

MICROBIOLOGY LABORATORY SERVICES & DEFINITIONS

| Fungistasis (B&F) - Study for Sterility Testing C(P) a light with the total and Not Yeves (TO- Sterility Testing) Cell lines; for cell therapy and tissue Tissue Culture Swab Copan ESwab TM media aseptically inoculated into IAST (aerobic) & INST (anearobic) BACT/ALERT® bottles using a sterile syring and needle for the detection of viable microorganisms. QualTex provide pre-process tissue Copan ESwab TM QualTex provide pre-process tissue Copan ESwab TM QualTex provide pre-process tissue Copan ESwab TM Endotoxin - LAL Kinetic Limulus Amebocyte Lysate Assay (LAL - Lonza) that determines the concentration of endotoxin. Water, liquids, cell lines Endotoxin - LAL Kinetic Limulus Amebocyte Lysate Assay (LAL - Lonza) that 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 sam type has chelators or hightic pH is o sample can be pretre appropriately. Contact 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 Residual Moisture Staining technique used to detect the presence of boone samples Sone powdor, boone ehips, anaerobic BACT/ALERT® bottles using sterile syringe and needle. Soneples one ehips, anaerobic BACT/ALERT® bottl | Test | Definition | Example Sample Types |
|---|-------------------------------|--|--|
| Tissue Culture Swab(aerobic) & NIST (anaerobic) EACT/ALERT® bottles using a sterile syringe and needle for the detection of viabletissue Copan ESwab™ Outflex provided In-process tissue Copan ESwab™Endotoxin - LALKinetic Limulus Amebocyte Lysate Assay (LAL - Lonza) that determines the concentration of endotoxin.Water, liquids, cell linesEndotoxin Method Suitability StudyProduct 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 linesContact Plate- Environmental MonitoringIncubation and analysis of environmental culture plates submitted by client.Trypticase Soy Agar Contact Plate, 56-65mmICR Swab- Environmental MonitoringIncubation and analysis of environmental culture plates submitted by client.Plate, 90mmICR Swab- Environmental MonitoringIncubation and analysis of environmental ICR swabsPlate, 90mmGeram StainStaining 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 bottle blood products, cell therapy productResidual MoistureLiquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT® bottles using sterile syringe and needbeAmalysis of residual moisture in lyophilized/freeze-dried and needbeSamples must be wrapped i individually sealed moisture broductsEliquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT® bot | Fungistasis (B&F) – Study for | <71> are spiked into client material at low levels (10 – 100 cfu) to verify that the test sample does not inhibit | Solid products, liquid products, cell lines; for cell therapy and tissue |
| Endotoxin = Exc. that determines the concentration of endotoxin. Water, inquites, 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 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 bottle 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/ demineralized or similar. Sterility Testing – Liquid Product Liquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT* bottles using sterile syringe and neecle. Armion fluid, cell culture liqu products, | Tissue Culture Swab | (aerobic) & iNST (anaerobic) BACT/ALERT® bottles using a sterile syringe and needle for the detection of viable | QualTex provided In-process |
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| Monitoringsubmitted by client.Plate, 55-65mmSettle Plate- Environmental MonitoringIncubation and analysis of environmental culture plates submitted by client.Trypticase Soy Agar Settle Plate, 90mmICR Swab- Environmental MonitoringIncubation and analysis of environmental ICR swabs submitted by client.Millipore ICR swabGram StainStaining 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 bottle blood products, cell therapy productsResidual MoistureAnalysis of residual moisture in lyophilized/freeze-dried bone samplesBone powder, bone chips, bone cubes, bone and/or cancellous, mineralized and/ demineralized or similar.Sterility Testing - Liquid ProductLiquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT® bottles using sterile syringe and needle. Normally use IAST/INST bottles, but if product mayAmnion fluid, cell culture liqu products, cell culture media | - | 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 | Client should disclose if sample type has chelators or high/low pH so sample can be pretreated |
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| Sterility Testing – Liquid Liquid product is aseptically inoculated into aerobic & anaerobic BACT/ALERT® bottles using sterile syringe and needle. Amnion fluid, cell culture liquid product may | Residual Moisture | | bone cubes, bone and/or cancellous, mineralized and/or demineralized or similar. Samples must be wrapped in |
| Sterility Testing - Liquid Productanaerobic BACT/ALERT® bottles using sterile syringe and needle.Amnion fluid, cell culture liqu product may | | | |
| contain inhibitors, iFA Plus/iFN Plus bottles with neutralizers are used. | | 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 | Amnion fluid, cell culture liquid products, cell culture media |

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MICROBIOLOGY LABORATORY SERVICES & DEFINITIONS

| Test | Definition | Example Sample Types |
|---|---|---|
| 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. |

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