

Data Sheet

Sterility Testing Media and Rinse Fluids

Easy-to-use, reliable, sterile products to ensure accurate sterility testing

Easy to use with all Steritest™ EZ devices

A non-coring, large diameter septum area is easy to pierce for operator safety and productivity.

Reduce the risk of cross contamination and growth inhibition

In the screw cap version, the **rimless cap** design (see picture) minimizes the risks of cross contamination and optimizes the disinfection procedures, avoiding the risk of inhibition from disinfectant residuals. The **crimp cap** version provides a tamperproof closure to ensure a high level of security (see picture p. 2).

Test with the highest level of confidence

Manufactured in ISO® 9001 controlled environments where each lot is certified for pH, sterility, and growth promotion using ATCC® strains specified by the USP/EP/JP as well as strict Merck Millipore QC procedures.



Applications

- Sterility testing (filtration and direct inoculation)
- Bioburden testing

Multiple configurations and volumes

Whether the product is filterable or not, our sterility media and rinse fluids come in multiple configurations and volumes

Fluid A

Suitable as a general rinse buffer, and **compatible with most samples**. Excellent for dissolving or diluting samples, reconstituting commercial microorganisms, or as a transport medium for microorganisms.

Fluid K

Suitable for testing specimens that contain **petrolatum, oils, or oily solutions**. Excellent for rinsing pathways of medical devices, and for samples that are "difficult" to filter or dissolve.

Fluid D

Suitable for testing specimens that contain **lecithin or oil**, and compatible with most **antibiotics**. Excellent for rinsing sterile pathways of devices, and typically needed for rinse method testing of medical devices.

Fluid Thioglycollate Medium

is primarily intended for the detection of **anaerobic bacteria**. However, it also enables aerobic bacterial detection. This medium is used for sterility testing by membrane filtration or direct inoculation as described in the USP, EP and JP.



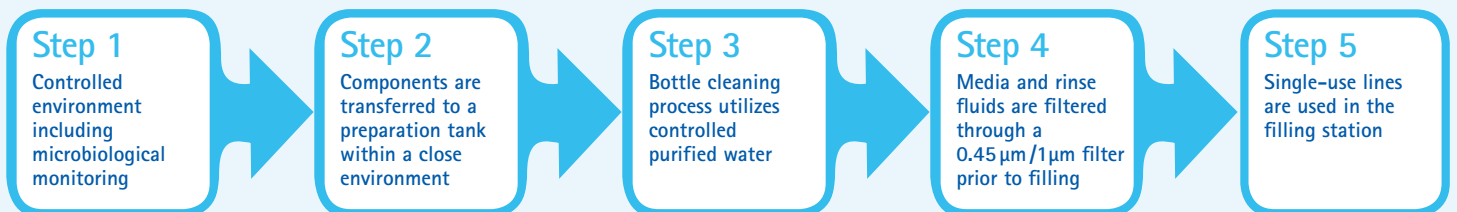
Soybean-Casein Digest Medium

(Trypase Soy Broth) suitable for the culture of both **fungi and aerobic bacteria**. This medium is used for sterility testing by membrane filtration or by direct inoculation. It is also used as pre-enrichment broth for non sterile products. Compliant to the USP, EP and JP.

Clear Thioglycollate Medium has the same growth promotion properties as the standard FTM. The alternative formulation, compliant to pharmacopeia recommendations, brings **extra visual clarity** versus the FTM which has a slight turbidity or haze. A high visual clarity medium is preferred by many users, when compared with the hazy or opalescent appearance of FTM.

Septum bottles with either crimp cap closure (left) or rimless cap closure (center), and also tubes (right) are available.

The Merck Millipore manufacturing steps ensure reliable testing



Increased test method reliability with the Double Packed Sterilized Media and Fluids

- Streamline and optimize your cleaning procedures
- Minimize the risk of cross contamination and false results
- Reduce the bioburden load on your testing environment
- Secure an efficient decontamination of isolator chambers



Specifications

Description	pH at room temperature*	Storage**	QC Organisms	Formula Screw cap and double pack media
Trypase Soy Broth (TSB)	7.3 ±0.2	2–25 °C	<i>Staphylococcus aureus</i> ATCC 6538, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Bacillus subtilis</i> ATCC 6633, <i>Candida albicans</i> ATCC 10231, <i>Aspergillus brasiliensis</i> ATCC 16404, <i>Geobacillus stearothermophilus</i> ATCC 7953(1)	For 1 L of purified water: Casein peptone 17.0 g, Soy peptone 3.0 g, Sodium Chloride 5.0 g, Dibasic potassium phosphate 2.5 g, Dextrose Monohydrate/Anhydrous 2.5/2.3 g
Fluid Thioglycollate Medium (FTM)	7.1 ±0.2	2–25 °C	<i>Clostridium sporogenes</i> ATCC 19404, <i>Staphylococcus aureus</i> ATCC 6538, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Clostridium sporogenes</i> ATCC 11437 (2)	For 1 L of purified water: Casein peptone 15.0 g, L-Cystine 0.5 g, Monohydrated/Anhydrous dextrose 5.5/5.0 g, Yeast extract 5.0 g, Sodium Chloride 2.5 g, Sodium thioglycollate 0.5 g, or Thioglycolic acid 0.3 mL, Resazurin 0.001 g, Agar 0.75 g
Clear Thioglycollate Medium (CTM)	7.1 ±0.2	2–25 °C	<i>Clostridium sporogenes</i> ATCC 19404, <i>Staphylococcus aureus</i> ATCC 6538, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Clostridium sporogenes</i> ATCC 11437 (2)	For 1 L of purified water: Casein peptone 15.0 g, L-Cystine 0.5 g, Monohydrated/Anhydrous dextrose 5.5/5.0 g, Yeast extract 5.0 g, Sodium Chloride 2.5 g, Sodium thioglycollate 0.5 g, or Thioglycolic acid 0.3 mL, Resazurin 0.001 g, Synthetic Agar
USP Rinse Fluid A	7.1 ±0.2	2–25 °C	<i>Staphylococcus aureus</i> ATCC 6538, <i>Bacillus subtilis</i> ATCC 6633, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Candida albicans</i> ATCC 10231, <i>Escherichia coli</i> ATCC 8739 (2), <i>Clostridium sporogenes</i> ATCC 19404(3), <i>Aspergillus brasiliensis</i> ATCC 16404 (3),	Per liter of purified water: Meat peptone (peptic digest of animal tissue) 1.0 g
USP Rinse Fluid D	7.1 ±0.2	2–25 °C	<i>Staphylococcus aureus</i> ATCC 6538, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Candida albicans</i> ATCC 10231, <i>Bacillus subtilis</i> ATCC 6633 (3), <i>Aspergillus brasiliensis</i> ATCC 16404 (3), <i>Clostridium sporogenes</i> ATCC 19404 (3)	Per liter of purified water: Meat peptone (peptic digest of animal tissue) 1.0 g, Polysorbate 80 1.0 mL
USP Rinse Fluid K	6.9 ±0.2	2–25 °C (2) 15–25 °C (3)	<i>Staphylococcus aureus</i> ATCC 6538, <i>Bacillus subtilis</i> ATCC 6633, <i>Pseudomonas aeruginosa</i> ATCC 9027, <i>Candida albicans</i> ATCC 10231, <i>Clostridium sporogenes</i> ATCC 19404, <i>Aspergillus brasiliensis</i> ATCC 16404 (3),	Per liter of purified water: Meat peptone (peptic digest of animal tissue) 5.0 g, Beef Extract 3.0 g, Polysorbate 80 10.0 g

* Measured after product sterilization

** Do not store in direct sunlight

(1) Only for tubes

(2) Only for bottles with crimp cap and for tubes

(3) Only for products with Screw cap with septum and double packed media

Pharmacopeia references

- European Pharmacopeia, 2.6.1 Sterility, 2.6.12 Et 2.6.13. Microbiological examination of non sterile products.
- United States Pharmacopeia, <71> Sterility tests, <61> Et <62> Microbiological examination of non sterile products; <1227> Validation of microbial recovery from pharmacopeial articles.
- Japanese Pharmacopeia, 4.06 Sterility test.

Ordering Information

Medium/rinse solution bottle	Closure	Volume (mL)	Qty	Catalog No.
Trypase Soy Broth (Soybean-Casein Digest Medium)	Screw cap with septum	100	12	STBMTSB12
	Screw cap with septum – double packed	100	12	STBMTSB12DP
	Crimp cap with septum	100	10	1.46317.0010
	Tube	9	20	1.46432.0020
	Tube	9	100	1.46432.0100
Fluid Thioglycollate Medium	Screw cap with septum	100	12	STBMFTM12
	Screw cap with septum – double packed	100	12	STBMFTM12DP
	Crimp cap with septum	100	10	1.46406.0010
	Tube	9	20	1.46220.0020
	Tube	9	100	1.46220.0100
Clear Fluid Thioglycollate Medium	Screw cap with septum	100	12	STBMCTM12
	Screw cap with septum – double packed	100	12	STBMCTM12DP
	Crimp cap with septum	100	10	1.46456.0010
USP Rinse Fluid A	Screw cap with septum	100	12	STBMRFA12
	Screw cap with septum – double packed	100	12	STBMRFA12DP
	Crimp cap with septum	100	10	1.46470.0010
	Screw cap with septum	300	4	STBMRFA34
	Crimp cap with septum	300	6	1.46415.0006
	Screw cap with septum	600	4	STBMRFA64
	Crimp cap with septum	600	6	Contact a sales representative
USP Rinse Fluid D	Screw cap with septum	300	4	STBMRFD34
	Crimp cap with Septum	300	6	1.46483.0006
USP Rinse Fluid K	Screw cap with septum	300	4	STBMRFK34
	Crimp cap with Septum	300	6	Contact a sales representative
Recommended Accessories				
Sterile vent needles for liquid media growth promotion tests			25	TEFG02525



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