Celltechgen Laboratory

2024 Microbiology Testing Services & Price List

Test Name	Test Code	USP	Description	TRD (day)	Amount of Sample	Price
Antimicrobial Effectiveness (USP)	AME	<51>	Test if the antimicrobial agent in the formulation is effective. Required for <795> <797> multi-dose formulations.	35	60 ml	$1,200
Antimicrobial Effectiveness Antimicrobial Drugs				35	70mL or 70g	$3,300
Antimicrobial Effectiveness Method Suitability				10		$550
Antimicrobial Effectiveness Method Suitability (Antimicrobial Drugs)				10		$1,650
Biological Indicator Spore Count (USP)	BIS	<55>	Bacterial spores in a growth medium or inoculated to a spore or paper strip, which are sterilized for the drug or medical device, recovered and then counted for survivors.	10	1 strip or ampoule per media jar	$400
Biological Indicator Incubation (Spore Strips)				10	1 strip per media jar	$85
Biological Indicator Incubation (Ampoules)				10	1 ampoule per media jar	$60
Biological Indicator Incubation (Dry Ampoules)				10	1 ampoule per media jar	$85
Endotoxin USP <85>	EDT	<85>	Checks the levels of bacterial endotoxin in finished product. Required for <797> batch release. Validation of the Endotoxin test method.	3	1mL or 100mg	$120
Method Validation				7	5mL or 250mg	$480

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Endotoxin USP <161>(Medical Device)		<161>	Bacterial endotoxin tests (BETs) follow the Limulus Amoebocyte Lysate (LAL) testing procedures guided by USP 85			
<1L of LAL reagent				5	10 articles	$280
1L to 2L				5	10 articles	$420
>2L to 3L				5	10 articles	$535
>3L to 5L				5	10 articles	$650
>5L				N/A	10 articles	quote
Endotoxin Method Validation USP <161> (Medical Device)		<161>	Bacterial endotoxin tests (BETs) follow the Limulus Amoebocyte Lysate (LAL) testing procedures guided by USP 85			
<1L of LAL reagent				10	1 article	$550
1L to 2L				10	1 article	$700
>2L to 3L				10	1 article	$815
>3L to 5L				10	1 article	$935
>5L				Quote		
Environmental Plate	EMP	<797>	Incubation and enumeration by <797>. Microbial Identification required if limits are exceeded.	10	1 plate	$50
Environmental Swab	EMS	<797>	Processed day of receipt. Microbial Identification required if limits are exceeded.	10	1 swab	$65
Fungal (USP)	FNG	<71>	Check for fungal contamination.	14-18	1 container	$85
Fungal (Method Suitability)				10	5mL or 5g	$110
Fungal (Method Suitability Library Verification)				3	N/A	$60
Gloved Fingertip Testing	GFT	<797>	Incubation and enumeration by <797>, which requires one hand per competency evaluation.	10	1 plate	$50
Tests for Burkholderia cepaci complex (USP)	BCC	<60>	Check the possible presence of Burkholderia Cepacia Complex in product.	10	10 ml	$200
Tests for Burkholderia cepacia complex (Method Suitability)				15	2mL or 2g	$1,400
Tests for Burkholderia cepacia complex			Check the level at which a particular antimicrobial drug inhibits the growth of Burkholderia Cepacia.	10	2mL or 2g	$550

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(Antimicrobial Active)						
Tests for Burkholderia cepacia complex (Method Suitability (Antimicrobial Active))				15	N/A	$2,800
Tests for Specified Microorganisms Dietary Supplements (USP)	SMDS	<2022>	Determine the presence or absence of a specified list of microorganisms within nutritional and dietary supplements: Clostridium species, Escherichia coli, Salmonella species, and/or Staphylococcus aureus.	15	N/A	$130
Tests for Specified Microorganisms Dietary Supplements (Method Suitability)				15	N/A	$230
Microbial Enumeration Test (USP)	MET	<61>	Quantitative enumeration of mesophilic bacteria and fungi that may grow under aerobic conditions.	10	N/A	$275
Microbial Enumeration Test (Method Suitability)				15	12mL or 12g	$275
Microbial Enumeration Test (Antimicrobial Active)			Check the level at which a particular antimicrobial inhibits the growth of a specific microbial strain.	10	12mL or 12g	$550
Microbial Enumeration Test (Method Suitability (Antimicrobial Active))				15	12mL or 12g	$1,420
Microbial Enumeration Test Dietary Supplements (USP)		<2021>	Quantitative test (plate count) to enumerate bacteria and fungi that may be present in non-sterile Nutritional and Dietary supplements. The tests performed are Total Aerobic Microbial Count (TAMC) and Total Yeast and Mold Count (TYMC).	15	N/A	$275
Microbial Enumeration Test Dietary Supplements (Aerobic Microbial Count Method Suitability)				15	12mL or 12g	$475
Microbial Enumeration Test Dietary Supplements (Yeast and Mold Count Method Suitability)				15	12mL or 12g	$250
Tests for Specified Microorganisms USP	SMG	<62>	This Test consists of an initial enrichment of the sample in an appropriate neutralizer broth, and then streaking	10	2mL or 2g	$130

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Candida albicans			the enriched sample onto selective media for determination of the presence or absence of the specified objectionable microorganisms. Tests for Specified Microorganisms (Antimicrobial Active) measures the level at which a particular antimicrobial inhibits the growth of a specific microbial strain.	10	2mL or 2g	$130
Clostridia sporogenes				10	4mL or 4g	$130
Escherichia coli				10	2mL or 2g	$130
Pseudomonas aeruginosa				10	2mL or 2g	$130
Salmonella enterica				10	12mL or 12g	$130
Staphylococcus aureus				10	2mL or 2g	$130
Bile-Tolerant, Gram-Negative				10	2mL or 2g	$130
Tests for Specified Microorganisms (Antimicrobial Active)				10	2mL or 2g	$230
Method Suitability				15	2mL or 2g	$230
Method Suitability (Antimicrobial Active)				15	2mL or 2g	$350
Media Fill (≤100 mL per container)	MDF	<797>	This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding according to <797>.	14	1-20 Containers	$100
Media Fill (>100 mL per container)				14	1-20 Containers	$200
Gram Stain	GMS	<1113>	The Gram stain is used to determine bacteria as Gram positive or Gram negative based on the chemical and physical properties	3	Plate or vial	$50
Growth Promotion (Contact Celltechgen to request unlisted organisms)						
Aspergillus brasiliensis	GWP	<797>	Th test (GPT) is performed by inoculating new batches of media with a small number of microorganisms and compare with prior tested or approved media batches.	10	10mL or 1 plate	$70
Bacillus subtilis				10		$70
Candida albicans				10		$70
Clostridia sporogenes				10		$70
Escherichia coli				10		$70
Pseudomonas aeruginosa				10		$70
Salmonella enterica				10		$70
Staphylococcus aureus				10		$70

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Pooling				10		$70
Mycoplasma	MPT	<63>	Check specifically for presence of Mycoplasma contamination.		10mL or 1 plate	
1-10 samples				3		$420
11-100 samples				3		$280
Feasibility Study				N/A		Quote
Method Validation				N/A		Quote
Sterility USP <71>	STL	<71>				
Sterility			Test for microbial contamination of sterile products. Must be compliant with <71> batch sizes. Required for <797> batch release.	14-18	1 container	$130
Sterility				14-18	2-5 containers	$160
Sterility				14-18	6-10 containers	$175
Sterility				14-18	11+ containers	$205
Sterility				14-18	3 x USP batch	$500
Method Suitability			Verify the suitability of the sterility testing method. Required for <797> compliance.	10	3x certification	$550
Method Suitability (Antimicrobial Active/Metered Devices)				10	N/A	$840
Method Suitability Library Verification				3	N/A	$60
Rapid Sterility	RDS	USP <71><1071><1223>	Rapid test for microbial contamination of sterile products. Must be compliant with <71> batch sizes. Required for <797> batch release.	5	1 container	$210
Rapid Sterility				5	2-5 containers	$235
Rapid Sterility				5	6-10 containers	$260
Rapid Sterility				5	11+ containers	$290
Antimicrobial Active				5	Certify per USP <71>	$405

Metered Devices (predetermined dose sequence)				14	per USP <71>	$405
Method Suitability				14	4x certification	$1,295
Method Suitability (Antimicrobial Active/Metered Devices)				14	N/A	$2,000
Method Verification				14	1x certification amount	$800