



CONFIDENTIAL  
REPORT

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**

20190228/20190330/20190430

**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: RA44

Article Tested	Number of Articles Tested	Type of Medium	Incubation Temperature (Degrees C)	Number of Days Incubated	Number of Positive Articles
Spore Strip	10	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 ID:

- 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

B/F Testing performed on:

DATE:

B/F Testing performed on:

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