

Sterility Testing

Sterility Testing is a crucial step in quality control that must be taken to ensure the safety of products in the cosmetic, pharmaceutical, medical device, and diagnostic equipment industries.

In the United States Pharmacopoeia, methods for Sterility testing (<71>), Microbial Evaluation of Clean Rooms (<116>) and Pharmaceutical Compounding-Sterile Preparations (<797>) all outline the need for validated sterility procedures including environmental monitoring. While there are some commonalities among the products used for these various testing methods, it is critical to validate each chosen methodology to avoid costly false positives and loss of critical product.



Checklist for Sterility Testing

Sampling and Growth

- Fluid Thioglycollate Medium
- Tryptic Soy Broth (TSB)
- Animal-free alternatives
- Cold Filterable options

Environmental Monitoring

- Contact Plates
- Settling Plates
- Environmental Swabs

Positive Control Organisms

- Staphylococcus aureus* ATCC® 6538™*
- Bacillus subtilis* ATCC® 6633™*
- Pseudomonas aeruginosa* ATCC® 9027™*
- Clostridium sporogenes* ATCC® 19404™*
- Candida albicans* ATCC® 10231™*
- Aspergillus niger* ATCC® 16404™*



Diluting/Rinsing Fluids

- Fluid A
- Fluid D
- Fluid K



Mycoplasma Transport & Isolation

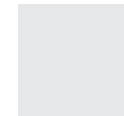
- A-8 Agar
- A-8 Agar, Selective
- SP4 Glucose Agar/Broth
- PPLO Agar/Broth
- Mycoplasma Agar/Broth
- Mycoplasma Broth Base, Frey
- Collection and Transport System

* ATCC Licensed Derivative

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Validate & Verify with a comprehensive portfolio of Remel Products

Remel has the media you need for Sterility Testing as indicated in the Pharmacopeia (USP <71>, <797>, <1116>). Additional custom options are available upon request for your specific testing needs. Products listed are representative only, please contact us at 800-255-6730 or visit www.remel.com for a complete list.



Sampling and Growth

Product	REF	Type/Fill
Fluid Thioglycollate Medium	R07174	10ml tube, 20/pk
	R112646	100ml bottle w/septum
	R112642	500ml bottle w/septum
	R112641	100 ml serum bottle
	R112640	100ml wide mouth bottle
Fluid Thioglycollate Medium, Dehydrated	R453451	100g
	R453452	500g
	R453454	2.5kg
Tryptic Soy Broth (TSB)	R117834	10ml tube , 20/pk
	R112745	100ml bottle w/septum
	R112732	500ml bottle w/septum
	R112740	1000ml bottle
	R112731	100ml serum bottle
	R112730	100ml wide mouth bottle
Vegetable Peptone Broth (VPB)	VG0101B	500g
	VG0101T	5kg
Cold filterable TSB	CM1065B	500g
	CM1065T	5kg
Cold filterable Vegetable Peptone Broth	VG0104B	500g
	VG0104T	5kg

Diluting/Rinsing Fluids

Product	REF	Type/Fill
Fluid A	R112312	300ml bottle w/septum
	R112314	1000ml polypropylene bottle
	R112490	100ml serum bottle
	R112311	300ml serum bottle
Fluid D	R112323	100ml bottle
	R112322	300ml bottle w/septum
	R112321	300ml serum bottle
	R112325	100ml wide mouth bottle
Fluid K	R112332	100ml serum bottle

Environmental Monitoring

Category	Product	REF	Type/Fill
Contact Plates*	Sterile D/E Neutralizing Agar	R111803	10/pk Double + bag
		R111804	100/pk Double + bag
	Sterile Sabouraud Dextrose Agar w/Lecithin	R111805	10/pk Double + bag
		R111806	100/pk Double + bag
	Sterile Tryptic Soy Agar w/Lecithin, Polysorbate 80	R111800	10/pk Double + bag
		R111802	100/pk Double + bag
Settling Plates*	Sterile Tryptic Soy Agar	R111870	10/pk Double + bag
		R111872	100/pk Double + bag
Swabs	Sani-Cult™	R723141	5ml, 100/pk

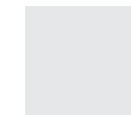
(*non-irradiated plates also available in a variety of formulations)

Mycoplasma Transport & Isolation

Product	REF	Type/Fill
MicroTest™ M4®	R12502	3ml/tube, 12/pk
	R12500	3ml tube, 72/pk
MicroTest™ M5®	R12516	3ml tube, 12/pk
	R12515	3ml tube, 72/pk
MicroTest™ M6®	R12535	1.5ml tube, 12/pk
	R12530	1.5ml tube, 72/pk
10B Arginine Broth	R20305	1.8ml tube (15x45mm)
A-8 Agar	R20205	10/pk monoplate
A-8 Agar, selective	R20204	10/pk monoplate
SP4 Glucose Agar/Broth	R20276	10/pk monoplate
	R112585	100ml clear square bottle
PPLO Agar/Broth	R20261	10/pk monoplate
	R20260	15x60mm plate
	R20360	5ml tube
Mycoplasma Broth Base	R454172	500g
Mycoplasma Agar Base	CM0401B	500g
Mycoplasma Broth, Frey	R454162	500g

Positive Control Organisms

Product	REF	Type/Fill
<i>Staphylococcus aureus</i> ATCC® 6538™*	R4737016	10 tests/kit
	R4717016	100 tests/kit
<i>Bacillus subtilis</i> ATCC® 6633™*	R4731221	10 tests/kit
	R4711221	100 tests/kit
<i>Pseudomonas aeruginosa</i> ATCC® 9027™*	R4735210	10 tests/kit
	R4715210	100 tests/kit
<i>Clostridium sporogenes</i> ATCC® 19404™*	R4711700	100 tests/kit
<i>Candida albicans</i> ATCC® 10231™*	R4731503	10 tests/kit
	R4711503	100 tests/kit
<i>Aspergillus niger</i> ATCC® 16404™*	R4731100	10 tests/kit
	R4711100	100 tests/kit



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