



CROSS CONTAMINATION STUDY

LABORATORY NUMBER: 52659
PROCEDURE NUMBER: SOP/ARO/007B
SAMPLE SOURCE: ARC Medical
SAMPLE IDENTIFICATION: Thermo Flo I Filter™
TEST REQUESTED: Cross Contamination Study
START DATE: 03 Aug 93
COMPLETION DATE: 09 Aug 93
REPORT DATE: 11 Aug 93

PROCEDURE:

The procedure used for these tests is described in Nelson Laboratories' Procedure No. ARO/007B in accordance with MIL Spec MIL-M-36954C, 4.4.1.1.1 and 4.4.1.2.

A culture of *Staphylococcus aureus* was diluted in 1.5% peptone water to a precise concentration. The culture suspension was pumped through a 'Chicago' nebulizer at a controlled flow rate and fixed air pressure. The constant challenge delivery at a fixed air pressure formed aerosol droplets with a mean particle size (MPS) of approximately 3.0 μm . The aerosol droplets were generated in a glass aerosol chamber and drawn through a six-stage, viable particle, Andersen sampler. The collection flow rate through the test sample and Andersen sampler was maintained at 28.3 LPM (1 CFM). Test controls and test samples were challenged for a 2 minute interval.

The delivery rate of the challenge also produced a consistent level of 2200 ± 500 colony forming units (CFU) on the test control plates. A test control (no filter medium in the airstream) and reference material are included after every 7-10 test samples. The standard reference material used at Nelson Laboratories has consistently resulted in filtration efficiencies of $97.5\% \pm 1.0\%$ for the past few years.

The Andersen sampler, a sieve sampler, impinged the aerosol droplets onto the six agar plates based on the size of each droplet. The agar medium used was soybean casein digest agar (SCDA). The agar plates were incubated at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 48 hours and the colonies formed by each bacteria laden aerosol

droplet counted and converted to 'probable hit' values using the hole conversion chart provided by Andersen. These converted counts were used to determine the challenge level delivered to the test samples. The distribution ratio of colonies for each of the six agar plates were used to calculate the mean particle size (MPS) of the challenge aerosol.

RESULTS:

The filtration efficiencies were calculated as a percent difference between test sample runs and the control average using the following equation:

$$BFE \% = \frac{C - T}{C} \times 100$$

Where: C = Average of control values.
T = Count total for test material.

This test procedure produces a more severe challenge to most filtration devices than would be experienced in use. Our purpose with this procedure is not to optimize the filtration efficiency, but to consistently measure, as accurately as possible, the differences between materials, or differences in the same material over time, thereby alerting the manufacturer to significant trends or changes which can then be dealt with promptly.

Several Quality Control steps have been taken to insure and monitor our own ability to consistently perform the Bacterial Filtration Efficiency procedure:

- 1 - The test control average, determined from control runs where no filter medium is in the airstream, must be maintained at 2200 ± 500 CFU for the test to be valid, unless sponsor approves another control average.

- 2 - We include at least one reference material with every 7-10 samples tested. Statistical evaluation of these reference material data are recorded on Quality Control charts. The filtration efficiency of the reference material must be within ± 3 standard deviations of the average filtration efficiency of the reference material tested from the previous months.

- 3 - The test sample results are statistically analyzed to alert us to unusual variations which may indicate a need for retest before data are reported.

Reproducibility of the BFE procedure varies directly with test material efficiency. Therefore, our test reports express results below 90% to the nearest whole percent, between 90 to 99 to the nearest 0.1% and above 99 to the nearest 0.01%.



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TABLE OF RESULTS

UNIT NUMBER	SAMPLE IDENTIFICATION	PERCENT BFE
1	Thermo Flo I Filter™ #1	>99.99*
2	Thermo Flo I Filter™ #2	>99.99*
3	Thermo Flo I Filter™ #3	>99.99*
4	Thermo Flo I Filter™ #4	>99.99*
5	Thermo Flo I Filter™ #5	>99.99*

CONTROL AVERAGE: 1957

MEAN PARTICLE SIZE: 3.2 Microns