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Bacterial Filtration Efficiency Test of the Intersurgical Pulmo-Protect, code 1691050

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Introduction

The procedure described below was performed to determine the Bacterial 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 Bacterial filtration efficiency test[1] 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 Bacterial 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, staphylococcus aureus, has a MPS maintained at 3.0 ± 0.3 µm.

Challenge Procedure

The challenge is prepared by inoculating 100ml of SCDB with staphylococcus aureus. The culture is incubated at 37 ± 2°C for 24 ± 4 hours with mild shaking. The challenge solution is then diluted as required in peptone solution to achieve a concentration of ≥1 x 106 CFU/test sample.

A flow rate of 30L/min is maintained through the test apparatus and test samples. The challenge is delivered to the nebulisers for 1 minute and then stopped. The flow is allowed to run for another minute to clear the nebuliser and aerosol chamber of excess aerosol particles. A positive control run is then performed to measure the number of viable aerosol particles being delivered to each test sample. The titre of the AGI control run assay fluid is determined using a standard plate count. The MPS of the challenge aerosol is measured using a six-stage Anderson sampler.

Assay Procedure

The AGI fluid was assayed using standard plaque assay techniques. All plates were incubated at 37 ± 2°C for 48 ± 4 hours.

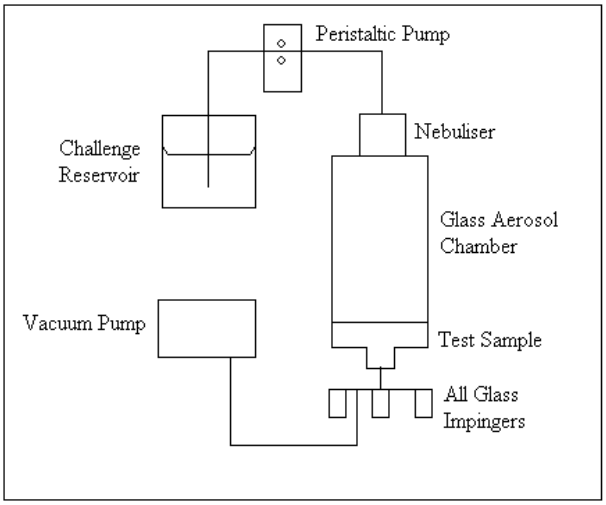

Figure 1: Experimental set up.

The Bacterial filtration efficiencies are calculated using the following equation:

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

Results

Filter	Bacterial Filtration Efficiency (%)
1691050	>99.999[1]

Table 1: Bacterial filtration efficiency of the 1691050 Pulmo-Protect filters.

Conclusion

This protocol shows the Pulmo-Protect (1691050) to be greater than 99.999% efficient against a Bacterial Aerosol Challenge.

References

1. 167887

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