Guide to Testing Services

Sterility Testing

Sterility testing is qualitative; it determines whether there is growth or no growth of a sample. After incubation, media is inspected for turbidity which indicates growth of organisms. Results are reported as number of samples positive for growth out of total number samples tested.

CODE	TEST NAME	DESCRIPTION
ST/07	Native Product – Direct Transfer (2 media)	Samples are placed directly into 2 different media; TSB and FTM and incubated for 14 days. TSB samples are incubated at 20 – 25 °C, FTM samples at 30 – 35 °C.
ST/08	Native Product – Filtration (2 media)	Samples are processed in extraction fluid, the extraction fluid filtered, filters cut in half, and each half is placed into 2 different media; TSB and FTM and incubated for 14 days. TSB samples are incubated at 20 – 25 °C, FTM samples at 30 – 35 °C.
ST/09	Native Product – Direct Transfer (1 media)	Samples are placed directly into a single media; TSB and incubated for 14 days at 20 – 25 °C.
ST/10	Native Product – Filtration (1 media)	Samples are processed in extraction fluid, the extraction fluid filtered, filter is placed into TSB and incubated for 14 days at 20 – 25 °C.
ST/11	Media Fill	Media is incubated for 14 days at 28 – 32 °C.
ST/01	Spore Strip / PCD	Strips are placed into TSB and incubated for 7 days.
ST/02	Inoculated Thread	Inoculated threads are placed into TSB and incubated for 7 days.
ST/03	Self-Contained / PCD	Self-contained BIs are incubated per manufacturer specifications.
ST/05	Inoculated Product – Direct Transfer	Inoculated products are placed directly into TSB and incubated for 7 days.
ST/06	Inoculated Product - Filtration	Samples are processed in extraction fluid, the extraction fluid filtered, the filters placed in TSB and incubated for 7 days.
BF/01	Method Validation (1 media), 3 samples	Suitability of the recovery method is validated in TSB using ~100 CFU *Bacillus subtilis*, *Aspergillus brasiliensis*, and *Candida albicans*. Up to 5-day incubation at 20 – 25 °C. Results are reported in number of days until samples are positive for growth. Method validation samples will not be returned.
BF/02	Method Validation (2 media), 6 samples	Suitability of the recovery method is validated in TSB and FTM using ~100 CFU *Bacillus subtilis*, *Aspergillus brasiliensis*, *Candida albicans, Staphylococcus aureus, Clostridium sporogenes, and Kocuria rhizophilia / Pseudomonas aeruginosa. Up t*o 5-day incubation at 20 – 25 °C and 30 – 35 °C for TSB and FTM, respectively. Results are reported in number of days until samples are positive for growth. Method validation samples will not be returned.

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Endotoxin Testing

Assay for measuring active bacterial endotoxin.

CODE	TEST NAME	DESCRIPTION
TX/01a	Extraction of Individual device	Extraction of each single device. Results reported for each device in EU / device.
TX/01b	Pooled extraction of (4-10) devices	Extraction of 4 – 10 devices and tested as one extract. One result is reported in EU / device.
TX/02	Liquid Sample	Analysis of each liquid sample. Results are reported for each sample in EU / mL.
TX/04	Method Validation Report	Summary of inhibition/enhancement testing of 3 independent lots.

Bioburden Testing

Testing performed to describe the population and characterization of viable organisms present on or in a product and/or a sterile barrier system.

CODE	TEST NAME	DESCRIPTION
BB/01a	Total Aerobes	Incubation of tryptic soy agar at 30 - 35 °C for 3 – 5 days in the presence of oxygen.
BB/02a	Total Aerobes & Anaerobes	Incubation of tryptic soy agar at 30 - 35 °C for 3 – 5 days in the presence of oxygen. Incubation of tryptic soy agar at 30 - 35 °C for 3 – 5 days in the absence of oxygen.
BB/02b	Total Aerobes & Sporeformers	Incubation of tryptic soy agar at 30 - 35 °C for 3 – 5 days in the presence of oxygen. A portion of the sample is heat shocked prior to culturing for sporeformers.
BB/02c	Total Aerobes & Fungi	Incubation of tryptic soy agar at 30 - 35 °C for 3 – 5 days in the presence of oxygen. A portion of the sample is cultured with potato dextrose agar and incubated at 20 – 25 °C for 5 – 7 days.
BB/03a	Total Aerobes, Anaerobes & Sporeformers	Testing of total aerobes, anaerobes, aerobic sporeformers and anaerobic sporeformers.
BB/03b	Total Aerobes, Sporeformers & Fungi	Testing of total aerobes, aerobic sporeformers and fungi.
BB/03c	Total Aerobes, Anaerobes & Fungi	Testing of total aerobes, anaerobes and fungi.
BB/04	Total Aerobes, Anaerobes, Sporeformers & Fungi	Testing of total aerobes, anaerobes, aerobic sporeformers, anaerobic sporeformers, and fungi.
BB/06	Method Validation – Inoculated (Preferred)	Product is spiked with a known quantity of spore forming organisms. Product is then extracted along with a set of control samples. Recovery is determined by comparison of product and control samples. Three to five samples are required.
BB/06	Method Validation – Exhaustive (Native)	Repeated extraction of a device. Recovery is determined by comparing total population recovered from all extractions to population recovered from initial extractions. Method validation samples will not be returned.

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Liquids Testing

Testing of water systems to screen for microorganisms or residual carbon.

CODE	TEST NAME	DESCRIPTION
BB/05a	Filtration (Recommended)	Filtration using 1-4 media types. Common water testing performed on tryptic soy agar for high nutrient general recovery and R2A for low nutrient general recovery
BB/05c	Pour Plate	Pour plate using 1-4 media types.
ML/04a	Coliform Test	100 mL sample required. Tested on m-Endo agar. Incubated at 35 ± 0.5 °C for 24 hours. Samples are accepted Monday through Thursday.
ML/07a	*Pseudomonas aeruginosa*	100 mL sample required. Tested on *Pseudomonas*-isolation agar. Incubated at 30 - 35 °C for 72 hours.
TOC/01	Total Organic Carbon	Testing of water samples. Concentration should be less than 30 ppm and should be free of visible particulate matter.
BB/04a	Additional Dilutions	If elevated results are anticipated, please identify additional required dilutions.

EO Residuals Testing

A quantitative analysis for ethylene oxide and ethylene chlorohydrin residual in accordance with ISO 10993-7.

CODE	TEST NAME	DESCRIPTION
REO/13	EO & ECH Simulated Use Extraction	Liquid extraction recommended for limited patient contact devices. Minimum extraction time of 1 hour.
REO/08	EO & ECH Exhaustive Water Extraction	Liquid extraction recommended for prolonged or permanent contact devices. Standard extraction interval is 24-hours. Includes first 2 extractions-as required by ISO 10993-7.
REO/06	Liquid Sample (EO & ECH)	Testing of compatible liquid samples directly on gas chromatograph. No extraction performed. Method development may be required for some samples.
REO/01	EO Headspace Extraction	Heated extraction of device in sealed container and analysis of vapor headspace for EO. Used for Prolonged/Permanent Device, includes first 2 extractions-as required by ISO 10993-7.
REO/03	EO Headspace and ECH Exhaustive Water Extraction	REO/01 with an additional exhaustive liquid extraction for ECH.

Supply Purchase

STERIS supplies biological indicators, agar plates, swabs, and other materials to support microbiological testing.

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Microbiological Services

Miscellaneous services not appearing on other forms.

CODE	TEST NAME	DESCRIPTION
GM/01	Population Verification or Recovery (per sample or strip)	Four samples are recommended for population verification. Overall average results are reported in CFU/Carrier.
MS/04	Out-of-Specification Evaluation	Request for investigation into aberrant or unexpected result. Must be initiated by Customer.
GM/04a	Organism Stain and colony morphology	The description of the visual appearance of the colony with Gram stain results.
GM/04i	Organism Identification (MALDI-TOF)	Genus-level and or species-level identification utilizing protein- based analysis
GM/04h	Organism Identification (genetic)	Genus-level and or species-level identification utilizing DNA sequencing
IPCD/01	Placement of BI / Inoculated Carrier in Product	Must also purchase or supply biological indicators for placement utilizing Supply Purchase Request Form (Form 7). Code is per BI placement and a set-up fee is included for each sample set.
GM/03a	Inoculation of Product with *B. atrophaeus* suspension	Code is per inoculation location and a set-up fee is included for each sample set.
MS/01c	BI Management (per quote)	This program was developed in order to assist Customers with routine sterilization runs and maintenance of proper biological indicator storage requirements.

USP <51/61/62> Testing

Testing of products to confirm the effectiveness to control organism growth and / or determine the presence / absence of specific organisms. Microbiological recovery should be validated at Steris prior to submitting routine monitoring.

ML/02	Heterotrophic Plate Count	USP <61> tested for 3-5 days on TSA media at 30 - 35 °C
ML/03	Yeast and Mold Plate Count	USP <61> Plated on SAB for 5-7 days at 20 - 25 °C
ML/05	*Eschericia coli*	UPS <62> Pre enrichment for 18-24 hours at 30 - 35 °C and then transferred to MacConkey Agar for 18 to 72 hours at 30 - 35 °C
ML/06	*Salmonella* species	Pre-enrichment for 18-24 hours at 30 - 35 °C and then transferred to Rappaport Vassiliadis Salmonella Enrichment Broth for 18-24 hours at 30 - 35 °C, then transferred to XLD Agar for 18 to 48 hours at 30 - 35 °C

ML/07	*Pseudomonas aeruginosa*	Pre-enrichment for 18-24 at 30 - 35 °C and then transferred to Cetrimide Agar for 18-72 hours at 30 - 35 °C
ML/08	*Staphylococcus aureus*	Pre-enrichment for 18-24 at 30 - 35 °C and then transferred to Mannitol Salt Agar and incubated 18-72 hours at 30 - 35 °C
ML/09	*Candida albicans*	Transfer pre-enrichment to SAB Broth for 3-5 days at 30 - 35 °C and then transfer to SAB plates and incubated 24-48 hours at 30 - 35 °C
ML/10	Bile-tolerant Gram-negative bacteria	Can perform qualitative or quantitative test. Pre-enrichment 2-5 hours at 20 - 25 °C. then transfer to Enterobacteria Enrichment Broth Mossel and incubated 24-48 hours at 30 - 35 °C then transfer to violet red bile glucose agar for 18-24 hours at 30 - 35 °C
ML/11	*Clostridia* species	Transfer pre-enrichment to reinforced media for clostridium and incubate 48 hours 30 - 35 °C and then transfer to Columbia Agar and incubate 48 hours at 30 - 35 °C
ML/14	*Burkholderia cepacia*	
ML/01	Method Validation, Microbial Limits	Validates recovery efficiency of general and specified organisms at Steris. This should be done prior to any routine testing.
AME/01	Anti-Microbial Effectiveness	Testing performed over the period 28 days in accordance with USP <51> to determine antimicrobial effectiveness
AME/02	Method Validation, Anti-Microbial Effectiveness	Validates recovery efficiency of general and specified organisms at Steris. This should be done prior to any routine testing.

Dose Audit

Customer submits routine unsterilized products to STERIS. STERIS coordinates the dose exposure and laboratory testing of test samples. A comprehensive final report will be provided.

Environmental Monitoring

Incubation and enumeration of microbiological cultures from controlled environment samples according to ISO 14698.

CODE	TEST NAME	DESCRIPTION
BM/01	Contact Plate	RODAC plate used to contact a flat surface to transfer and culture organisms. Standard incubation is in microbial content agar 3 to 5 days at 30 – 35 °C, potentially followed by 2 to 4 days at 20 – 25 °C.
BM/02	Settle Plate	Standard agar plate used to passively collect airborne organisms. Standard incubation is in tryptic soy agar 3 to 5 days at 30 – 35 °C, potentially followed by 2 to 4 days at 20 – 25 °C.

BM/03	Air Impact	Agar plate used to actively collect organisms in a defined volume of air. Standard incubation is in tryptic soy agar 3 to 5 days at 30 – 35 °C, potentially followed by 2 to 4 days at 20 – 25 °C.
BM/04	Compressed Air	Organisms are collected on filter medium from a compressed air system. Filter is placed on tryptic soy agar. Standard incubation is 3 to 5 days at 30 – 35 °C, potentially followed by 2 to 4 days at 20 – 25 °C.
BM/05	Swab Enumeration	A wetted swab is used to collect organisms from a surface and is placed into diluent tube and shipped to STERIS. The swab and tubes are extracted and cultured. Potato dextrose agar is used for fungal incubation at 20 - 25 °C for 5 – 7 days. Tryptic soy agar is used for aerobic incubation at 30 – 35 °C for 3 – 5 days.

Cytotoxicity

Cytotoxicity testing is a quantitative estimation of the number of viable cells in a culture. Results are reported as percent viability.

CODE	TEST NAME	DESCRIPTION
CYTO	Cytotoxicity – Neutral Red Uptake (NRU) Method	The Neutral Red Uptake is performed in conformance to ISO 10993-5 Annex A. It is important to include the surface are of samples being submitted. Also please send notification 2 weeks prior to samples expected receipt date.