ChannelCheck™ Sample Policy

SUBJECT: Detection of residual organic soils inside various channels, no matter the channel size of the lumen items.

DEPARTMENT: Central Service / Endoscopy

APPROVED BY:

EFFECTIVE:

REVISED: 2/18/16

PURPOSE: For detection of various residual organic soils inside lumened items to help ensure proper cleaning and to reduce risk to personnel or patients.

POLICY: The ChannelCheck™ tests for three common organic soils at once: blood, protein and carbohydrates. Random testing of various instruments with lumens is to be performed in accordance with the manufacturer’s guidelines to ensure that the cleaning process is being conducted properly.

RATIONALE:

According AAMI ST91, healthcare facilities should establish a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing. This program should incorporate both visual inspections and testing of the equipment to identify conditions that may affect the cleaning or disinfecting processes. Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes. Therefore, the use of methods that are able to measure organic residues that are not readily detectable using visual inspection alone should be considered in facility cleaning policy and procedures.

The following statements from professional societies and governing bodies support the use of a cleaning verification process for flexible endoscopes:

1. ANSI/AAMI ST91:2015, “Flexible and semi-rigid endoscope processing in health care facilities”

“Testing cleaning efficacy: The facility’s onsite quality assurance program should include ways to verify that the cleaning equipment used for processing of medical devices is working. Testing the equipment upon installation, during routine use (daily) and on all cycles used, after repairs, and when changing to a new type of cleaning solution allows the user to verify its continued effectiveness... Manufacturer’s written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing. The frequency of testing the efficacy
of the manual cleaning step should occur on a regular basis, weekly or preferably daily (Drosnock 2014, Alfa 2014).”

Numerous studies have identified the nature of microbial contamination likely to be found in improperly reprocessed endoscopes and have demonstrated the value of surveillance testing...

2. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES 2016:
   a. Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (eg, after each use, daily).

   i. Cleaning verification tests are used to verify the ability of the cleaning process to remove, or reduce to an acceptable level, the organic soil and microbial contamination that occurs during use of a reusable device. Cleaning verification tests include chemical reagent tests for detecting clinically relevant soils (eg, protein, carbohydrate) and ATP. Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve effectiveness.

   ii. Auditing the manual cleaning of flexible endoscopes provides an objective method for verifying cleanliness and helps ensure that insufficiently cleaned flexible endoscopes are recleaned before HLD or sterilization.

   iii. There are a number of tests that can be used to assess cleaning efficacy. Chemical tests involve the use of a reagent and observing for a color change that indicates the presence of organic markers such as protein or blood. In a dual phase (ie, simulated-use, inuse) study to validate the use of an audit tool composed of reagent test strips in 43 endoscopy clinics across Canada, Alfa et al collected samples from 30 patient-used endoscopes (ie, 10 colonoscopes, 10 duodenoscopes, 10 gastrosopes) and tested them for residual protein, carbohydrate, and hemoglobin using the audit tool test strips. The test strips had three reagent pads designed to rapidly detect organic residualsof protein, carbohydrate, and hemoglobin after manual cleaning. The researchers confirmed that the audit tool flagged endoscopes with residual protein, hemoglobin, or carbohydrate.

   v. There are quantitative tests that can be used for cleaning verification testing of other residual soils, including:
      • protein,
      • carbohydrate,
      • hemoglobin,

   vi. The multidisciplinary team should evaluate the need to implement protocols for cleaning verification testing of flexible duodenoscopes with elevator channels.

 b. Records related to flexible endoscope processing should include the date and time, identity of the endoscope and endoscope accessories, method and verification of cleaning and results of cleaning verification testing.
3. SGNA Standard of Infection Prevention in the Gastroenterology Setting:

a. The use of cleaning monitors for automated washers may help to ensure adequate functioning (Alfa, 2013).

b. “Visibly clean” is a method routinely used to assess the adequacy of manual cleaning (Alfa et al., 2012; Rutala et al., 2008). This may involve the use of a magnifying glass to inspect for gross soil. Visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa, 2014). **Rapid cleaning monitors are available. These monitors can provide documentation on cleaning efficacy but do not reflect microbial activity. Real-time testing of endoscope lumens/elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are re-cleaned prior to HLD.** Facilities should consider the use of monitors to verify ongoing cleaning adequacy (Alfa, 2013).

c. Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use (Rutala & Weber, 2004; CDC, 2015)

4. SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes:

a. **Note:** It is impossible to visualize internal channels. Literature suggests that, to confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to high-level disinfection (Visrodia et al., 2014). If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions (Alfa et al., 2013, 2014; AAMI, 2015; ASGE, 2014).

5. ANSI/AAMI ST79 and Quality Monitoring:

- “Some types of mechanical cleaning equipment are designed to clean and/or disinfect specific kinds of medical devices, such as endoscopes... Mechanical cleaning equipment should be tested upon installation, weekly (preferably daily) during routine use, and after major repairs... (7.5.3.3)
- Section 10.2 and ANNEX D states“...Health care personnel may perform verification tests as part of the overall quality assurance program. This verification may include the use of test devices that monitor the functionality of the cleaning equipment in cleaning surfaces and that ensure adequate fluid flow in equipment that has adaptors for lumened devices...”
- “Current data (Alfa, et al., 2002) indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers are as follows: protein, < 6.4 μg/cm2; carbohydrate, < 1.8 μg/cm2; hemoglobin, < 2.2 μg/cm2; sodium ion, < 1 μmole/cm2; and endotoxin, < 2.2 EU/cm2 in the biopsy/suction channel... (Section - D.2 Markers)”
- Regarding verification of the cleaning process: “... processing personnel are increasingly aware of the need to control and standardize the steps taken to
ensure the sterility of devices for patient use. Because disinfection and sterilization cannot be assured unless the cleaning process is successful, professionals in the field ought to seek out whatever means are available and practical to verify this function. A quality system would call for monitoring and documenting decontamination processing parameters, whether the process is accomplished by hand or mechanically....” (Section 7.7.5)

• “Furthermore, visual inspection is not possible for the inner components of medical devices that have lumens or that are of nonsealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps). Ideally, cleaning verification by users should include (a) visual inspection combined with other verification methods that allow the assessment of both external surfaces and inner housing and channels of medical devices, (b) testing the cleaning efficacy of equipment, and (c) monitoring key cleaning parameters (e.g., temperature)....”

6. ASGE: Technologies for monitoring the quality of endoscope reprocessing, 2014:

a. Bioburden assays: Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels (e.g. EndoCheck and ChannelCheck; HealthMark Industries, Fraser, Mich.)...EndoCheck is able to detect protein and blood residues within the biopsy channel of endoscopes while ChannelCheck is able to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes.

b. Methodology. All of the above tests are easily and rapidly performed... The EndoCheck test uses a long probe with a swab attached to its tip. The probe is inserted into the endoscope’s biopsy channel, and a swab of the channel is obtained. The swab is then cut off the probe and dropped into a test vial containing the test reagent and shaken. The presence of blood or protein residue is displayed by a color change in the reagent. The ChannelCheck test offers the advantages of ease of test sample collection, simple test methodology using a test strip similar to a urine dipstick, as well as detection of a wider range of biological soils. The assay uses test strips with 3 pads that allow detection of residual carbohydrate, protein, and hemoglobin. The endoscope’s biopsy channel is flushed with 10 mL of sterile deionized water, followed by 10 mL of air to promote expulsion of the water from the distal end of the endoscope. This water is collected into a sample collection container, and the test strip is immersed within it for 10 seconds. The 3 test pads on the test strip indicate the presence of residual carbohydrate, protein, and hemoglobin by a color change within 90 seconds. The colors on the test strip are compared with those on a color indicator chart provided on the test strip bottle.
c. Potential Clinical Applications: Minimizing the potential for transmission of pathogens by using flexible endoscopes is an important issue for facilities at which endoscopy is performed. These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing. Emerging technologies for monitoring the quality of endoscope reprocessing offer the ability to perform rapid surveillance, which may potentially help reinforce adherence to the many steps in reprocessing.”

   1. Recommendations: Ensure reprocessing practices meet or exceed standards
   2. Use rapid indicators to monitor cleaning effectiveness

8. FDA, CDC, VA Joint Safety Communication
   - Establish an institutional program for endoscope processing, along with written procedures for monitoring adherence to the program and a chain of accountability. Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle.
   - Train employees to set-up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence.

9. CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008:
   - Clusters of infections “highlight the importance of training, proper model-specific endoscope connector systems, and quality-control procedures to ensure compliance with endoscope manufacturer recommendations and professional organization guidelines.
   - To achieve and maintain competency, train each member of the staff that reprocesses semicritical and/or critical instruments as follows: 1) provide hands-on training according to the institutional policy for reprocessing critical and semicritical devices; 2) supervise all work until competency is documented for each reprocessing task; 3) conduct competency testing at beginning of employment and regularly thereafter (e.g., annually); and
   - Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented.

- Non-culture methods have been used to assess duodenoscope reprocessing by detecting residual organic material after cleaning. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations. They might, however, provide insight regarding the quality of duodenoscope reprocessing if systematically validated.

Non-culture methods are indicators of the presence of residual organic material after cleaning such as protein, carbohydrate and hemoglobin. These include EndoCheck, ChannelCheck, ProCheck, HemoCheck, and FlexiCheck. ATP is another marker that can be used to indicate the presence of residual patient material.

The ChannelCheck™ is designed to allow in-house testing of any cleaned channel/lumened item (instrument) and allows facilities to verify that adequate cleaning has been achieved.

ChannelCheck is the first product capable of testing for residual organic soils inside the various channels / lumens (such as a flexible endoscopes & suction tubes) no matter the channel / lumen size. ChannelCheck tests for three common organic soils at once: blood, protein and carbohydrates.

As noted, channels/lumened items (instruments) provide a difficult challenge regardless if it is a suction tube or a flexible endoscope. A quality improvement system that allows you to monitors the inside of any channel / lumen is an important function of any Infection Control program. Testing channels / lumen instruments with the ChannelCheck and recording results in a log is one such system.

The use of the ChannelCheck is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether manual or automatic cleaning of these items is done properly. The frequency of testing of the various channel / lumen instruments (including flexible endoscopes) should be done at least weekly (preferably with each reprocessing cycle or daily for flexible endoscopes).
Lot Control

Control Test: The first step when opening a new bottle of ChannelCheck residual soil test strips is to check the performance of the lot with the included vial of control soil. This will insure that the reagent in each of the test pads has remained active after shipment. This is only done once per bottle and only 2 control vials (1 per bottle) are included. To test, remove the vial of dehydrated test soil from the box. The test vial holds enough lyophilized test soil to create a single milliliter of test soil.

1. Re-hydrate Soil: To re-hydrate, unscrew the cap from the vial, then add exactly 1ml of sterile deionized water to the vial. Screw the cap back on the vial, being sure you have a tight seal.
2. Shake Vigorously: Shake the vial vigorously for at least one minute. Check the vial to make sure the soil has been completely re-hydrated.
3. Retrieve a Single Test Strip: Retrieve a single ChannelCheck test strip from the pack.
4. Dip Test Strip into Vial: Dip the test into the vial, making sure to completely immerse all three test pads into the solution.
5. Swish Test Strip: Swish the test strip in the vial for 10 seconds.
6. Dab Side of Test Strip on Absorbent Pad: After 10 seconds, remove the test strip and dab the side of the moistened test pad on a clean, dry absorbent pad, to wick off excess water.
7. Wait 5 minutes: The reagents in the test pads require time to interact with the residual soil, so wait a complete 5 minutes before reading the results.
8. Compare Results to Control Color Chart: After 5 minutes, compare the results to the Control Result Color Chart. The colors of each test pad should closely approximate the colors found on the Control Color Chart.
9. Record Results: On a log sheet, record the results of each pad.
PROCEDURE:

After the cleaning process is complete is when you will test the channel /lumen item. This is done before sterilization or High Level Disinfection.

Lumened Item Procedure:

1. Using a new 20 ml or larger syringe (preferably a slip tip syringe), draw 10ml of air followed by 10ml of commercially available pre-packaged sterile water (i.e., sterile water for irrigation into the syringe, drawing the syringe to the 20ml level. Place the distal end of the lumen item inside a clean collection container (e.g., sterile urine specimen container or supplied Zip-lock bag).
2. Inject 10 ml of sterile water through the proximal part of the lumen/channel followed by the 10 ml of air in order to aid in complete flushing of the fluid. Collect all the fluid that drains from the distal end into the sample collection container.
3. Mix the sample well (swishing).
4. With the three pads fully submerged, stir the recovered water for 10 seconds with the test strip.
5. Remove the test strip.
6. Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture.
7. After 90 seconds, compare the colors on the test strip to the color indicator chart provided.
8. Record the results for all 3 pads.

Should any of the pads indicate there is residual soil, re-clean the device (according to facility policy) and then retest. Record your results in a log book.

Once all three pads are negative, proceed to the next step in your facilities process.
Flexible Endoscope Procedure:

After the manual cleaning process is complete is when you will test the flexible endoscope with ChannelCheck™. This is performed before High Level Disinfection or sterilization.

1. Using a new 20 ml or larger syringe (preferably slip tip), draw 10ml of air followed by 10ml of commercially available pre-packaged sterile water. (i.e., sterile water for irrigation) into the syringe, drawing the syringe to the 20ml level. With the distal end of the scope held lower than the biopsy/suction channel, place the distal end of the flexible endoscope inside a clean collection container (e.g., sterile urine specimen container or supplied Zip-lock bag).
2. Inject 10 ml of sterile water through the biopsy/suction channel followed by the 10 ml of air in order to aid in complete flushing of the fluid. Collect all the fluid that drains from the distal end into the sample collection container.
3. Mix the sample well (swishing).
4. With the three pads fully submerged, stir the recovered water for 10 seconds with the test strip.
5. Remove the test strip.
6. Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture.
7. After 90 seconds, compare the colors on the test strip to the color indicator chart provided.
8. Record the results for all 3 pads.

Should any of the pads indicate there is residual soil, re-clean the device (according to facility policy) and then retest. Record your results in a log book. Once all three pads are negative, proceed to the next step in your facility’s process.

Note: Facilities using an AER that has an FDA-cleared cleaning claim can test after high-level disinfection but must ensure they use sterile water for testing and follow all required drying steps to ensure that the endoscope is completely dry after testing (using the correct amount of air flush and alcohol rinse according to the IFU) prior to storage.

Also, a facility may choose to use the ChannelCheck to test the endoscope just prior to use in the next patient procedure. It is recommended to use the endoscope within 1 hour after testing with ChannelCheck. If not, the endoscope must be dried thoroughly or reprocessed again.

All test results must be documented.
Flush a flexible endoscope channel  
Capture the solution and test the solution
ChannelCheck™ Testing Log Sheet

<table>
<thead>
<tr>
<th>Test Date</th>
<th>Strip Lot #</th>
<th>Testers Initials</th>
<th>Item Tested</th>
<th>Carbohydrate Result</th>
<th>Protein Result</th>
<th>Blood Result</th>
<th>*Comment / Action</th>
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Note: Read Product insert before use. Do not touch the test area of any strip. Store strip at temperatures between 59°F and 86°F (15º-30ºC). Do not remove desiccant from bottle. Remove only enough strips for immediate use. Replace cap promptly and tightly. Testing reading time is 90 seconds and record results immediately. Compare results to chart on bottle. Record results as a (N) negative result, no residual; or as (P) positive for residual.

*If a flexible endoscope is tested make sure you document the serial number.

Comments:
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________
________________________________________________________________


Sample Competency for Using the ChannelCheck™

Name: ________________________________________________________

**Competency Statement:** Complies with policy and procedure for cleaning and testing endoscopes (biopsy channels) using the ChannelCheck.

**Key**
- 1 = Performs independently and consistently. Ask for assistance in new situations.
- 2 = Performs with minimal guidance and direction. Asks for assistance when necessary.
- 3 = Performs with maximal guidance and direction. Preceptor dependent.

Consistently needs assistance.

**Comments:**

**Competency Achieved:** _____________________________(Date)

**Evaluator:** ______________________________________________________

**Learner:** _______________________________________________________

Flexible endoscopes have significantly improved the quality of care by providing less invasive methods of performing surgery and diagnostic tests. A critical issue of importance in the reprocessing of any reusable medical device is adequate cleaning in preparation for disinfection/sterilization. Compliance with accepted cleaning practices for flexible endoscopes has been shown to be less than optimal in many centers.

The ChannelCheck is a simple to use and interpret end-user test of the cleanliness of flexible endoscopes. The method is simple and fast. The user flushes sterile-DI water through the channel to be tested. They recapture from the distal end and sample it with a test strip (dipstick). After 90 seconds, the user compares the pads on the test strip to a chart for a color change which indicates either no residue (clean) or any of three residues (dirty). Each pad is sensitive to one of three soils: carbohydrate, protein or hemoglobin. Any endoscope with a positive result (dirty) should be immediately reprocessed and retested.
**Lot Control:**

Control Test: The first step when opening a new bottle of ChannelCheck™ residual soil test strips is to check the performance of the lot with the included vial of control soil. This will insure that the reagent in each of the test pads has remained active after shipment. This is only done once per bottle and only 2 control vials (1 per bottle) are included. To test, remove the vial of dehydrated test soil from the box. The test vial holds enough lyophilized test soil to create a single milliliter of test soil.

1. Re-hydrate Soil: To re-hydrate, unscrew the cap from the vial, then add exactly 1ml of sterile deionized water to the vial. Screw the cap back on the vial, being sure you have a tight seal.

2. Shake Vigorously: Shake the vial vigorously for at least one minute. Check the vial to make sure the soil has been completely re-hydrated.

3. Retrieve a Single Test Strip: Retrieve a single ChannelCheck test strip from the pack.

4. Dip Test Strip into Vial: Dip the test into the vial, making sure to completely immerse all three test pads into the solution.

5. Swish Test Strip: Swish the test strip in the vial for 10 seconds.

6. Dab Side of Test Strip on Absorbent Pad: After 10 seconds, remove the test strip and dab the side of the moistened test pad on a clean, dry absorbent pad, to wick off excess water.

7. Wait 5 minutes: The reagents in the test pads require time to interact with the residual soil, so wait a complete 5 minutes before reading the results.

8. Compare Results to Control Color Chart: After 5 minutes, compare the results to the Control Result Color Chart. The colors of each test pad should closely approximate the colors found on the Control Color Chart.

9. Record Results: On a log sheet, record the results of each pad.
<table>
<thead>
<tr>
<th>Critical Behavior</th>
<th>1</th>
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<tbody>
<tr>
<td>Review Hospital Policy on cleaning of Endoscopes</td>
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<td>Describes the purpose of cleaning and decontamination of the Endoscope</td>
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<td>Selects and wears the appropriate personal protective equipment</td>
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<td>Gather appropriate supplies to perform test on the Endoscope (ChannelCheck, brushes, etc.)</td>
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<td>Understands when to Leak test the Endoscope</td>
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<td>• If endoscope fails leak test understands the process for returning endoscope for repair</td>
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<td>Removal of all detachable parts</td>
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<td>Cleaning (brush and syringe) with approved solution (irrigation of all channels) and surface cleaning.</td>
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<td><strong>Follows manufacture guidelines for cleaning (all steps).</strong></td>
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<td>Check channel with ChannelCheck after cleaning is done (2 people may be required for testing/collection).</td>
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<td>After cleaning, a test of the biopsy/suction channel should be performed (other channels can be tested but at least the biopsy/suction channel should be tested).</td>
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<td>Using a new 20 ml syringe or larger, draw 10ml of air followed by 10ml of commercially available prepackaged sterile water (i.e sterile water for irrigation) into the syringe, drawing the syringe to the 20ml level. With the distal end of the endoscope held lower than the biopsy/suction channel, place the distal end of the flexible endoscope inside a clean collection container (e.g., sterile urine specimen container or supplied Zip-lock bag).</td>
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Residual soil, re-clean the device (according to facility policy) and then retest. **All three pads must show a negative result before proceeding to the next step of high level disinfection or sterilization, according to facility policy.**

Follow Hospital Policy on the sterilization/disinfection of the endoscope.

Remember to always follow manufacturers guidelines on cleaning and sterilization of all endoscopes.

**References:**

1. ANSI/AAMI ST91:2015, “Flexible and semi-rigid endoscope processing in health care facilities.”
2. AORN GUIDELINE FOR PROCESSING FLEXIBLE ENDOSCOPES, Revised February 2016 for publication in Guidelines for Perioperative Practice, 2016 edition.
8. FDA, CDC, VA Joint Safety Communication: [http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm](http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm190273.htm)