

## Viral Filtration Efficiency (VFE) at an Increased Challenge Level Final Report

Test Article: 100756-NT/120912 Pulmonary Function Test Filter/Technostat T070 Filter Media  
 Purchase Order: 1757  
 Laboratory Number: 668887  
 Study Received Date: 20 Dec 2012  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0010 Rev 05

**Summary:** This procedure was performed to evaluate the VFE at an increased challenge level of the test article. A suspension of  $\Phi$ X174 bacteriophage was delivered to the test article to determine filtration efficiency. A challenge level of greater than  $10^6$  plaque-forming units (PFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and a fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a one minute interval and sampling through the AGIs was conducted for two minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc., standard VFE test in order to employ a more severe challenge than would be experienced in normal use. All test method acceptance criteria were met.

Challenge Flow Rate: 30 Liters per Minute (L/min)  
 Area Tested: Entire Test Article  
 Side Tested: ~29 mm OD Port

**Results:**

| Test Article Number | Total PFU Recovered | Filtration Efficiency (%) |
|---------------------|---------------------|---------------------------|
| 1                   | $2.1 \times 10^3$   | 99.917                    |

Challenge Level:  $2.5 \times 10^6$  PFU  
 Mean Particle Size (MPS): 2.7  $\mu$ m



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*02 Jan 2013*

**Study Completion Date**

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FRT0010-0001 Rev 4

Page 1 of 1

## Bacterial Filtration Efficiency (BFE) at an Increased Challenge Level Final Report

Test Article: 100756-NT/120912 Pulmonary Function Test Filter/Technostat T070 Filter Media  
 Purchase Order: 1757  
 Laboratory Number: 668888  
 Study Received Date: 20 Dec 2012  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0009 Rev 05

**Summary:** This procedure was performed to evaluate the BFE at an increased challenge level of the test article. A suspension of *Staphylococcus aureus*, ATCC #6538, was delivered to the test article to determine filtration efficiency. A challenge level of greater than  $10^6$  colony forming units (CFU) was pumped through a nebulizer using a peristaltic pump at a controlled flow rate and fixed air pressure. The aerosol droplets were generated in a glass aerosol chamber and drawn through the test article into all glass impingers (AGIs) in parallel. The challenge was delivered for a 1 minute interval and sampling through the AGIs was conducted for 2 minutes to clear the aerosol chamber.

This test procedure was modified from Nelson Laboratories, Inc., standard BFE procedure in order to employ a more severe challenge than would be experienced in normal use. This method was adapted from ASTM F2101. All test method acceptance criteria were met.

Challenge Flow Rate: 30 Liters per Minute (L/min)  
 Area Tested: Entire Test Article  
 Side Tested: ~29 mm OD Port

### Results:

| Test Article Number | Total CFU Recovered                    | Filtration Efficiency (%) |
|---------------------|--|---------------------------|
| 1                   | $1.9 \times 10^3$                      | 99.975                    |
|                     | Challenge Level: $7.8 \times 10^6$ CFU |                           |
|                     | Mean Particle Size (MPS): 3.3 $\mu$ m  |                           |



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02 Jan 2013

Study Completion Date