Viral Filtration Efficiency Test of the Intersurgical Clear-Therm 3 HMEF, code 1541

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Introduction

The procedure described below was performed to determine the viral filtration efficiency of the breathing filters using a ratio of the challenge to effluent to determine percent efficiency. This test procedure was modified from Nelson Laboratories Inc standard viral filtration efficiency test to allow a reproducible aerosol challenge to be delivered to each of the breathing filters, whilst employing a more severe challenge than would be expected in normal use.

The viral filtration efficiency test provides a number of advantages over other filtration efficiency tests. The use of all glass impingers (AGIs) in the collection process allowed a high concentration of challenge to be delivered to each breathing filter. Monitoring the airflow and challenge flow through the nebuliser can tightly control the aerosol challenge particle size, and the aerosol particles can be sized using a six-stage viable particle Anderson sampler.

The model organism, ΦX174 bacteriophage, has a diameter of 27nm (0.027 µm) and therefore provides a severe challenge to the test filter.

Challenge Procedure

The stock bacteriophage ΦX174 was prepared by inoculation of ΦX174 into a log phase culture of E.coli. The culture was shaken at 37± 2°C until bacterial turbidity cleared, and the virus stock was centrifuged to remove large cellular debris and then filtered through a 0.2-µm membrane filter to remove remaining host cell debris. The stock culture was stored at 2-8°C.

The challenge suspension was pumped through a 'Chicago' nebuliser using a peristaltic pump at a controlled flow rate and fixed air pressure. The constant challenge delivery formed aerosol droplets of defined size. The challenge level was adjusted to provide a consistent challenge of greater than 10^6 plaque-forming units (PFU) per test sample.

The aerosol droplets were generated in a glass aerosol chamber and drawn through the sample holder and into All Glass Impingers (AGI) in parallel. Each AGI contained 30mL aliquots of sterile peptone water to collect the aerosol droplets. The aerosol challenge flow rate was maintained at 30L/min.

The challenge was delivered for a 1 minute interval and sampling through the AGIs was conducted for 2 minutes to clear the aerosol chamber. Control runs (no media in sample holder) were performed every 5-7 test samples to determine the number of viable particles being generated in the challenge aerosol.

The AGI fluid was assayed using standard plaque assay techniques. All plates were incubated at 37± 2°C for 12-24 hours.

The viral filtration efficiencies were calculated using the following equation:

$$\%VFE = \frac{\text{Plaques without filter (PFU)} - \text{Plaques with filter}}{\text{Plaques without filter (control)}} \times 100$$

Results

Sample identification	Total PFU recovered	Filtration Efficiency
1541	9	99.99925%
1541	1.8×10^1	99.9985%
1541	1.8×10^1	99.9985%

Challenge level: 1.0×10^6 PFU, MPS: 3.1µm

Conclusion

This protocol shows the Clear-Therm 3 HMEF (1541) to be greater than 99.99% efficient against a Viral Aerosol Challenge.

References:

1. 331606/SOP/ARO/18G.1