

## Latex Particle Challenge Final Report

Test Article: 20FB-423059-02  
Laboratory Number: 635640  
Study Received Date: 21 May 2012  
Test Procedure(s): Standard Test Protocol (STP) Number: STP0005 Rev 03

**Summary:** This procedure was performed to evaluate the non-viable particle filtration efficiency of the test article. Monodispersed polystyrene (latex) microspheres were nebulized, dried, and passed through a test article. The particles passing through the test article were enumerated using a laser particle counter.

Three one-minute counts were performed and the results averaged. Three one-minute control counts were performed, without a test article in the system, before and after each test article. The filtration efficiency was calculated using the average of the test article value compared to the average of the control values.

The procedure employed the basic particle filtration method described in ASTM F2299, with some exceptions; notably the procedure incorporated a non-neutralized challenge. In real use, particles carry a charge, thus this challenge represents a more natural state. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks. All test method acceptance criteria were met.

Test Side: Outside  
Area Tested: 91.5 cm<sup>2</sup>  
Particle Size: 0.1  $\mu$ m (0.102  $\pm$  0.003  $\mu$ m)  
Laboratory Conditions: 20°C, 32% relative humidity (RH) at 1448; 20°C, 32%RH at 1623  
Average Filtration Efficiency: 99.30%  
Standard Deviation: 0.078

  
Study Director

Adrienne Sandall, B.S.

07 Jun 2012  
Study Completion Date



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**Results:**

Test Date: 05 Jun 2012

Test Article Number	Average Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	77	10,722	99.28
2	77	10,243	99.25
3	78	12,422	99.37
4	74	11,967	99.38
5	85	10,693	99.20

**Acceptance Criteria:** The filtration efficiency of the reference material must be within  $\pm 3$  standard deviations of the mean established in the control chart for the Latex Particle Challenge. Ambient background particles detected through the sample holder must be below 1% of the challenge total (<100 particles).

**Procedure:** Testing was conducted in an ISO Class 5 (class 100) HEPA filtered hood. The inlet air to the test system was filtered through a 0.2  $\mu\text{m}$  rated air filter. Extraneous particulate "background noise" through the sample holder produced an average of <1 particle at one cubic foot per minute (CFM) with the nebulizer output clamped. The flow rate through the test system was maintained at 1 CFM  $\pm 5\%$ .

The latex microspheres, traceable to the International System of Units (SI) through the National Institute of Standards and Technology, were manufactured by Duke Scientific. An aliquot of the latex spheres was transferred to particle free water for irrigation and then aerosolized using a Particle Measuring System (PMS) Model PG-100 generator. The latex aerosol was mixed with additional filtered, dried air and passed through the test system. The particles delivered were collected and enumerated using a laser based particle counter.

A test article was placed into the sample holder and the system was allowed to stabilize. Then triplicate one-minute counts were recorded. Triplicate one-minute control readings were taken prior to and after every test article. Control count averages were maintained at a level of 10,000 - 15,000 particles per cubic foot.

The percent filtration efficiency was determined by subtracting the average particle counts of the test article from the average particle counts of the system and dividing by the average particle counts of the system.