

SAMPLE PRODUCT PROCEDURE – M4214EN
Verify™ RESI-TEST™ SWAB Cleaning Indicators

Product Number:

LCC100 Verify™ RESI-TEST™ SWAB Cleaning Indicators

This document contains sample procedures for the detection of residual protein on medical devices after cleaning within sterile processing department and other healthcare applications. The procedures contained in the document are only intended to provide a foundation for developing specific policies and procedures for your facility. It is the responsibility of the individual healthcare facility to ensure compliance with all applicable laws, regulations, standards and industry-recommended practices. The healthcare facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, expressed or implied, with respect to compliance with local or federal laws, regulations, standards or industry recommended practices. STERIS shall not be responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained herein.

Title:

Residual detection testing for protein using Verify™ RESI-TEST™ SWAB

Purpose:

“Cleaning encompasses the removal of patient secretions and excretions and of microorganisms from the patient or from handling or water exposure during reprocessing. After completing the cleaning process, personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures (see Annex D for available methods.)”

(ANSI/AAMI ST79:2013, 7.5.5.)

“After devices are rinsed, they should be visually inspected for cleanliness and working condition and then dried, in accordance with the device manufacturer’s written IFU, to remove residual fluids. Personnel should visually inspect each item carefully to detect any visible soil. Inspection using magnification might identify residues more readily than the unaided eye. Visual inspection alone may not be sufficient for assessing the effectiveness of the cleaning process. The use of methods that are able to measure cleaning effectiveness that is not detectable using visual inspection may be considered in facility cleaning policy and procedures.”

(ANSI/AAMI ST58:2013, 6.6.6.)

Procedures:

| Cleaning Type | Usage | Medical Device Type |
|----------------------|--------------------------------------|---------------------------------|
| Pass-Through | Varies | Historically Difficult to Clean |
| Automated | Once a Day/Per Washer/Per Rack Level | Historically Difficult to Clean |

Instructions for Use:

Perform verification after manual or automated cleaning. Wear appropriate PPE per facility policies. Note that not wearing gloves may affect results.

- 1) Remove swab from foil bag and verify expiration date. Holding swab tube firmly, twist and pull top of swab out of swab tube with gloved hands. Do not touch swab tip nor medical device with fingers.
- 2) Thoroughly swab medical device. It is important in any testing program to establish a consistent and easy-to-replicate procedure.
- 3) Replace swab in swab tube.
- 4) To activate RESI-TEST™ SWAB, hold swab tube firmly and use thumb and forefinger to break ‘Snap-Valve’ by bending bulb forward and backward. Squeeze bulb twice, expelling solution down swab shaft.
- 5) Bathe swab tip in solution by gently shaking for 5 seconds.
- 6) Observe color change of solution. There is no need to remove the swab from the holder after activation.

Evaluation of Results:

- 1) Hold RESI-TEST™ SWAB against a blank, white sheet of paper
- 2) Compare color of *solution* against label to evaluate surface cleanliness
- 3) Refer to color chart for result/action and document results on included log sheet

| Color Range | Result | Action |
|----------------------------|--------|--------------------------|
| Light Brown to Light Green | Pass | Proceed to Sterilization |
| Light Blue to Dark Blue | Fail | Reprocess & Retest |

Negative Control Test:

- 1) Perform (1) negative control test per box.
- 2) Do not remove swab from holder.
- 3) Hold swab tube firmly and use thumb and forefinger to break ‘Snap—Valve’ by bending bulb forward and backward. Squeeze bulb twice, expelling solution down swab shaft.
- 5) Bathe swab tip in solution by gently shaking for 5 seconds.
- 6) Observe color change of solution. There is no need to remove the swab from holder after activation.
- 7) Color change should be light brown or light green indicating a Pass result.
- 8) If color change is not light brown or light green, consider the test a Fail and do not use the lot.

General Notes:

- 1) Swab tip will have a blue color. This is normal. The swab tip is hidden under the label once in the tube. There is no need to remove the swab from the holder after activation.
- 2) At very low levels of protein/protein residue, care should be taken to interpret results. Any blue color solution should be regarded as positive for protein and therefore a failing result.

- 3) A darker blue color corresponds to greater protein residue.
- 4) Due to natural progression, the color of the pass can vary from light brown to light green.
- 5) A negative control test (RESI-TEST™ SWAB activated without sample collection) may be conducted for comparison. It is recommended to run (1) negative control test per box.
- 6) Keep foil bag sealed between uses.
- 7) Some condensation on inner walls of foil bag is normal.
- 8) RESI-TEST™ SWAB is used to verify that a medical device is free from protein. While it is indicative of efficacious cleaning, it is not intended as a guarantee that all medical devices in a load are free from protein.

Documentation:

Document results on log sheet included within the product IFU.

Shelf Life:

Refer to label for expiration date.

Storage:

Store device between 36°F and 77°F (2°C and 25°C).