



# TEST SERVICES BRASS

## STERILITY ASSURANCE REQUIREMENTS FOR BIOMEDICAL PRODUCTS

### ▼ BIOBURDEN PROGRAM

| Code                                  | Test Services  | Purpose of Test   |
|---------------------------------------|--|---|
| <b>Bioburden Tests</b>                |  |   |
| BIO-001                               | <b>ISO Validation of Bioburden Techniques, Repetitive Recovery Method</b>  | To validate the ability of a specified technique to remove microorganisms from product utilizing the naturally occurring microbiological contamination.<br><br><i>Turnaround time: 10 days</i>    |
| BIO-002                               | <b>ISO Validation of Bioburden Techniques, Inoculative Recovery Method</b> | To validate the ability of a specified technique to remove microorganisms from product through product inoculation with known levels of microorganisms.<br><br><i>Turnaround time: 10 days</i>    |
| BIO-003                               | <b>ISO Bioburden Enumeration, Aerobic</b>                                  | To determine the population of viable microorganisms present on a material or product.<br><br><i>Turnaround time: 10 days</i>   |
| <b>Microbial Identification Tests</b> |  |   |
| GRM-001                               | <b>Gram Stain and Colony Morphology</b>                                    | Differential staining procedure in which the microorganism is classified and its macroscopic appearance is described.<br><br><i>Turnaround time: 2 days</i>                                       |
| API-001                               | <b>Identification of Microorganism, Test Card</b>                          | To identify the species or genus of the microorganism isolate.<br><br><i>Turnaround time: 5 days</i>  |
| <b>Microbial Limit Tests</b>          |  |   |
| MLT-001                               | <b>USP Microbial Limit Preparatory Test</b>                                | To demonstrate that test specimens do not inhibit the multiplication of microorganisms.<br><br><i>Turnaround time: 10 days</i>  |
| MLT-002                               | <b>USP Total Aerobic Microbial Count</b>                                   | To estimate the number of viable aerobic microorganisms present and freedom from designated microbial species in the material or product.<br><br><i>Turnaround time: 2 days</i>                   |
| MLT-003                               | <b>Microbial Confirmation Test, Test Card</b>                              | To confirm the presence or absence of <i>Staphylococcus aureus</i> , <i>Escherichia coli</i> , <i>Pseudomonas aeruginosa</i> and <i>Salmonella</i> species.<br><br><i>Turnaround time: 5 days</i> |

▼ ANTIMICROBIAL PROGRAM

| Code                                     | Test Services  | Purpose of Test  |
|--|--|--|
| <b>Antimicrobial Effectiveness Tests</b> |  |  |
| DET-001                                  | <b>USP Preservative Effectiveness Test</b>   | To demonstrate the effectiveness of antimicrobial preservatives added to non-sterile dosage forms to protect them from microbiological growth or contamination.<br><br><i>Turnaround time: 40 days</i> |
| DET-002                                  | <b>BS EN Quantitative Suspension Test for Chemical Disinfectants and Antiseptics</b> | To validate the ability of a specified technique to remove microorganisms from product through product inoculation with known levels of microorganisms.<br><br><i>Turnaround time: 10 days</i>         |

▼ BACTERIAL ENDOTOXIN PROGRAM

| Code                                 | Test Services  | Purpose of Test  |
|--------------------------------------|--|--|
| <b>LAL Bacterial Endotoxin Tests</b> |  |  |
| LGC-001<br>LGC-002                   | <b>USP LAL Gel Clot, Liquid<br/>USP LAL Gel Clot, Device</b>                           | Semi-quantitative determination of endotoxin limit in a substance, material or product.<br><br><i>Turnaround time: 3 days</i>  |
| LGC-003                              | <b>FDA LAL Gel Clot Validation,<br/>1-Lot OR 3-Lots</b>                                | To validate the suitability of the LAL test method for the test sample involving the qualification of the laboratory and interference testing.<br><br><i>Turnaround time: 3 days</i> |
| LGC-004                              | <b>LAL Gel Clot Dilution Assay</b>   | To determine the semi-quantitative endotoxin value on a substance, material or product.<br><br><i>Turnaround time: 3 days</i>  |
| LKT-001<br>LKT-002                   | <b>USP LAL Kinetic Turbidimetric, Liquid<br/>USP LAL Kinetic Turbidimetric, Device</b> | Qualitative determination of endotoxin limit in a substance, material or product, by detection and measurement of turbidity.<br><br><i>Turnaround time: 3 days</i>                   |
| LKT-003                              | <b>FDA LAL Kinetic Turbidimetric Validation,<br/>1-Lot OR 3-Lots</b>                   | To validate the suitability of the LAL test method for the test sample involving the qualification of the laboratory and interference testing.<br><br><i>Turnaround time: 3 days</i> |
| LKC-001<br>LKC-002                   | <b>USP LAL Kinetic Chromogenic, Liquid<br/>USP LAL Kinetic Chromogenic, Device</b>     | Qualitative determination of endotoxin limit in a substance, material or product, by detection and measurement of colour.<br><br><i>Turnaround time: 3 days</i>                      |
| LKC-003                              | <b>FDA LAL Kinetic Chromogenic Validation,<br/>1-Lot OR 3-Lots</b>                     | To validate the suitability of the LAL test method for the test sample involving the qualification of the laboratory and interference testing.<br><br><i>Turnaround time: 3 days</i> |

▼ STERILITY PROGRAM

| Code                              | Test Services  | Purpose of Test   |
|-----------------------------------|--|---|
| <b>Sterility Tests</b>            |  |   |
| STR-001                           | USP Sterility Test, Membrane Filtration, Liquid                | To confirm the absence of microbial contamination after a sterilization process, using sterile filtration.  |
| STR-002                           | USP Sterility Test, Membrane Filtration, Device                | <i>Turnaround time: 14 days</i>   |
| STR-003                           | USP Sterility Test, Direct Transfer, Liquid                    | To confirm the absence of microbial contamination after a sterilization process, using direct immersion or dispersion of product in the media.          |
| STR-004                           | USP Sterility Test, Direct Transfer, Device                    | <i>Turnaround time: 14 days</i>   |
| STR-005                           | USP Validation Test for Bacteriostasis and Fungistasis, Liquid | To ensure that any bacteriostatic and fungistatic activity inherent in the test sample does not adversely affect the reliability of the sterility test. |
| STR-006                           | USP Validation Test for Bacteriostasis and Fungistasis, Device | <i>Turnaround time: 7 days</i>  |
| <b>Biological Indicator Tests</b> |  |   |
| SSC-001                           | USP Total Viable Spore Count, Spore Suspension                 | To verify the spore population on a new lot of biological indicators for sterilization process validation.  |
| SSC-002                           | USP Total Viable Spore Count, Spore Strip                      | <i>Turnaround time: 3 days</i>  |
| STR-007                           | USP Biological Indicator Recovery, Direct Transfer             | To determine the presence or absence of microorganism growth after completion of the sterilizing procedure.   |
|                                   |  | <i>Turnaround time: 7 days</i>  |

▼ ENVIRONMENTAL MONITORING PROGRAM

| Code   | Test Services  | Purpose of Test  |
|--|--|--|
| <b>On-Site Environmental Microbial Tests</b> |  |  |
| EMS-001                                      | USP Environmental Microbial Evaluation Air Sampling                                  | To quantitate the microbial content of controlled rooms using USP methods or client's protocol.  |
| EMS-002                                      | Contact Sampling (RODAC plate or swab) Environmental Microbial Evaluation Customized | <i>Turnaround time: 3 days</i>   |
| <b>Remote Environmental Microbial Tests</b>  |  |  |
| EMS-003                                      | Soy-Casein Digest Sample Plates and Microbial Quantification                         | To equip client with the necessary materials for the conduct of environmental monitoring in-house, and to provide the GPT media check and final test report. |
| EMS-004                                      | RODAC Sample Plates and Microbial Quantification                                     | <i>Turnaround time: 3 days</i>   |
| EMS-005                                      | Evaluation and Trending of Environmental Monitoring Data                             | To analyze environmental microbial data and provide detailed evaluation in the final test report.  |
|  |  | <i>Turnaround time: 3 days</i>   |

▼ STERILIZATION VALIDATION PROGRAM

| Code                                    | Test Services   | Purpose of Test   |
|---|---|---|
| <b>Sterilization Process Validation</b> |   |   |
| SVD-001                                 | <b>Steam Sterilization Process Validation</b>                     | <p>To demonstrate that the probability of microbial survival in replicate cycles is not greater than the prescribed limits via the conduct microbiological tests recommended by ISO and AAMI standards and the use of the appropriate biological indicators.</p> <p><i>Turnaround time: Inquire</i></p> |
| SVD-002                                 | <b>Dry-Heat Depyrogenation / Sterilization Process Validation</b> |   |
| SVD-003                                 | <b>Ethylene Oxide Sterilization Process Validation</b>            |   |
| SVD-004                                 | <b>Radiation Sterilization Process Validation</b>                 |   |
| SVD-005                                 | <b>Ethylene Oxide Residual/Dissipation Studies</b>                |   |
|   |   | <p>To analyze ethylene oxide residues in sterilized products.</p> <p><i>Turnaround time: Inquire</i></p>  |

▼ SPECIAL PROGRAM

| Code                       | Test Services                                | Purpose of Test  |
|----------------------------|--|--|
| <b>Biotechnology Tests</b> |  |  |
| MYC-001                    | <b>Mycoplasma Detection Study</b>            | <p>To demonstrate the presence or absence of mycoplasma in cell culture media using the ELISA method</p> <p><i>Turnaround time: 3 days</i></p> |
| <b>Customized Studies</b>  |  |  |
| CUS-001                    | <b>Filter Effectiveness Study</b>            | <p>To determine the effectiveness of a water filtration system.</p> <p><i>Turnaround time: Inquire</i></p>                                     |
| CUS-002                    | <b>Disinfectant Effectiveness Study</b>      | <p>To determine the general effectiveness of a disinfectant system.</p> <p><i>Turnaround time: Inquire</i></p>                                 |
| CUS-003                    | <b>Bioburden Quantification of Packaging</b> | <p>To analyze environmental microbial data and provide detailed evaluation in the final test report.</p> <p><i>Turnaround time: 3 days</i></p> |