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CONFIDENTIAL

REPORT

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Test Facility
6750 Wales Road
Northwood, OH 43619
419.666.9455

STUDY TITLE

Test of Sterility

TEST ARTICLE NAME

BI Lab testing for full cycle EO

TEST ARTICLE IDENTIFICATION

20181130/20181230/20190130

TEST ARTICLE PHYSICAL DESCRIPTION

See test specification.

TEST ARTICLE RECEIVED

June 4, 2019

SPONSOR

Jason Mercer
Kingpin Tattoo Supply
9715 International Court North
St. Petersburg, FL 33716

SUMMARY

This qualitative test was performed according to a NAMSA specification to determine if the biological indicators were sterile.

RESULTS

Bioindicator: *Bacillus atrophaeus* @10^6 BI Lot Number: RA14

Article Tested	Number of Articles Tested	Type of Medium	Incubation Temperature (Degrees C)	Number of Days Incubated	Number of Positive Articles
Spore Strip	3	SCDB – 15 mL	30-35	7	0
Spore Strip Positive Control	1	SCDB – 15 mL	30-35	1	1

SCDB = Soybean Casein Digest Broth

Test Start Date: June 4, 2019
Control Start Date: June 4, 2019

Test Termination Date: June 11, 2019
Control Termination Date: June 5, 2019

METHOD

See the attached sterility test specification T0000732-05.

APPROVAL for 11 June 2019

Lisa A. Schwalenberg, BS
Laboratory Supervisor, Sterility Assurance

Date

Results apply only to the test article tested. Any extrapolation of these data to other articles is the sponsor's responsibility. This test was performed under all applicable GMP regulations and in compliance with the ISO 13485 standard, with the test method accredited to the ISO 17025 standard.

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Test Process Specification/Document

Test:	Sterility	
Company:	NAMSA	
Customer ID:	20303	
Test Article Name:	Spore Strips/Spore Discs - nonembedded	No photograph per exception clause in NAMSA SOP_00706.
Description:	Biological indicators	

Test Method: Direct Transfer (Immersion)

Culture Medium (check all that apply):

- ☒ USP Soybean Casein Digest Broth (SCDB)
- ☐ Supplemented Soybean Casein Digest Broth (S-SCDB)
- ☐ USP Fluid Thioglycollate Medium (FTM)
- ☐ USP Dilution Fluid A (DFA)
- ☐ USP Dilution Fluid D (DFD)
- ☐ USP Sterile Water for Injection (SWFI)
- ☐ Other:

Media Container:

- ☐ 100 mL jar (~58 x 135 mm)
- ☐ 400 mL (~89 x 170 mm)
- ☐ 600 mL jar (~89 x 170 mm)
- ☐ 600 mL jar (~110 x 138 mm)
- ☐ 1000 mL (~110 x 230 mm/~105 x 230 mm)
- ☒ 10 - 20 mL tube (~25 x 150 mm)
- ☐ 30 mL tube (~25 x 150 mm)
- ☐ 80 mL tube (~25 x 300 mm)
- ☐ Bag:
- ☐ Cylinder:
- ☐ Other:

Sample Preparation: Wipe the outer package with sterile cleanroom wipe moistened with a NAMSA approved germicide. Avoid wetting through outer package.

Testing performed utilizing a ☒ primary technician or ☒ primary and secondary technician.

Test Procedure: In an ISO class 5 laminar flow hood, ☒ aseptically open sample packaging. ☐ with flamed forceps and scissors, aseptically open sample packaging.

With ☒ flamed forceps ☐ flamed forceps and scissors, grasp the sample and ☒ transfer directly to media container. ☐ cut into sections directly into the media container.

- ☐ Steritest specific preparation
  1.
- ☐ Client specific preparation
  1.
- ☐ With flamed forceps and scissors, grasp the sample and disassemble by:
  1.
- ☐ Test half the number of samples received in SCDB and the other half in FTM.
- ☐ Cut filter in half and place half the filter in SCDB and the other half in FTM.
- ☐ Test the whole filter
- ☐ Place the whole filter in SCDB and the other whole filter in FTM

☐ Test half the sample in SCDB and the other half in FTM.

☒ Test all samples received in SCDB.

☐ Test all samples received in FTM.

Incubate cultures at: ☐ 20-25°C for SCDB and 30-35°C for FTM ☐ 30-35°C ☐ 45°C ☐ 55-60°C

☐ 28-32°C ☐ 20-25°C ☒ Other Steam or *Geobacillus stearothermophilus* bioindicators at 55-60°C, Ethylene oxide or *Bacillus atrophaeus* bioindicators at 30-35°C, or incubate per manufacturer's recommendations.

Incubation time: ☐ Minimum of ☒ 7 days ☐ 10 days ☐ 14 days ☐ 30 days

☐ Other

Background Info: ☐ USP ☐ AAMI: ☐ VD max ☐ EP ☒ Other: Not Applicable

B/F Testing performed on: Date: Not Applicable

Lab Number (if test performed at NAMSA): Not Applicable

Reference(s): NAMSA Sterility test SOP series