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Validation of ScopeFlow Pure™

CUSTOMER	PRODUCT
PFE Medical Hartley House, Galveston Grove Fenton, Stoke-on-Trent Staffordshire, ST4 3PE	ScopeFlow Pure™

Author	Title	Author's Signature	Date
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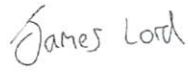
REPORT APPROVAL

Company	Name	Title	Approval Signature	Date
Andersen Caledonia Ltd	James Lord	Microbiological Services Manager		12/03/2020
PFE Medical	Rob Hartley	Managing Director		12/3/20

1.0 PURPOSE

The purpose of this procedure is to validate the efficacy of the ScopeFlow Pure™ system in preventing the contamination of the sterile water bottle employed in endoscopy procedures

2.0 RELATED DOCUMENTS

2.1 Reference Documents

- BSEN ISO/IEC 17025:2017 General requirements for the competence of testing and calibration Laboratories

2.2 Related Documents

1021	Laboratory Test Release
4174	Laboratory Test Sample Receiving Procedure
4177	Reference Organisms Procedure
4197	Selection of Laboratory Method
2001	Receive and Inspection Procedure
3137	Positive & Negative Controls for Routine Samples
3125	Temperature Record Form
3146	Laboratory Test Worksheet
4184	Temperature Monitoring of Laboratory, Incubators, Fridges & Freezer
3357	Daily microbiology control record

3.0 DEFINITIONS

- See 1010 Company Definitions

4.0 EQUIPMENT & MATERIALS

- *Geobacillus stearothermophilus ATCC* 7953 spore suspension (40% EtOH)
  Supplier: MESA Laboratories; Lot#: SSS-850; Population: 10^6 CFU per 0.1ml
- Sterile medical grade talcum powder
- Sterile 50ml syringes
- Sterile 125ml containers
- ScopeFlow Pure™ + adaptor, tubing etc.
- ScopeFlow™ + adaptor, tubing etc.
- 1 litre sterile endoscopy water bottles
- Sterile 90mm Tryptone Soya Agar (TSA) plates
- Incubator capable of 55 ± 1°C
- Sartorius filtration manifold
- Biosart Monitors 0.45µm
- Vortex mixer
- General laboratory equipment

5.0 PROCEDURE

5.1 Inoculum

5.1.1 1g sterile talcum powder was inoculated with 100µl neat spore suspension
5.1.2 The talc was mixed well and allowed to stand at room temperature until visibly dry
5.1.3 50mg of inoculated talc was added to 100ml sterile water and shaken vigorously
5.1.4 100µl of the suspension was plated onto a sterile TSA plate and incubated at 55°C for 7 days
5.1.5 The target organism was enumerated to calculate CFU/50mg talcum powder

5.2 Positive & Negative Controls

5.2.1 1x sterile TSA plate (same lot number as culture media) was incubated at 55°C for 7 days to represent the negative control
5.2.2 Section 5.1 represents a positive media control

5.3 Validation

5.3.1 The ScopeFlow Pure™ or the ScopeFlow™ was removed from the sterile barrier and attached to the sterile water bottle
5.3.2 50mg inoculated talc was aseptically introduced into the air intake tubing of the assembly
5.3.3 The talc/tubing was flushed thoroughly with air using sterile 50ml syringe
5.3.4 The tubing assembly was removed and the full volume of water (1 litre) was filtered using a Biosart Monitor
5.3.5 The membrane was placed onto a sterile TSA plate and incubated at 55°C for 7 days
5.3.6 This procedure (5.3.1 – 5.3.4) was repeated for a total of 7x replicates for each device

6.0 RESULTS

6.1 Reading of tubes

6.1.1 After 7 days incubation; all plates were removed from the incubator and the target organism was enumerated

6.1.2 All results were recorded on form 3146 laboratory test worksheet

6.2 Results

Table 1: Post-inoculation recovery from 1 litre sterile water

Replicate	Inoculum Log CFU	ScopeFlow™ Recovery CFU/litre	ScopeFlow Pure™ Recovery CFU/litre
R1	1.6 x 10^4	TNTC	Not Detected
R2	1.6 x 10^4	TNTC	Not Detected
R3	1.6 x 10^4	TNTC	Not Detected
R4	4.7 x 10^4	TNTC	Not Detected
R5	4.7 x 10^4	TNTC	Not Detected
R6	4.7 x 10^4	TNTC	Not Detected
R7	4.7 x 10^4	TNTC	Not Detected

TNTC: Too Numerous to Count

7.0 DISCUSSION

The minor variation in inoculum levels represents the actual counts obtained on each occasion of testing as detailed in section 5.1

Although the inoculum level is higher than would be expected in a procedure room, this was selected to demonstrate the efficacy of the ScopeFlow Pure™ system in removing airborne contamination and maintaining the sterility of the endoscopy water bottle.

The efficacy of the in-line filter employed in the ScopeFlow Pure™ system was validated by comparison with the ScopeFlow™ system which does not employ an in-line filter.

8.0 CONCLUSION

All 7 replicates performed using the ScopeFlow Pure™ system demonstrated zero recovery from the sterile water bottle. All 7 replicates performed using the ScopeFlow™ system demonstrated recovery TNTC. Although TNTC is technically defined as counts >300 CFU, confluent growth generally indicates much higher counts.

9.0 QUALITY CONTROL

All records are archived for a minimum of 15 years