:	06 Nov 2009
REPORT ISSUE DATE:	10 Nov 2009
STUDY COMPLETION DATE:	10 Nov 2009
AMENDED REPORT ISSUE DATE:	23 Feb 2010

AMENDMENT JUSTIFICATION:

At the request of the sponsor, "Type II" was changed to "Type IIR" in the results paragraph.

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

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.

Testing was conducted as directed in Annex B (BFE testing) and Annex C (Delta P testing) of EN 14683:2005.

ACCEPTANCE CRITERIA:

The BFE control average was within 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 sponsor's approval.



EN 14683:2005
Bacterial Filtration Efficiency
and Differential Pressure

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

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

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

BFE PROCEDURE:

Testing was conducted as directed in Annex B of EN 14683:2005. A culture of *Staphylococcus aureus* ATCC #6538 (Designation FDA 209 strain) 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 $3.0 \pm 0.3 \mu\text{m}$. 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 L/min (1 cubic foot/min (CFM)). The samples were conditioned for a minimum of four hours prior to testing at $20 \pm 2^\circ\text{C}$ and a relative humidity of $65 \pm 2\%$. Test samples, positive controls and reference material received a one minute challenge followed by a one minute vacuum cycle. The samples were tested at normal room temperature. The dimensions of the test samples are located in Table 1. The outside surface of each sample was facing towards the challenge aerosol. The area of each sample tested was approximately 3.0 inches (75 mm) in diameter.

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 were included at the beginning and after the last test sample. A negative control run (without addition of bacterial challenge) was also performed. 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 $37 \pm 2^\circ\text{C}$ for 48 ± 4 hours and the colonies formed by each bacteria laden aerosol droplet 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 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.

DELTA P PROCEDURE:


Testing was conducted as directed in Annex C of EN 14683:2005. The ΔP test simply measured the differential air pressure on either side of the test sample using an incline, U-tube, or digital manometer. Test samples were conditioned at $20 \pm 2^\circ\text{C}$ and a relative humidity of $65 \pm 2\%$ for a minimum of four hours prior to testing. Testing was conducted at a flow rate of 8 liters per minute (Lpm) (volumetric). This value represents a corrected flow rate, which compensates for temperature and altitude differences. At least one reference material is included with each set of test samples.

RESULTS:

The results are summarized in Table 1. Testing met the acceptance criteria previously stated in this report. The average of the BFE and Delta P results met the performance requirements of EN 14683:2005 as Type 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.



Stacey Cushing, B.S.
Study Director

25 Feb 2010

Amended Report Date

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TABLE 1. Results
Sample Identification: flat face mask
BFE Test Date: 03 Nov 2009

UNIT NUMBER	PERCENT BFE	ΔP (Pa /cm ²)
1	99.8%	26.9
2	99.9%	24.9
3	>99.9%	24.6
4	99.9%	25.4
5	99.7%	26.5

Mean Total Plate Count of Positive Controls: 2314 CFU

Negative Control Plate Count: <1 CFU

Mean Particle Size (MPS): 2.8 μm

Sample Dimensions: 6 ½ inches x 6 inches



EN 14683:2005
Bacterial Filtration Efficiency
and Differential Pressure

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Page 1 of 6



EN 14683:2005
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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.

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EN 14683:2005 Bacterial Filtration Efficiency and Differential Pressure

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EN 14683:2005 Bacterial Filtration Efficiency
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Stacey Cushing, B.S.
Study Director



Study Completion Date

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