

Microbial limits testing

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Simple and reliable

There is a need for all companies utilizing Microbial Limits Testing (MLT) to revalidate all products and raw materials under the harmonized MLT methods. This requires additional products with specific ingredients in itemized amounts and methods not seen in previous chapters.

Thermo Fisher Scientific has all of the media you need for the harmonized MLT methods. The media have been formulated to meet or exceed harmonized USP specifications while ensuring consistent, reproducible results and growth performance, and minimizing the risk of costly false positives.

Checklist for harmonized microbial limits testing:

Harmonized microbial limits test enumeration agars and MLT dilution buffers

Agar	Incubation parameters	REF	Type/fill
Phosphate Buffer Butterfield's		R23700	90 mL 72 bottles/PK
		R23701	99 mL 72 bottles/PK
TSA (Soybean – Casein Digest Agar)	30-35°C not more than 3 days	R112700	500 mL
		R455002	500 g
TSB (Soybean – Casein Digest Broth)	30-35°C not more than 3 days	R112728	500 mL
		R455052	500 g
Potato Dextrose Agar	20-25°C not more than 5 days	R112534	200 mL
		R112535	500 mL
		R454312	500 g
Sabouraud Dextrose Agar 5.6	20-25°C not more than 5 days	R112551	500 mL
		R454462	500 g

Harmonized microbial limits test specified microorganisms

ALL of the specified ATCC® microorganisms needed to meet or exceed harmonized USP specifications are available.

Product	REF	Type/fill
<i>Staphylococcus aureus</i> – ATCC® 6538*	R4737016	10 test/kit
	R4717016	100 tests/kit
<i>Escherichia coli</i> – ATCC® 8739*	R4737085	10 test/kit
	R4717085	100 tests/kit
<i>Pseudomonas aeruginosa</i> – ATCC® 9027*	R4735210	10 test/kit
	R4715210	100 tests/kit
<i>Salmonella enterica</i> serovar Typhimurium – ATCC® 14028*	R4716000	100 tests/kit
<i>Bacillus subtilis</i> – ATCC® 6633*	R4731221	10 test/kit
	R4711221	100 tests/kit
<i>Candida albicans</i> – ATCC® 10231*	R4731503	10 test/kit
	R4711503	100 tests/kit
<i>Aspergillus brasiliensis</i> – ATCC® 16404*	R4731100	10 test/kit
	R4711100	100 tests/kit

Harmonized microbial limits test media

Test	Medium	Property	REF	Type/fill
Test for bile-tolerant gram-negative bacteria	Violet Red Bile Glucose Agar	Nutritive & Indicative for <i>Escherichia coli</i> and <i>Pseudomonas aeruginosa</i>	R110097	15x100 mm plate
			R455302	500 g
Test for <i>Escherichia coli</i>	MacConkey Broth	Nutritive for <i>Escherichia coli</i> and selective for <i>Staphylococcus aureus</i>	R112456	100 mL bottle
			R061336	5 mL tube
			R453822	500 g
	MacConkey Agar	Nutritive & indicative for <i>Escherichia coli</i>	R09542	10 mL tube
			R01550	Monoplate
			R453802	500 g
Test for <i>Salmonella enterica</i> serovar typhimurium	Rappaport Vassiliadis Salmonella Enrichment Broth	Nutritive for <i>Salmonella enterica</i> serovar Typhimurium	R117661	10 mL tube
			R455432	500 g
	XLD Agar	Nutritive & Indicative for <i>Salmonella enterica</i> serovar typhimurium	R01980	Monoplate
			R459902	500 g
Test for <i>Pseudomonas aeruginosa</i>	Cetrimide Agar	Nutritive for <i>Pseudomonas aeruginosa</i> and selective for <i>Escherichia coli</i>	R110100	Monoplate
			R112040	200 mL bottle
			R452802	500 g
Test for <i>Staphylococcus aureus</i>	Mannitol Salt Agar	Nutritive for <i>Staphylococcus aureus</i> and selective for <i>Escherichia coli</i>	R01580	Monoplate
			R453902	500 g
Test for <i>Clostridia</i>	Reinforced Medium for Clostridia	Nutritive for <i>Clostridium sporogenes</i>	R112548	100 mL bottle
			R455402	500 g
	Columbia Agar Medium	Nutritive for <i>Clostridium sporogenes</i>	R110165	Monoplate
			R455412	500 g
Test for <i>Candida albicans</i>	Sabouraud Dextrose Broth	Nutritive for <i>Candida albicans</i>	R112558	990 mL bottle
			R112554	100 mL bottle
	Sabouraud Dextrose Agar 5.6	Nutritive & indicative for <i>Candida albicans</i>	R112562	100 mL bottle
			R01768	Monoplate
			R112551	500 mL
			R454462	500 g



The United States Pharmacopeia (USP) and the European Pharmacopoeia (EP) have been harmonized so that each utilizes identical test methodologies.

The most obvious change for the USP is that there are now two chapters dealing with Microbial Limits: USP<61> Microbial Examination of Nonsterile Products: Microbial Enumeration Tests, and USP<62> Microbiological Examination of Nonsterile Products: Tests for Specified Organisms.

Let us support your laboratory in implementing new protocols that ensure effective, efficient, ongoing compliance with harmonized methods.

Learn more at thermofisher.com/pharmamicrobiology

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