

PEOPLE > SCIENCE > SOLUTIONS

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<sup>6</sup>

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

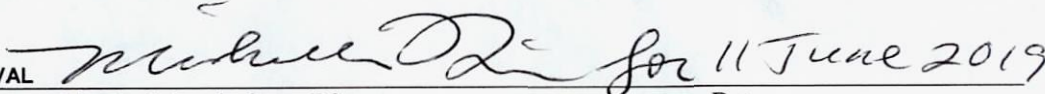
Test Termination Date: June 11, 2019

Control Start Date: June 4, 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 Date  
 Laboratory Supervisor, Sterility Assurance

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.



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

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