

Section: Division of Nursing  
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PROCEDURE  
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HACKETTSTOWN REGIONAL MEDICAL CENTER

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OR/CSR  
(Scope)

**TITLE: STERIS BIOLOGICAL MONITORING PROCEDURE**

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**PURPOSE:** To provide a mechanism to ensure that the STERIS is functioning properly and that sterilization and/or the disinfection process has been accomplished.

**FREQUENCY:** Biological monitoring will be done daily as the second load of the day.

- EQUIPMENT LIST:**
1. Clean gloves
  2. 2 Spore strips
  3. 2 Vials culture media
  4. 2 Orange vascu-stat clips
  5. Incubator
  6. 1 chemical indicator strip

- CONTENT:** PROCEDURE STEPS:
1. Load the System 1 Sterile Processing System as indicated in the System 1 Operator Manual.
  2. Aseptically open the glassine envelope by peeling the glassine apart at the indicated end.
  3. Grasp indicator with transfer clip. Remove indicator from envelope.
  4. Place transfer clip and indicator in processing tray channel, accessory rack or in processing container.
  5. Complete sterile processing cycle per Operator Manual. A STERIS Chemical Indicator should be used in conjunction with each biological indicator. Refer to Chemical Indicator Instructions.
  6. Put on clean gloves. If using processor container remove lid.
  7. Retrieve chemical monitoring strip and interpret results. If color change is complete, go to next step. If color change is incomplete, STOP; assume load is not sterile. Discontinue biological monitoring test, disposing of biological indicator test strip and refer to chemical monitoring strip directions.
  8. Holding vial in one hand, at an angle, grasp vial cap with little finger of the other hand.

Remove cap from vial.

9. Aseptically remove the transfer clip with indicator from the processor, taking care not to touch biological indicator.
10. Insert indicator into vial. Screw vial into cap. Make sure indicator is fully immersed.
11. Prepare label for vial. Mark "test" and place vial in incubator for 24 hours. Maintain incubator temperature 55-60°C (131-140°F).
  - If the rest culture starts to demonstrate turbidity or a color change from red to yellow, conditions for sterilization were not achieved. Follow departmental procedure for reporting sterility failures.
  - If the test culture remains red and clear, conditions for sterilization of the biological indicator were achieved. Record results as "pass".
12. Biological Control
  - Biological controls should be performed, preferably every day a microbial test is performed
  - Using the transfer clip, transfer control indicator into fresh vial of culture medium. Prepare label for vial, mark "control" and place vial in incubator for 24 hours. Maintain incubator temperature 55-60°C (131-140°F)

If the control is positive for growth record results as a "pass." If growth of the control does not occur, immediately begin incubation of a second control culture. Growth of a second culture must occur within 24 hours for test to be considered valid. If growth of a second culture does not occur, follow departmental procedures for sterility failures.
13. Investigation of failed biological indicator tests
  - If test culture exhibits growth (color change and/or turbidity), have microbiology lab identify organism type using Gram stain.
  - If growth is not a Gram-positive rod, assume contamination. Thoroughly review challenge and culturing techniques to identify possible causes prior to any subsequent testing.
  - If growth is identified as Gram-positive rod, sterilizer operation is suspect. Thoroughly review challenge and culturing techniques to identify possible other causes. Repeat challenge test.
  - If repeat test also shows growth of a Gram-positive rod, discontinue sterilizer operation until cause can be identified. Assume that any items processed since the last negative test results were not sterile. Follow departmental procedures for sterility failures.

The test organism is a Gram positive to Gram variable spore forming rod. Growth of other types of organisms suggests likely environmental contamination.

In particular, ensure that transfer clip supplied by Steris was used during testing, and that gloves were put on after start of challenge cycle (to minimize potential for transfer of spores that may have been removed during initial handling of strip).

#### OTHER

#### Storage Conditions

- The Verify ® Biological Monitoring Kit should be stored at 36 - 76°F (2 - 24°C), 30-80% relative humidity (RH)
- Do not store the kit near sterilizing agents or expose to excessive heat

Expiration Date

- Do not use beyond the expiration date provided on the kit label. The kit has a 12-month expiration from the date of manufacture.

Disposal Instructions

- Culture media showing growth and expired indicators: before discarding, treat as appropriate for standard microbial waste, non-pathogenic species (e.g. stream autoclave at 121°C (250°F) for not less than 30 minutes, or use other suitable means.
- Media showing no growth and expired culture media vials can be discarded as standard waste.

REFERENCE: VERIFY<sup>®</sup> Biological Monitoring of the STERIS PROCESS Instructions