HIGHPOWER
Validation Testing & Lab Services

TEST CODE DEFINITION

STERRAD H_2O_2

125 Highpower Road. Rochester, NY 14623
(888) -722-1529 • www.highpowervtls.com

Test Code	Test Name	Testing Description
MC-100S	**STERRAD 100S Cycle**	Materials Compatibility testing in the STERRAD 100S process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more STERRAD 100S cycles. The objective of this testing is to look for degradation after repeated cycles. STERRAD 100S Feasibility Testing is also performed under this code.
SE-100S	**STERRAD 100S Efficacy**	Sterilization Efficacy testing in the STERRAD 100S process. This is a 55-minute cycle used for most surgical instruments. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 100S cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
SE-200	**STERRAD 200 Efficacy**	Sterilization Efficacy testing in the STERRAD 200 process. This is a 75-minute cycle used for most surgical instruments. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 200 cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
MC-NX	**STERRAD NX Cycle**	Materials Compatibility testing in the STERRAD NX process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more STERRAD NX cycles. The objective of this testing is to look for degradation after repeated cycles. STERRAD NX Feasibility Testing is also performed under this code.
SE-NX-STD	**STERRAD NX STD Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD NX Standard cycle. This is a 28-minute cycle used for most surgical instruments, including specific sizes of single channel stainless steel lumens. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD NX Standard cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
SE-NX-ADV	**STERRAD NX ADV Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD NX Advanced cycle. This is a 38-minute cycle used for most surgical instruments, including specific sizes of flexible endoscopes. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD NX Advanced cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
MC-100NX	**STERRAD 100NX Cycle**	Materials Compatibility testing in the STERRAD 100NX process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more STERRAD 100NX cycles. The objective of this testing is to look for degradation after repeated cycles. STERRAD 100NX Feasibility Testing is also performed under this code.

SE-100NX-STD	**STERRAD 100NX STD Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD 100NX Standard cycle. This is a 47-minute cycle used for most general surgical instruments including specific sizes of single channel stainless steel lumens. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 100NX Standard cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
SE-100NX-EXP	**STERRAD 100NX EXP Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD 100NX Express cycle. This is a 24-minute cycle used for general medical devices requiring surface sterilization, or sterilization of mated stainless steel and titanium surfaces also specific sizes of rigid or semi-rigid endoscopes. Currently not indicated for Polyurethane, mated Delrin®, mated Ultem®, and mated Aluminum. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 100NX Express cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
SE-100NX-FLX	**STERRAD 100NX Flex Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD 100NX Flex cycle. This is a 42-minute cycle used for specific sizes of single channel flexible endoscopes. Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 100NX Flex cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
SE-100NX-DUO	**STERRAD 100NX Duo Cycle Efficacy**	Sterilization Efficacy testing in the STERRAD 100NX Duo cycle. This is a 60-minute cycle used for specific sizes of single channel flexible endoscopes, flexible endoscopes without lumens, cameras and accessories (light cords). Please refer to ASP's website for complete instrument processing information. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a STERRAD 100NX Duo cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
RESID-H2O2	**H2O2 Residual Testing**	Residual Testing of hydrogen peroxide on devices or materials after exposure to the vaporized hydrogen peroxide sterilization process.

Steam Pre-Vacuum/Gravity/Steam Flush Pressure Pulse (SFPP)

Test Code	Test Name	Testing Description
MC-STEAM	**Steam Cycle**	Materials Compatibility testing in the steam sterilization process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more steam cycles. The objective of this testing is to look for degradation after repeated cycles. Steam Sterilization Feasibility Testing is also performed under this code.

SE-STEAM	**Steam Sterilization Efficacy**	Sterilization Efficacy testing in the steam gravity or dynamic air removal (prevacuum or SFPP) process. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a steam cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
TP-STEAM	**Steam Thermal Profile Study**	Thermal Profiles are performed to demonstrate that proper sterilant penetration and thermal conditions can be achieved and maintained in the sterilizer chamber or packaging system within a sterilizer chamber. Temperature sensors are set in locations throughout the chamber or packaging system to determine if proper exposure temperatures occur during the exposure cycle.
DT-STEAM	**Dry Time Study**	Dry Time studies are necessary to ensure that all forms of moisture are minimized following steam sterilization processing. Moisture could provide a vector for microorganisms to enter a packaging system and contaminate the items within. There are many variables that can cause a sterilization packaging system to retain moisture.
MISC –STEAM	**Bowie Dick, Air Leak or Miscellaneous Steam Test**	This is a generic test code that allows us to evaluate items such as Bowie Dick Test packs to ISO 11140-4 or ISO 11140-5. It may also be used for checking air leaks in various steam sterilizers as indicated in the AAMI ST-08 and AAMI ST-55 steam sterilizer standards. Additionally, any feasibility testing in the steam process can also be performed using this code.
VAL-ST55	**AAMI ST-55 Sterilizer Validation**	The validation of a steam tabletop sterilizer (sterilizer with less than 2 ft.^{3} of chamber space) to ensure it meets the requirements of the AAMI ST-55 Standard.
VAL-ST8	**AAMI ST-08 Sterilizer Validation**	The validation of a steam hospital sterilizer (sterilizer with more than 2 ft.^{3} of chamber space) to ensure it meets the requirements of the AAMI ST-08 Standard.

Ethylene Oxide

Test Code	Test Name	Testing Description
MC-ETO	**ETO Concentration Cycles run at 446 mg/l, 567 mg/l, 725 mg/l or 759 mg/l**	Materials Compatibility testing in the ethylene oxide (ETO) sterilization process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more ETO cycles. The objective of this testing is to look for degradation after repeated cycles. ETO Sterilization Feasibility Testing is also performed under this code.
SE-ETO	**ETO Efficacy Validation**	Sterilization Efficacy testing in the ethylene oxide sterilization process. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively an ETO cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
RESID-ETO	**ETO Residual Testing**	Residual Testing of ethylene oxide residuals on devices or materials after exposure to the ETO sterilization process. Testing assures that the device/material is within acceptable safety limits and provides proper documentation of ethylene oxide and ethylene chlorohydrin (a by-product of EO sterilization) residuals.

Dry Heat

Test Code	Test Name	Test Description
MC-DRY	**Dry Heat Cycle**	Materials Compatibility testing in the Dry Heat sterilization process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse. The device or material is typically run through one or more Dry Heat cycles. The objective of this testing is to look for degradation after repeated cycles. Dry Heat Sterilization Feasibility Testing is also performed under this code.
SE-DRY	**Dry Heat Efficacy**	Sterilization Efficacy testing in the Dry Heat sterilization process. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a Dry Heat cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
TP-DRY	**Dry Heat Thermal Profile Study**	Thermal Profiles are performed to demonstrate that proper penetration and thermal conditions can be achieved and maintained in the sterilizer chamber or packaging system within a sterilizer chamber. Temperature sensors are set in locations throughout the chamber or packaging system to determine if proper exposure temperatures occur during the exposure cycle.

STERIS V-PRO*Plus* H2O2

Test Code	Test Name	Test Description
MC-VPRO	**V-Pro Lumen/Non-lumen cycle**	Materials Compatibility testing in the STERIS V-Pro sterilization process. This test is also sometimes referred to as Reusability Testing or Limits of Reuse. The device or material is typically run through one or more V-Pro cycles. The objective of this testing is to look for degradation after repeated cycles. Feasibility Testing is also performed under this code.

Chemical Immersion

Test Code	Test Name	Test Description
SE-COLD	**Chemical Immersion Efficacy** **(OPA, Glutaraldehyde)**	Sterilization Efficacy test used to determine how effectively chemical immersion will sterilize a device being tested. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing. This test is used to determine how effectively a cold or heated soak in chemicals will sterilize the device/devices being immersed. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^6 spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).
MC-COLD	**Chemical Immersion Cycle**	Materials Compatibility testing in a chemical immersion sterilization process. This test is also sometimes referred to as Reusability Testing or Limits of Reuse. The device or material is typically run through one or more cycles. The objective of this testing is to look for degradation after repeated cycles. Feasibility Testing is also performed under this code.

High Level Disinfection

Test Code	Test Name	Test Description
HLD	**High Level Disinfection**	High Level Disinfection studies are required for semi-critical medical instruments - items that contact intact mucous membranes or non-intact skin (but not sterile areas) which cannot tolerate sterilization. The US FDA requires testing with Thermophilic Mycobacterium species and vegetative organisms, such as a mixture of Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, and representatives from the Klebsiella - Enterobacter group.
TP-WASH	**Thermal Disinfection**	A thermal disinfection study to determine Ao according to ISO 15883

Chemical Vapor

Test Code	Test Name	Test Description
MC-CHEMI	**Chemiclave Cycle**	Materials Compatibility testing in the Chemiclave (Chemical Vapor) sterilization process. This test is also sometimes referred to as Reusability Testing, Functional Compatibility Testing or Limits of Reuse and is primarily run for devices used in the dental market. The device or material is typically run through one or more Chemiclave cycles. The objective of this testing is to look for degradation after repeated cycles. Chemiclave Sterilization Feasibility Testing is also performed under this code.
SE-CHEMI	**Chemiclave Efficacy**	Sterilization Efficacy testing in the Chemiclave sterilization process. This test is also sometimes referred to as ½ Cycle Testing, 100% Overkill Method or Sterilization Validation Testing and is primarily run in the dental market. This test is used to determine how effectively a Chemiclave cycle will sterilize the device/devices being tested. A device/devices are run in a sterilization cycle for half the time they normally would be run in a clinical environment with at least 10^{6} spores of a highly resistant organism being placed on the device/devices in locations that would be the most difficult to sterilize. A full cycle would indicate a kill rate of at least 10^{-12} SAL (sterility assurance level).

TSO3 STERIZONE

Test Code	Test Name	Test Description
MC-SZ	**STERIZONE Cycle**	Materials Compatibility testing in the TSO3 Sterizone sterilization process. This test is also sometimes referred to as Reusability Testing or Limits of Reuse. The device or material is typically run through one or more Sterizone cycles. The objective of this testing is to look for degradation after repeated cycles. Feasibility Testing is also performed under this code.

Resistometer Testing/ISO 11140

Test Code	Test Name	Test Description
RES-STEAM	**Steam Resistometer Cycle**	Resistometer Testing in an AAM/ISO compliant steam vessel, sometimes also called a BIER (biological indicator evaluator resistometer) vessel. Tests the performance of steam chemical and biological indicators.
RES-ETO	**ETO Resistometer Cycle**	Resistometer Testing in an AAM/ISO compliant ethylene oxide vessel, sometimes also called a BIER (biological indicator evaluator resistometer) vessel. Tests the performance of ETO chemical and biological indicators.
RES-DRY	**Dry Heat Resistometer Cycle**	Resistometer Testing in an AAM/ISO compliant dry heat vessel, sometimes also called a BIER (biological indicator evaluator resistometer) vessel. Tests the performance of dry heat chemical and biological indicators.
RES-VHP	**VHP Resistometer Cycle**	Resistometer Testing in an AAM/ISO compliant hydrogen peroxide vessel, sometimes also called a BIER (biological indicator evaluator resistometer) vessel. Tests the performance of H2O2 chemical indicators.
RES-FORM	**Formaldehyde Resistometer Cycle**	Resistometer Testing in an AAM/ISO compliant Formaldehyde vessel, sometimes also called a BIER (biological indicator evaluator resistometer) vessel. Tests the performance of Formaldehyde chemical indicators.

CI-1SO1	**Table 2 of ISO 11140-1: Steam Indicators**	A steam chemical indicator is tested according to the ISO 11140-1 standard. The testing verifies that a class 1 process indicator meets the requirements of the ISO 11140-1 Standard. Test for ISO class 3, 4, 5 (integrating indicators) and 6 indicators (emulating indicators) are also tested under this code.
CI-1SO2	**Table 3 of ISO 11140-1: Dry Heat Indicators**	A dry heat chemical indicator is tested according to the ISO 11140-1 standard. The testing verifies that a class 1 process indicator meets the requirements of the ISO 11140-1 Standard. Test for ISO class 3, 4, 5 (integrating indicators) and 6 indicators (emulating indicators) are also tested under this code.
CI-1SO3	**Table 4 of ISO 11140-1: ETO Indicators**	An ethylene oxide chemical indicator is tested according to the ISO 11140-1 standard. The testing verifies that a class 1 process indicator meets the requirements of the ISO 11140-1 Standard. Test for ISO class 3, 4, 5 (integrating indicators) and 6 indicators (emulating indicators) are also tested under this code.
CI-1SO5	**Table 6 of ISO 11140-1: Formaldehyde CI's**	A formaldehyde chemical indicator is tested according to the ISO 11140-1 standard. The testing verifies that a class 1 process indicator meets the requirements of the ISO 11140-1 Standard.
CI-1SO6	**Table 7 of ISO 11140-1: VHP Indicators**	A hydrogen peroxide chemical indicator is tested according to the ISO 11140-1 standard. The testing verifies that a class 1 process indicator meets the requirements of the ISO 11140-1 Standard. **NOTE: Class 5/6 indicator testing available for above processes.**
BD-ISO	**ISO 11140-5**	Bowie Dick Test Pack Validation to the requirements of ISO 11140-5.

Accelerated Aging/Shelf Life

Test Code	Test Name	Test Description
SL-ETO	**Real Time Shelf Life after ETO exposure**	A real time Shelf Life study after exposure to the ethylene oxide sterilization process. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-STERRAD	**Real Time Shelf Life after STERRAD Exposure**	A real time Shelf Life study after exposure to the STERRAD sterilization process. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-STEAM	**Real Time Shelf Life after Steam Exposure**	A real time Shelf Life study after exposure to the steam sterilization process. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-VPRO	**Real Time Shelf Life after V-Pro Exposure**	A real time Shelf Life studies after exposure to the V-Pro sterilization process. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-SZ	**Real Time Shelf Life after STERIZONE Exposure**	A real time Shelf Life studies after exposure to the STERIZONE sterilization process. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-MSCL	**Misc. Real Time Shelf Life Study**	A miscellaneous real time Shelf Life study. Demonstrates that a processed sterility packaging system can maintain a sterile barrier for a defined period of time. Articles are stored in a simulated central service department storage area.
SL-ACCEL	**Accelerated Aging Shelf Life**	Shelf Life testing in an accelerated aging chamber to ASTM F1980. The accelerated aging test simulates real-time shelf life by stressing the product to increased temperature, humidity and/or pressurized environment.

Aerosol Challenge

Test Code	Test Name	Test Description
AC-STEAM	**Steam Whole Package Integrity Test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in a steam cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.

AC-ETO	**ETO Whole Package Integrity Test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in an ethylene oxide cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.
AC-STERRAD	**STERRAD Whole Package Integrity Test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in a STERRAD cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.
AC-VPRO	**VPRO Whole Package Integrity Test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in a V-Pro cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.
AC-SZ	**TSO3 Whole Package Integrity test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in a Sterizone cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.
AC-CUSTOM	**Custom Whole Package Integrity Test**	An Aerosol Challenge test on a packaging system (wrap, rigid container or sterilization pouch) used as a microbial barrier. Is also known as a whole package integrity test. A packaging system is processed in a custom cycle and is then exposed to a high concentration of bacterial spores in an aerosol chamber. If the system maintains its package integrity there will be no microbial growth within the packaging system.

ISO 11607 Package Test

Test Code	Test Name	Test Description
DM-ISO	**Dye Migration (ASTM F 1929)**	Dye is added to the interior of the package (typically a sterilization pouch) and allowed to rest on the seal. If the seal is compromised the dye will visibly channel through the seal.
BT-ISO	**Burst Test (ASTM F 1140)**	The Burst Test will compromise the weakest seal on a package (typically a sterilization pouch) by pressurizing it. Air pressure is applied steadily until the package fails. The pressure where the package fails is documented and compared to the product specifications.
BE-ISO	**Bubble Emission (ASTM F 2096)**	The test is a “whole package” integrity test. A package (typically a sterilization pouch) is inflated to a pressure within its tolerance range and immersed in water. Bubbles coming from a single point can indicate that there is a failure in the package integrity.
SP-ISO	**Seal Peel (ASTM F 88)**	The Seal Peel Test determines the amount of strength it takes to open a package (typically a sterilization pouch). A tensile machine is used with a one-inch sample of the package and the amount of force is measured in pounds per square inch. The results are documented and compared to the product specifications.
VIS-ISO	**Visual Inspection (ASTM F 1886)**	Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
BFE	**Bacterial Filtration Efficiency (ASTM F 2101)**	Bacterial Filtration Efficiency testing is performed according to the ASTM F2101-07 and EN14683:2014, Annex B standards to determine the filtration effectiveness of the test article (typically on articles such as CSR wrap, rigid container filters etc.) using a ratio of challenge organisms (*Staphylococcus aureus)* to determine the percent efficiency.

Sterility

Test Code	Test Name	Test Description
STERILITY	**Article Sterility Test**	A test to determine if an item is sterile after processing. Sometimes used for routine quality control and release of processed industrial loads. Devices are typically tested by directly transferring the device into test media and incubating for 14 days.
BIO-BURDEN	**Article Bioburden Test**	A Bioburden test determines the total number of viable organisms on a device or product. Used to determine the amount of organisms created on the device through the manufacturing process, and assist in determining the proper challenge for sterility validation.

Device Cleaning Validation

Test Code	Test Name	Test Description
MAN-3LOG	**Manual TIR 12 – 3 Log Reduction**	A device is inoculated with 10^6 bacterial spores then run through a manual (Hand-washed) cleaning cycle. A 10^3 reduction should occur in the number of bacterial spores after cleaning. A popular test used in Europe to validate a cleaning process.
MEC-3LOG	**Mechanical TIR 12 – 3 Log Reduction**	A device is inoculated with 10^6 bacterial spores then run through a mechanical cleaning cycle. A 10^3 reduction should occur in the number of bacterial spores after cleaning. A popular test used in Europe to validate a cleaning process.
MAN-PRO	**Manual TIR 30 – Protein Marker**	A device is inoculated with a defined amount of protein over the surface of the device. The device is then processed according to the manufacturers' recommended manual cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MEC-PRO	**Mechanical TIR 30 – Protein Marker**	A device is inoculated with a defined amount of protein over the surface of the device. The device is then processed according to the manufacturers' recommended mechanical cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MAN-TOC	**Manual TIR 30 – TOC Marker**	A device is inoculated with a defined amount of TOC (total organic carbon) over the surface of the device. The device is then processed according to the manufacturers' recommended manual cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MEC-TOC	**Mechanical TIR 30 – TOC Marker**	A device is inoculated with a defined amount of TOC (total organic carbon) over the surface of the device. The device is processed according to the manufacturers' recommended mechanical cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MAN-HEMO	**Manual TIR 30 – Hemoglobin Marker**	A device is inoculated with a defined amount of hemoglobin over the surface of the device. The device is then processed according to the manufacturers' recommended manual cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MEC-HEMO	**Mechanical TIR 30 – Hemoglobin Marker**	A device is inoculated with a defined amount of hemoglobin over the surface of the device. The device is then processed according to the manufacturers' recommended mechanical cleaning protocol. After cleaning, soil left on device is compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. The process is repeated two additional times.
MAN-PRO3	**Manual TIR 30/ Abbreviated FDA – Protein Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of protein and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MEC-PRO3	**Mechanical TIR 30/ Abbreviated FDA – Protein Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of protein and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.

MAN-TOC3	**Manual TIR 30/ Abbreviated FDA – TOC Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of TOC and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MEC-TOC3	**Mechanical TIR 30/ Abbreviated FDA – TOC Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of TOC and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MAN-HEMO3	**Manual TIR 30/ Abbreviated FDA – Hemoglobin Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of hemoglobin and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MEC-HEMO3	**Mechanical TIR 30/ Abbreviated. FDA – Hemoglobin Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for an abbreviated FDA compliant study. A device is inoculated with a defined amount of hemoglobin and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated multiple times before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MAN-PRO6	**Manual TIR 30/ Full FDA – Protein Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of protein and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MEC-PRO6	**Mechanical TIR 30/ Full FDA – Protein Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of protein and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MAN-TOC6	**Manual TIR 30/ Full FDA – TOC Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of TOC and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MEC-TOC6	**Mechanical TIR 30/ Full FDA – TOC Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of TOC and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MAN-HEMO6	**Manual TIR 30/ Full FDA – Hemoglobin Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of hemoglobin and is processed according to the manufacturers' recommended manual cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.

MEC-HEMO6	**Mechanical TIR 30/ Full FDA – Hemoglobin Marker**	The U.S. FDA requires repetitive cycling during the cleaning validation of a medical device in order to determine if an accumulation of contamination occurs over time either on or within the device. This test code is for a full FDA compliant study. A device is inoculated with a defined amount of hemoglobin and is processed according to the manufacturers' recommended mechanical cleaning protocol. This process is repeated more times than for an abbreviated FDA study before the soil left on the device/s is extracted and compared to the defined acceptance criteria within TIR 30 or as defined in the test protocol. Three efficacy extractions performed.
MC-WASH	**Mechanical Washer - Repetitive Cleaning**	Materials Compatibility testing of a device by evaluating the cleaning process according to the manufacturers' mechanical cleaning protocol a recommended number of times. Any degradation noted on the device is observed. This test is also sometimes referred to as Reusability Testing or Limits of Reuse. Cleaning Feasibility Testing is also performed under this code.
MC-MANUAL	**Manual Wash - Repetitive Cleaning**	Materials Compatibility testing of a device by evaluating the cleaning process according to the manufacturers' manual cleaning protocol a recommended number of times. Any degradation noted on the device is observed. This test is also sometimes referred to as Reusability Testing or Limits of Reuse. Cleaning Feasibility Testing is also performed under this code.

Biological Indicator Testing – ISO 11138/USP

Test Code	Test Name	Test Description
BI-DV-STEAM	**STEAM D-Value Analysis**	D-Value determines the resistance of a biological indicator in a resistometer. D-values are the time required to achieve inactivation of 90% of a population of the test microorganism under exposure conditions. This test is typically performed to verify the resistance values as listed on the biological indicator certification. Test typically follow the procedures as recommended by the biological indicator manufacturer.
BI-DV-DRY	**Dry Heat D-Value Analysis**	
BI-DV-ETO	**ETO D-Value Analysis**	
BI-SK	**Survival/Kill**	A Survival/Kill test determines the resistance of a Biological Indicator. It requires fewer BIs then a D-Value and determines the processing time to totally kill the organisms on a BI and the time where all organisms on a BI survive. This test is typically performed to verify the resistance values as listed on the biological indicator certification.
BI-ASSAY	**BI Population Verification**	A determination of the population on a lot of biological indicators. Also known as a population assay. The samples are typically heat shocked to ensure that only the spore forming bacteria are being counted and activating the spore forming cells to germinate. Test typically follow the procedures as recommended by the biological indicator manufacturer.
BI-PURITY	**Product Purity Test**	An assay is done on a biological indicator to test the population of non-indicator organisms on the BI.

Biocompatibility - ISO 10993

Test Code	Test Name	Test Description
BIO-CYTO	**Cytotoxicity – MEM Elution**	A cytotoxicity test is performed by extracting the tested device in Minimal Essential Media (MEM), and then the media is plated over a field of cells. Cytotoxicity is an "in vitro" test which is determined by how the cells are affected by the MEM and whether any cell lysis occurs. MEM test are very sensitive and most failures occur in cytotoxicity testing, as compared to other biocompatibility test. Cytotoxicity tests can be done at any time during the device design process as the raw materials for the device can be used.
BIO-SENS	**Sensitization**	Sensitization tests use animal models to determine if repeated exposure to a device will cause a reaction. The animal's immune system is monitored as it is exposed and re-exposed to a device extraction. A water based and oil-based extraction is created to test both polar and non-polar leachable from the device. A sensitization test takes a longest time period for results and should be done on a final product once the cytotoxicity is finished.
BIO-IRRI	**Irritation**	Irritation testing is similar to sensitization testing, except irritation testing tests whether an immediate reaction is created by a device. The test determines if toxic levels of chemicals are leaching from plastics.
BIO-SYST	**Systemic Toxicity**	There are various Systemic Toxicity test coved in the ISO standard. Systemic toxicity is a potential adverse effect of the use of medical devices. Generalized effects, as well as organ and organ system effects can result from absorption, distribution, and metabolism of leachates from the device or its materials to parts of the body with which they are not in direct contact.

BIO-GENO	**Genotoxicity**	There are various Genotoxicity test covered in the ISO standard. A genotoxicity test uses mammalian or non-mammalian cells, bacteria, yeasts, fungi or whole animals to determine whether gene mutations, changes in chromosome structure, or other DNA or gene changes are caused by the test samples
BIO-HEMOL	**Blood Hemolysis**	Hemolysis testing is a type of biocompatibility test used to determine whether use of a medical device can have any potentially harmful physiological effects. The test involves extracting leachable substances from the device or components and analyzing the leachable extracts for potentially harmful chemicals or toxicity. Typically, the Blood Hemolysis AAMI/ISO-4, ASTM method is followed.
BIO-TESTING	**Custom Biocompatibility Test**	A custom biocompatibility test developed for the client or a biocompatibility test other than those listed on HIGHPOWER's Sample Submission Form.

Simulated and In Use Testing

Test Code	Test Name	Test Description
SIM-USE	**Simulated Use**	Simulated use testing of medical devices or sterilizers per the required FDA guidance document.
IN-USE	**In Use**	In use testing of medical devices or sterilizers per the required FDA guidance document.

Miscellaneous

Test Code	Test Name	Test Description
CONSULT	**Consulting**	Consulting services provided by HIGHPOWER Labs on medical device development, validation, 510k pre-submissions, quality and regulatory requirements.
HFACTOR	**Human Factors Testing**	Human factors testing of medical devices and sterilizers per the required FDA guidance document and the AAMI HE75 standard and other associated AAMI documents.
TRAINING	**Training**	Training provided at a customer site or at HIGHPOWER Labs. HIGHPOWER has a number of presentations on medical devices which include but are not limited to, device cleaning, packaging and sterilization efficacy validations, sterilizer validations, human factors etc.
FEASIBILITY	**Feasibility Testing**	Feasibility testing on medical devices or a miscellaneous test performed that is not identified by another code on the HIGHPOWER Sample Submission Form.

NOTE: HIGHPOWER Labs is not responsible for misinformation or misrepresentation in the Test Code Definition Guide, this guide is for informational purposes only. Please contact HIGHPOWER at **info@highpowervtls.**com with any questions concerning the tests described in this guide or any other testing required that is not covered by reviewing this guide.

Revision: D
Issued: 2/2015
Revised 5/18/17
Authorized By: Ex. Management