

MICROBIOLOGY LABORATORY SERVICES & DEFINITIONS

Test	Definition	Example Sample Types
Bacteriostasis and Fungistasis (B&F) – Study for Sterility Testing	USP <71> compliant. Microorganisms listed in USP <71> are spiked into client material at low levels (10 – 100 cfu) to verify that the test sample does not inhibit detection of the organisms within a set time period.	Solid products, liquid products, cell lines; for cell therapy and tissue
Tissue Culture Swab	Copan ESwab™ media aseptically inoculated into iAST (aerobic) & iNST (anaerobic) BACT/ALERT® bottles using a sterile syringe and needle for the detection of viable microorganisms.	QualTex provide pre-processing tissue Copan ESwab™ QualTex provided In-process tissue Copan ESwab™
Endotoxin - LAL	Kinetic Limulus Amebocyte Lysate Assay (LAL - Lonza) that determines the concentration of endotoxin.	Water, liquids, cell lines
Endotoxin Method Suitability Study	Product is tested using multiple dilutions to determine which dilution produces the least inhibition or enhancement in samples spiked with known concentrations of endotoxin. Allowable maximum valid dilution (MVD) is determined based off client's allowable endotoxin limit.	Water, liquids, cell lines Client should disclose if sample type has chelators or high/low pH so sample can be pretreated appropriately.
Contact Plate- Environmental Monitoring	Incubation and analysis of environmental culture plates submitted by client.	Trypticase Soy Agar Contact Plate, 55-65mm
Settle Plate- Environmental Monitoring	Incubation and analysis of environmental culture plates submitted by client.	Trypticase Soy Agar Settle Plate, 90mm
ICR Swab- Environmental Monitoring	Incubation and analysis of environmental ICR swabs submitted by client.	Millipore ICR swab
Gram Stain	Staining technique used to detect the presence of bacteria and sometimes yeast/fungi. Distinguishes and classifies bacteria into gram-positive and gram-negative.	Plates, positive media bottles, blood products, cell therapy products
Residual Moisture	Analysis of residual moisture in lyophilized/freeze-dried bone samples	Bone powder, bone chips, bone cubes, bone and/or cancellous, mineralized and/or demineralized or similar. Samples must be wrapped in individually sealed moisture barriers.
Sterility Testing – Liquid Product	Liquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT® bottles using sterile syringe and needle. Normally use iAST/iNST bottles, but if product may contain inhibitors, iFA Plus/iFN Plus bottles with neutralizers are used.	Amnion fluid, cell culture liquid products, cell culture media

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Sterility Testing – Solid Product	Solid product is eluted in a buffer/saline solution (i.e. Copan ESwab™) for 24 hours. Media is then aseptically transferred into iAST & iNST BacT/ALERT bottles using sterile syringe and needle. Normally use iAST/iNST bottles, but if product may contain inhibitors, iFA Plus/iFN Plus bottles with neutralizers are used.	Amnion membrane
Segments for Microbial Detection-Plate	Testing of a blood product. On an AGAR plate for investigational purposes.	Blood component
Transfusion Reaction Investigation	Testing of a blood product suspected to have caused a transfusion reaction.	Blood component
Aerobic Identification	Identification of aerobic bacteria	Reflex from positive BACT/ALERT® culture bottle or culture plate. Plate submitted by client for identification.
Anaerobic Identification	Identification of anaerobic bacteria	Reflex from positive BACT/ALERT® culture bottle or culture plate. Plate submitted by client for identification.
Yeast Identification	Identification of yeast	Reflex from positive BACT/ALERT® culture bottle or environmental monitoring culture plate. Plate submitted by client for identification.
Fungal Identification	Identification of fungi	Reflex from positive BACT/ALERT® culture bottle or environmental monitoring culture plate. Plate submitted by client for identification.