

ChannelCheck™ Sample Policy

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

DEPARTMENT: Central Service / Endoscope

APPROVED BY:

EFFECTIVE:

REVISED: 10/2010

PURPOSE: To test for detection of various residue organic soil inside lumen items to help ensure proper cleaning *and reduce risk to personnel or patients*¹,

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 done according to the manufacturer's guidelines to ensure that the cleaning process is being done properly.

RATIONALE:

" A problem analysis should be completed for any problem with any aspect of decontamination that can pose a risk to personnel or patients. The problem analysis should define and resolve the problem and the system should be monitored to ensure that the problem has been corrected.."²

There has been a growing concern about the effectiveness of decontamination technique for reusable medical instrumentation in healthcare facilities. Studies have shown the ability of sterilization technologies, which under normal conditions achieve acceptable sterility assurance levels, to be greatly impaired by the presence of residual soil containing serum and salt³. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate.^{4,5} Items with lumens or channels pose one of the most difficult challenges in cleaning and inspecting.

Testing any channel / lumen item (instrument) especially flexible endoscopes is important. One cannot see down the channel / lumen. One issue of critical importance in the reprocessing of any reusable medical device is to ensure it is adequately cleaned such that it can be reliably disinfected / sterilized⁶.

Compliance with accepted cleaning practices for flexible endoscopes has been shown to be less than optimal in many centers.⁷

"...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; ... in the biopsy/suction channel."⁸

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

AAMI TIR 12 recommends that users be able to test and validate their cleaning process⁹. The method is simple and fast.

ChannelCheck™ is the first product capable of testing for residual organic soils inside the various channels / lumens (such as a flexible endoscopes, suction tube,...) no matter the channel / lumen size.

ChannelCheck™ tests for three common organic soils at once: blood, protein and carbohydrates.

As noted channels / lumen items (instruments) provide a difficult challenge regardless if it is a suction tube or a flexible scope. A quality improvement system that allows you to monitor 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.¹⁰

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 scopes) should be done at least weekly (preferable daily for flexible scopes).

Lot Control

When opening the bottle for the first time prior to commencing testing of any channel, one test strip should be tested with the supplied control soil.

Inject 1 ml of sterile water into the supplied positive control vial. Mix by shaking well and let stand for 2 minutes to insure rehydration. Dip a test strip into the vial of solution and swish for 10 seconds. Blot excess fluid. Read results in 90 seconds by comparing the colors on the test strip to the color indicator chart. Record results on the log sheet provided.

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.

Lumen Item

1. Using at least a 20 ml syringe, draw 10ml of air followed by 10ml of sterile-DI water (e.g., 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).

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.

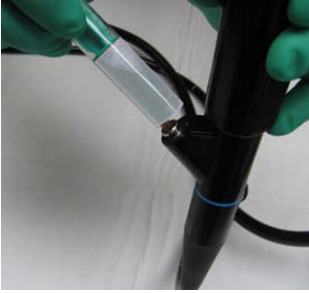
Flexible Endoscope

After the cleaning process is complete is when you will test the flexible scope. This is done before sterilization or High Level Disinfection.

1. Using at least a 20 ml syringe, draw 10ml of air followed by 10ml of sterile-DI water (e.g., 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).
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 facilities process.



Flush a flexible scope channel



Capture the solution and the Test the solution

Sample Competency for Using the ChannelCheck

Name: _____

Competency Statement: Complies with policy and procedure for cleaning and testing scopes (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/sterilization¹¹. Compliance with accepted cleaning practices for flexible endoscopes has been shown to be less than optimal in many centers.¹²

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 scope with a positive result (dirty) should be immediately reprocessed and retested.

Lot Control

Prior to commencing testing of flexible endoscopes, one test strip should be tested with the supplied control soil.

Inject 1 ml of sterile water into the supplied positive control vial. Mix by shaking well and let stand for 2 minutes to insure rehydration. Dip a test strip into the vial of solution and swish for 10 seconds. Blot excess fluid. Read results in 90 seconds by comparing the colors on the test strip to the color indicator chart. Record results on the log sheet provided.

Critical Behavior	1	2	3
Review Hospital Policy on cleaning of Scopes			
Describes the purpose of cleaning and decontamination of the Scope			
Selects and wears the appropriate personal protective equipment			
Gather appropriate supplies to perform test on the Scope (ChannelCheck, brushes...)			
Understands when to Leak test the Scope <ul style="list-style-type: none"> If scope fails leak test understands the process for returning scope for repair 			
Removal of all detachable Parts			
Cleaning (brush and syringing) with approved solution (irrigation of all channels) and surface cleaning. Follows manufacture guidelines for cleaning (all steps). Rinse according to manufactures guidelines.			
Check channel with ChannelCheck after cleaning is done (2 people may be required for testing / collection).			
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).			
Using at least a 20 ml syringe, draw 10ml of air followed by 10ml of sterile-DI water (e.g., 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).			
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 form the distal end into the sample collection container.			
Mix the sample well (swishing).			
With the three pads fully submerged, stir the recovered water for 10 seconds with the test strip			
Remove the test strip			
Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture			

After 90 seconds, compare the colors on the test strip to the color indicator chart provided			
Record the results for all 3 pads, on the log sheet provided. Should any of the pads indicate presence of 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 scope.

Remember to all ways follow manufactures guidelines on cleaning and sterilization of all scopes.

¹ ANSI/AAMI ST 79/2006

² ibid

³ Alfa,M.,et al, Comparison of Ion Plasma, Vaporized Hydrogen Peroxide, and 100% Ethylene oxide Sterilization to the 12/88 Ethylene oxide gas Sterilizer, Infection Control and Hospital epidemiology, 1996; 17:92-100

⁴ AORR Journal; July 1995,Vol62, NO1;DesCoteaux, Poulin, Julien, Guidoin

⁵ AORN Journal; March 2007,Volume 85,#3;page 566

⁶ Alfa MJ, Degagne P, Olsen N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning AJIC 1999

⁷ Martin MA, Reichfelderfer M., APIC guidelines for infection control practice; APIC guideline for infection prevention and control in flexible endoscopy. AJIC 1994 22; 19-38.

⁸ ANSI/AAMI ST 79 : 2006 – page 137

⁹ Designing, testing and labeling reusable medical devices for reprocessing in healthcare facilities: A guide for device manufactures. AAMI TIR 12;2004

¹⁰ Page 442;Recommendation quality XXII-a.2;AORN 2008 Perioperative Standards and Recommended Practices

¹¹ Alfa MJ, Degagne P, Olsen N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning AJIC 1999

¹² Martin MA, Reichfelderfer M., APIC guidelines for infection control practice; APIC guideline for infection prevention and control in flexible endoscopy. AJIC 1994 22; 19-38.