

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