

Prepared For:
Cosimo Cariolo
SDI Diagnostics, Inc.
10 Hampden Drive
Easton, MA 02375

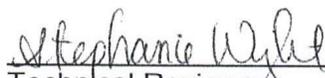
Submitted By:
Nelson Laboratories, Inc.
6280 South Redwood Road
Salt Lake City, UT 84123-6600
801-963-2600
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BACTERIAL FILTRATION EFFICIENCY – FINAL REPORT

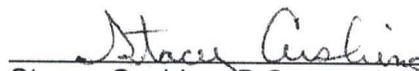
Laboratory Number:	341530
Procedure Number:	SOP/ARO/007L.1
Sample Source:	SDI Diagnostics, Inc.
Sample Identification:	Refer to Table 1 P.O. #2412
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Minimum Conditioning:	4 hours at $21 \pm 5^\circ\text{C}$ and $85 \pm 5\%$ relative humidity
Andersen Sampler Flow Rate:	28.3 L/min. (1 CFM)
Sample Received Date:	17 Aug 2006
Lab Phase Start Date:	22 Aug 2006
Lab Phase Completion Date:	31 Aug 2006
Report Issue Date:	31 Aug 2006
Results:	Refer to Table 1

This procedure is performed to determine the filtration efficiency of various materials and filtration devices using a challenge organism of *Staphylococcus aureus*.

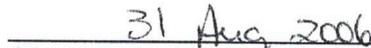
An approximately three inch diameter area was tested on the outside surface of the sample.



Technical Reviewer



Stacey Cushing, B.S.
Study Director



Study Completion Date

bav



TABLE 1. Results
Lot #001

SAMPLE IDENTIFICATION	PERCENT BFE
AstraGuard Filter – 1	>99.9%
AstraGuard Filter – 2	>99.9%

CONTROL AVERAGE: 2042 CFU

MEAN PARTICLE SIZE (MPS): 2.9 μm

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Page 1 of 2

VIRAL FILTRATION EFFICIENCY – FINAL REPORT

Laboratory Number:	341540
Procedure Number:	SOP/ARO/014J.1
Sample Source:	SDI Diagnostics, Inc.
Sample Identification:	Refer to Table 1 P.O. #2412
Deviations:	None
Statement of Uncertainty:	If applicable, available upon request
Andersen Sampler Flow Rate:	28.3 L/min (1 CFM)
Minimum Conditioning:	4 hours at 21 ± 5°C and 85 ± 5% relative humidity
Sample Received Date:	17 Aug 2006
Lab Phase Start Date:	28 Aug 2006
Lab Phase Completion Date:	01 Sep 2006
Report Issue Date:	01 Sep 2006
Results:	Refer to Table 1

This procedure is performed to determine the filtration efficiency of various materials and filtration devices using a challenge organism of the bacteriophage Φ X174.

Stephanie Wright
Technical Reviewer

Stacey Cushing
Stacey Cushing, B.S.
Study Director

05 Sep 2006
Study Completion Date

mlb



TABLE 1. Results
Lot #001

SAMPLE IDENTIFICATION	PERCENT VFE
AstraGuard Filter – 1	>99.9%
AstraGuard Filter – 2	99.9%

CONTROL AVERAGE: 2194 PFU

MEAN PARTICLE SIZE: 3.1 μm