



## STERILITY TESTING

A claim of sterility must be supported by some type of testing – either testing performed during the validation of the sterilization process or testing performed on representative products after sterilization. WuXi AppTec can perform a variety of sterility tests under strict aseptic conditions, with a wide range of capabilities for handling large or complex products.

### IN THIS SECTION

Contact your WuXi AppTec Account Manager regarding these tests and other available sterility tests.

- **Biological Indicators**
  - Direct Transfer
  - Within Product
  - Self-Contained
  - Total Viable Spore Count
- **Sterility Method Suitability Test (B/F)**
  - Two Media [USP]
  - One Medium
  - Per Organism, Per Medium
- **Product Sterility Tests**
  - Product Test of Sterility (ANSI / AAMI / ISO)
  - USP Product Sterility Test
- **Liquid Sterility Tests**
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  - Membrane Filtration
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- **Inoculated Product Tests**
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**WuXi AppTec offers additional sterility testing services including:**

- Fluid Path Flush
- HIMA Pyronema Screening
- Barrier Isolator Testing [Biopharmaceutical products]

## BIOLOGICAL INDICATORS

Biological indicators (BIs) are carriers, such as a paper strip, that are inoculated with a specified level of a particular organism (typically *Bacillus* species). BIs are used to validate and/or monitor certain sterilization processes. Testing is performed according to either the BI manufacturer's recommendations or USP, ISO, or AAMI requirements.

<b>1201000</b> – Laminar Flow Hood / Cleanroom	Individual spore strips are transferred from their primary package to SCDM and incubated for recovery of the indicator organism.
<b>1204000</b> – Laminar Flow Hood Only	<b>SAMPLE REQUIREMENTS</b> Spore strips (Client-provided positive control recommended.)
<b>Biological Indicator Direct Transfer</b>	<b>SHIPPING</b> Overnight air. Protect from temperature extremes.
	<b>TURNAROUND TIME</b> 7-9 days, unless directed otherwise by client
<b>1203000</b> – Laminar Flow Hood / Cleanroom	Spore strips that have been placed within a product or its package are retrieved from the product or package and transferred to SCDM for recovery of the indicator organism.
<b>1205000</b> – Laminar Flow Hood Only	<b>SAMPLE REQUIREMENTS</b> Spore strips (Client-provided positive control recommended.)
<b>Biological Indicator Within Product</b>	<b>SHIPPING</b> Overnight air. Protect from temperature extremes.
	<b>TURNAROUND TIME</b> 7-9 days, unless directed otherwise by client
<b>120080</b> Self-Contained	Self-contained BIs that have been placed within a product or its package are removed, activated and incubated for the recovery of the indicator organism.
<b>120081</b> Within Product	<b>SAMPLE REQUIREMENTS</b> Spore strips (Client-provided positive control recommended.)
<b>Biological Indicator – Self-Contained</b>	<b>SHIPPING</b> Overnight air. Protect from temperature extremes.
	<b>TURNAROUND TIME</b> Per BI manufacturer or as directed by client
<b>190300</b> 3 Sample Composite	Before using a new lot of BIs for sterilization load monitoring, the average population per unit should be independently confirmed per USP regulations.
<b>120200</b> Single Sample	<b>SAMPLE REQUIREMENTS</b> Dependent on selected test.
<b>Biological Indicator – Total Viable Spore Count</b>	<b>SHIPPING</b> Overnight air. Protect from temperature extremes.
	<b>TURNAROUND TIME</b> 3-5 days

## STERILITY METHOD SUITABILITY TEST (B/F)

The Sterility Method Suitability Test (B/F) is necessary to demonstrate that there are no substances produced by the test materials (in the specified volume of test medium) that would cause inhibition of bacterial or fungal growth in a sterility test (i.e., a false negative interpretation). Testing is performed by inoculating sterility test samples in media with low levels of selected organisms to ensure growth. The parameters for the Sterility Method Suitability Test (B/F) are based on USP, ISO, CFR or AAMI requirements.

Sample device or material in the sterility test medium is tested for growth inhibition using the current USP organisms for Soybean-Casein Digest Medium (SCDM) and Fluid Thioglycollate Medium (FTM). (Additional organisms available upon request.)

**SAMPLE REQUIREMENTS**      6 sterile product samples

**TURNAROUND TIME**            7-10 days

**190105** Immersion

**190104** Membrane Filtration

**Sterility Method Suitability  
Test (B/F) – Two Media [USP]**

Sample device or material in the sterility test medium is tested for growth inhibition using the current USP organisms for SCDM. This method is used when only SCDM (TSB) is used for sterility testing products. (Additional organisms available upon request.)

**SAMPLE REQUIREMENTS**      3 sterile product samples

**TURNAROUND TIME**            7-10 days

**190106** Immersion

**190107** Membrane Filtration

**Sterility Method Suitability  
Test (B/F) – One Medium**

Sample device or material in the sterility test medium is tested for growth inhibition using selected organisms in specified media.

**SAMPLE REQUIREMENTS**      1 sterile product sample per organism per medium

**TURNAROUND TIME**            7-10 days

**190111** Immersion

**190112** Membrane Filtration

**Sterility Method Suitability  
Test (B/F) –  
Per Organism, Per Medium**

## PRODUCT STERILITY TESTS

Product sterility testing is typically performed in the validation of sterilization processes, and, in some cases, for monitoring sterilization cycles. Sterility tests involve total immersion, membrane filtration, or a rinse method. The number of samples tested, the growth medium used, and the incubation conditions are based on the particular standard involved – USP, AAMI/ISO or FDA/CFR.

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### Product Test of Sterility (ANSI / AAMI / ISO)

**1103010**

Extra Small [≤ 100 mL of media]

**1103000**

Small [100 and 200 mL of media]

**1104000**

Medium [300 and 400 mL of media]

**1105000**

Large [500 and 600 mL of media]

**1106000**

Extra Large [800 and 1000 mL of media]

**1106020**

Jumbo [1200 and 1500 mL of media]

**1106050**

Extra Jumbo [2000 mL of media]

This test is used in sterilization validations (e.g., radiation, EO). Products are tested in Soybean-Casein Digest Medium (SCDM) at 30° ± 2°C for 14 days.

**SAMPLE REQUIREMENTS** Dependent on method used  
(e.g., AAMI 11137 Method 1 requires 100 samples,  
VDmax requires 10 samples)

**TURNAROUND TIME** 14-17 days

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### USP Product Sterility Test

**1220010**

Extra Small [≤ 100 mL of media]

**1220000**

Small [100 and 200 mL of media]

**1226000**

Medium [300 and 400 mL of media]

**1227000**

Large [500 and 600 mL of media]

**1228000**

Extra Large [800 and 1000 mL of media]

**1228010**

Jumbo [1200 and 1500 mL of media]

**1128010**

Extra Jumbo [2000 mL of media]

This testing is used to monitor sterilization loads. Products are tested in both Soybean-Casein Digest Medium (SCDM) and Fluid Thioglycollate Medium (FTM) per USP guidelines.

**SAMPLE REQUIREMENTS** Up to 40 product samples

**TURNAROUND TIME** 14-17 days

This test is typically designed for aliquots ≤100 mL. Aliquot is transferred directly into the sterility test medium.

**SAMPLE REQUIREMENTS** Sample requirement is dependent upon lot size.

**TURNAROUND TIME** 14-17 days

*For Test Codes, refer to Product Sterility Tests on Page G-4*

**Liquid Sterility Test – Direct Transfer**

Sterility testing is performed using sterile filtration. Liquid sample is filtered and filter is placed in a single medium (typically SCDM).

**SAMPLE REQUIREMENTS** Sample requirement is dependent upon lot size.

**TURNAROUND TIME** 14-17 days

**1223000** < 100 mL  
**1225000** 100-800 mL  
**1231000** > 800 mL

**Liquid Sterility Test – Membrane Filtration**

Sterility testing is performed using sterile filtration. Liquid sample is filtered and filter is halved – or, alternately, liquid is halved and two filters are used – and placed in two media (typically SCDM and FTM).

**SAMPLE REQUIREMENTS** Sample requirement is dependent upon lot size.

**TURNAROUND TIME** 14-17 days

**122310** < 100 mL  
**122510** 100-800 mL  
**123110** >800 mL

**USP Liquid Sterility Test – Membrane Filtration**

Sterility testing is performed by filling a device with liquid media and incubating the filled device.

**SAMPLE REQUIREMENTS** Sample requirement is dependent upon lot size.

**TURNAROUND TIME** 14-17 days

**1229500** ≤ 200 mL  
**1229600** 300-700 mL  
**1229650** ≥ 800 mL

**Fluid Path Fill**

## INOCULATED PRODUCT TESTS

Inoculated product consists of actual devices or materials that have been inoculated with a specified level of a liquid biological indicator (BI) suspension. Inoculated products are used to validate and / or monitor certain sterilization processes. Testing is performed by product immersion using either the BI manufacturer's parameters or those found in USP, ISO or AAMI standards.

**1902000** *B. atrophaeus*  
**1902100** *G. stearothermophilus*

Devices are inoculated (usually in a location determined as most difficult to sterilize) with an indicator organism appropriate to the sterilization system in use.

### Product Inoculation

**SAMPLE REQUIREMENTS** No minimum.

**TURNAROUND TIME** 2-5 days

*Indicate required population and sterilization method.*

### Inoculated Product Sterility

Product that has been inoculated with a liquid spore solution and exposed to a sterilization process is tested in SCDM to detect surviving organisms.

**1221010**  
Extra Small [ $\leq$  100 mL of media]

**SAMPLE REQUIREMENTS** Dependent on method and sterilizer volume.

**TURNAROUND TIME** 7-10 days (unless directed otherwise by client)

**1221000**  
Small [100 and 200 mL of media]

**1221210**  
Medium [300 and 400 mL of media]

**1221410**  
Large [500 and 600 mL of media]

**1221610**  
Extra Large [800 and 1000 mL of media]

**1221620**  
Jumbo [1200 and 1500 mL of media]

**1221630**  
Extra Jumbo [2000 mL of media]

**190501**

Liquid samples, including spore suspensions and inoculated liquids, are enumerated to confirm spore population.

### Liquid Sample Population Confirmation

**SAMPLE REQUIREMENTS** Dependent upon expected population.

**TURNAROUND TIME** 3-5 days