

## EN 14683:2005 Bacterial Filtration Efficiency (BFE) and Differential Pressure (Delta P) Final Report

Test Article: AntiVirus - Respilon  
 Laboratory Number: 754321  
 Study Received Date: 05 May 2014  
 Test Procedure(s): Standard Test Protocol (STP) Number: STP0004 Rev 10

**Summary:** The BFE test is performed to determine the filtration efficiency by comparing the bacterial control counts to test article effluent counts. A suspension of *Staphylococcus aureus* was aerosolized using a nebulizer and delivered to the test article at a constant flow rate. The aerosol droplets were drawn through a six-stage, viable particle, Andersen sampler for collection. This procedure allows a reproducible bacterial challenge to be delivered to test materials. The Delta P test determines the breathability by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. Testing was conducted as directed in Annex B (BFE testing) and Annex C (Delta P testing) of EN 14683:2005. All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820.

Test Side: Sponsor Labeled Side  
 BFE Area Tested: ~45.6 cm<sup>2</sup>  
 BFE Flow Rate: 28.3 Liters per minute (L/min)  
 Delta P Flow Rate: 8 Liters per minute (L/min)  
 Conditioning Parameters: 65 ± 2% relative humidity (RH) and 20 ± 2°C

**Results:** Test articles with a filtration efficiency greater than or equal to 95% meet the performance requirements of EN 14683:2005 as Type I and/or Type IR. Test articles with a filtration efficiency greater than or equal to 98% meet the performance requirements of EN 14683:2005 as Type II and/or Type IIR.

Test articles with a differential pressure less than 29.4 pascals (Pa)/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type I and/or Type II. Test articles with a differential pressure less than 49.0 Pa/cm<sup>2</sup> meet the performance requirements of EN 14683:2005 as Type IR and/or Type IIR.

Test Article Number	Percent BFE (%)	Delta P (Pa/cm <sup>2</sup> )
1	>99.9 <sup>a</sup>	46.7
2	99.9	48.8
3	99.9	43.5
4	99.9	46.8
5	99.9	43.8

<sup>a</sup> There were no detected colonies on any of the Andersen sampler plates for this test article.

Mean Positive Control Count: 1,945 colony forming units (CFU)  
 Negative Monitor Count: <1 CFU  
 Mean Particle Size (MPS): 2.9 µm  
 Test Article Dimensions: ~210 mm x ~210 mm

  
 Study Director

Sarah Smit, B.S.

13 May 2014  
 Study Completion Date