SAMPLE PROCEDURE
Microbial Verification Following Installation or Major Repair of the V-PRO® 1, V-PRO® 1 Plus, V-PRO® maX, V-PRO® maX 2, and V-PRO® 60 Low Temperature Sterilization Systems

Product Numbers:
LCB045 Celerity™ 20 HP Challenge Pack
LCB046 Celerity™ HP Incubator

This document contains sample procedures for microbial verification or qualification testing of the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2, and V-PRO 60 Low Temperature Sterilization Systems. The procedures contained in this document are intended only to provide a foundation for your development of specific policies and procedures for your facility. It is the responsibility of each health care facility to ensure compliance with applicable laws, regulations, standards, and industry-recommended practices. The health care facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, express or implied, with respect to this sample procedure's compliance with local or federal laws, regulations, standards, or industry-recommended practices. STERIS is not responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained in it.

Definitions:

Mechanical Monitor: Sterilizer time, temperature, and pressure recording devices.

Biological Indicator: Test system containing viable microorganisms providing a defined resistance to a specified sterilization process (ANSI/AAMI ST58:2013). A biological indicator does not verify that an item is sterile.

Biological Indicator "Control": An unprocessed biological indicator used to ensure viable organisms are present in the indicator lot and to monitor the operation of the incubator.

Chemical Indicators: System that shows exposure to sterilization processes by means of physical and/or chemical changes of substances, and which are used to monitor the attainment of one or more of the variables required for sterilization process. (ANSI/AAMI/ISO 11140-1:2014)

Title: Microbial Verification Following Installation or Major Repair of the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Low Temperature Sterilization Systems

Procedure:

Prior to use, examine the challenge pack to ensure the pouch and biological indicator is intact. Examine the chemical indicator, through the plastic, to ensure the challenge pack has not been used previously.

NOTE: Microbial verification shall occur after installation, relocation, malfunctions, major repair and for routine requalification testing of the V-PRO 1, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2 and V-PRO 60 Low Temperature Sterilization Systems.

NOTE: Three (3) consecutive test cycles for the shortest exposure cyle for the V-PRO Sterilizer must be successfully completed.

Sterilizer	Cycle Name	# of Test Cycles
V–PRO maX 2 Sterilizer	Fast Non Lumen Cycle	3
V–PRO maX Sterilizer	Non Lumen Cycle	3
V–PRO 1 Plus Sterilizer	Non Lumen Cycle	3
V–PRO 1 Sterilizer	Lumen Cycle	3
V–PRO 60 Sterilizer	Non Lumen Cycle	3

Initiating the test cycle:

1. Record the lot number and expiration date of the challenge pack on the appropriate Appendix 1, 2, 3, 4 or 5 depending on the subject sterilizer.

2. Place challenge pack in the empty chamber of the V-PRO Sterilizer on the bottom shelf near the sterilizer door.

3. Close the chamber door.

4. Initiate the appropriate sterilization cycle. Refer to the table above to identify the correct cycle for the V-PRO Sterilizer.

Upon completion of the cycle:

1. Review the cycle printout to verify that process parameters were met (i.e. sterilant within expiration; temperature, sterilize time and pressure are correct). Record the cycle number on Appendix 1, 2, 3, 4 or 5.
    a. If any parameter was not met, the sterilization cycle was not successful. Follow departmental procedures for investigating suspected sterilization

failures. Dispose biological indicator (BI) per manufacturer's instructions for use

b. If cycle parameters are met, go to Step 2.

2. Put on gloves and remove the pouch from the shelf. Look for any leakage of the media within the pouch or in the BI vial.
    a. Challenge packs which show leakage must be placed in a steam compatible container for disposal. Refer to the product instructions for disposal recommendations.

3. Remove the chemical indicator (CI) strip. Observe the strip for a "Pass" color change.
    a. The CI passes if the indicator ink changes from magenta to yellow. Continue to Step 4.
    b. The CI ink fails if any color other than yellow is seen. Determine the root cause of the cycle failure. Follow departmental procedures for investigating suspected sterilization failures.
    c. If indicator demonstrates a failure, dispose of BI per manufacturer's instructions for use.

4. Remove the BI, peel off top lot label and check process indicator on the BI vial label for a color change from magenta to yellow.
    a. If the process indicator is yellow, proceed to step 5.
    b. If the process indicator is not yellow, determine the root cause of the cycle failure. Follow departmental procedures for investigating suspected sterilization failures. Dispose of BI per manufacturer's instructions for use.

5. To activate the BI, twist the cap clockwise and transfer the media from the cap to the vial by holding the BI firmly by its cap and flicking the wrist down.

6. Label the BI with the pertinent identification information, ensuring the label is not placed on the side of the vial.

7. Place the activated BI in a Celerity HP Incubator and press the corresponding well number to start reading. The well light will blink red during incubation.

8. Repeat steps 1-7 for a total of three consecutive test cycles for the shortest exposure cycle for the V-PRO Sterilizer.

Control

A control must be performed each day of the test and whenever the challenge pack's lot number changes.

1. Obtain a control BI located within the box of challenge packs.

2. Seal, activate and incubate the BI as described in step 5 through 7 above.
    a. Note: Use an unprocessed BI as the control.
    b. Note: The process indicators on the label will remain magenta.

Interpretation of Biological Indicator Test Results

1. The Incubator will display results for the “Test” and “Control” BIs when incubation is completed (within 20 minutes).
    a. A Negative response (no organisms present) is confirmed when the Celerity HP Incubator demostrates a solid green light with no audible alarm.
    b. A Positive response (organism present) is confirmed when the Incubator demostrates a solid red light with an audible signal.

2. Record the BI “Test” and “Control” results in Appending 1, 2,3, 4 or 5.

3. The test passes when all three “Test” BIs demonstrates a negative response (no increase in fluorescence signal) and the “Control” BI demonstrates a positive response (increase in fluorescence signal). The Sterilizer may be put in to service.

4. The test fails if one or more of the “Test” BIs demonstrate a positive response (increase in fluoresecence signal) and the “Control” BI demonstrates a positive response (increase in fluoresecence signal). Follow departmental procedures for reporting and investigating suspected sterilization failures. The sterilizer may not be used.

5. The test is invalid whenever the “Control” BI demostrates a negative response (no increase in fluoresecence signal). Investigate the cause for the failure and repeat the testing.

Table 1: Action to be taken due to failures

Type of failure	Root Cause	Action
CI Strip or BI Process Indicator Fails	Cycle not run.	Run Cycle with new test pack.
	Chamber contains medical devices for sterilization.	Repeat cycle using an empty chamber.
	Expired sterilant.	Repeat cycle using non-expired sterilant.
	Sterilizer malfunction.	1. Remove the sterilizer from service and call service for repair. 2. Repeat entire test series after repair is completed.
Control is Negative for Growth	Incorrect incubator used	Use correct incubator and repeat test series.
	No root cause identified.	Obtain different box and repeat test series.
Test Biological Indicator Grows	Contaminant organism found.	Repeat test cycle.
	Biological indicator lid compressed prior to sterilization.	Repeat test cycle.
	Cycle not run	Run cycle with new test pack.
	Sterilizer malfunction.	1. Remove the sterilizer from service and call service for repair. 2. Repeat entire test series after repair is completed.

APPENDIX 1: Microbial Verification Report V-PRO maX 2 Sterilizer

V-PRO maX 2 Sterilizer Serial Number	
Department / Location	
Challenge Pack Lot Number	

Test Identification		Cycle Number	Date/Time in Incubation	Date/Time Results Read	Growth	No Growth
Control Biological Indicator		Not Applicable			☐	☐
Fast Non Lumen Cycle	Test Cycle 1				☐	☐
	Test Cycle 2				☐	☐
	Test Cycle 3				☐	☐

*Green cell indicates acceptable test result.

Interpretation

☐ All test BIs are negative and the control positive – **PASS**

☐ One or more test BIs are postive and the control positive - **FAIL**

☐ Control is negative – Inconclusive (determine cause for failure and repeat the test)

Technician: _____

Supervisor: _____

- Include all cycle printouts with this report

APPENDIX 2: Microbial Verification Report V-PRO maX Sterilizer

V-PRO maX Sterilizer Serial Number	
Department / Location	
Challenge Pack Lot Number	

Test Identification		Cycle Number	Date/Time in Incubation	Date/Time Results Read	Growth	No Growth
Control Biological Indicator		Not Applicable			☐	☐
Non Lumen Cycle	Test Cycle 1				☐	☐
	Test Cycle 2				☐	☐
	Test Cycle 3				☐	☐

*Green cell indicates acceptable test result.

Interpretation

☐ All test BIs are negative and the control positive – **PASS**

☐ One or more test BIs are postive and the control positive - **FAIL**

☐ Control is negative – Inconclusive (determine cause for failure and repeat the test)

Technician: _____

Supervisor:_____

- Include all cycle printouts with this report

APPENDIX 3: Microbial Verification Report V-PRO 60 Sterilizer

V-PRO 60 Sterilizer Serial Number	
Department / Location	
Challenge Pack Lot Number	

Test Identification		Cycle Number	Date/Time in Incubation	Date/Time Results Read	Growth	No Growth
Control Biological Indicator		Not Applicable			☐	☐
Non Lumen Cycle	Test Cycle 1				☐	☐
	Test Cycle 2				☐	☐
	Test Cycle 3				☐	☐

*Green cell indicates acceptable test result.

Interpretation

☐ All test BIs are negative and the control positive – **PASS**

☐ One or more test BIs are postive and the control positive - **FAIL**

☐ Control is negative – Inconclusive (determine cause for failure and repeat the test)

Technician: _____

Supervisor:_____

- Include all cycle printouts with this report

APPENDIX 4: Microbial Verification Report V-PRO 1 Plus Sterilizer

V-PRO 1 Plus Sterilizer Serial Number	
Department / Location	
Challenge Pack Lot Number	

Test Identification		Cycle Number	Date/Time in Incubation	Date/Time Results Read	Growth	No Growth
Control Biological Indicator		Not Applicable			☐	☐
Non Lumen Cycle	Test Cycle 1				☐	☐
	Test Cycle 2				☐	☐
	Test Cycle 3				☐	☐

*Green cell indicates acceptable test result.

Interpretation

☐ All test BIs are negative and the control positive – **PASS**

☐ One or more test BIs are postive and the control positive - **FAIL**

☐ Control is negative – Inconclusive (determine cause for failure and repeat the test)

Technician: _____

Supervisor:_____

- Include all cycle printouts with this report

APPENDIX 5: Microbial Verification Report V-PRO 1 Sterilizer

V-PRO 1 Sterilizer Serial Number	
Department / Location	
Challenge Pack Lot Number	

Test Identification		Cycle Number	Date/Time in Incubation	Date/Time Results Read	Growth	No Growth
Control Biological Indicator		Not Applicable			☐	☐
Lumen Cycle	Test Cycle 1				☐	☐
	Test Cycle 2				☐	☐
	Test Cycle 3				☐	☐

*Green cell indicates acceptable test result.

Interpretation

☐ All test BIs are negative and the control positive – **PASS**

☐ One or more test BIs are postive and the control positive - **FAIL**

☐ Control is negative – Inconclusive (determine cause for failure and repeat the test)

Technician: _____

Supervisor:_____

- Include all cycle printouts with this report