Example to test for detection of protein residue inside the channels of an endoscope and on surfaces.

NOTE: This document is an example of a policy that may be instituted in a health-care facility to test for detection of protein inside various channels of an endoscope. The actual policy in a facility must be based on variables, logistics and risk-assessments that are specific to your facility.

SUBJECT: Detection of protein residue inside the channels of an endoscope and on surfaces

DEPARTMENT: Central Service/ Endoscopy

APPROVED BY:

EFFECTIVE:

REVISED: Jan 2019

PURPOSE: To detect protein residue inside various channels like the biopsy channel of an endoscope in order to help ensure proper cleaning and reduce risk to personnel and patients.

POLICY: The EndoCheck™ -EDP test detects protein residues inside the various channels of an endoscope and on its surfaces. The random testing of endoscope channels such as the biopsy channel should be performed according to medical facilities guidelines to ensure that the cleaning process is being performed properly.

RATIONALE: "**A problem risk analysis should identify define and quantify the risk and identify actions that can be taken to resolve or prevent the risk. The system should be monitored to ensure that the risk has been corrected or prevented".**[1]

One such problem is protein residual inside the biopsy channel of an endoscope.

To ensure that the staff is properly cleaning any flexible endoscope verification of that process needs to take place. AAMI ST91 states the following in support of monitoring the cleaning process ***"…Cleaning verification tests are performed following cleaning and are used to verify the effectiveness of a cleaning process to remove or reduce to an***

acceptable level the organic soil and microbial contamination that occurs during the use of an endoscope…"[2]

Detection of protein residues inside the biopsy channel of a scope is very important and distinguishing between protein and other types of residues can be very confusing. Finding any protein residue left inside a biopsy channel that has been cleaned is never good and the implications are even more serious.

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 salt[3]. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate[4] .

- "Data indicate that for flexible endoscopes that have been cleaned after use on patients, the average levels of soil markers in the suction/biopsy channel 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 ug. cm2; sodium ion, <1 umole/cm^2; endotoxin, <2.2.EU/cm^2; and ATP, 200 relative light units (RLU) (Alfa, et al., 2002, 2012b, 2013)…(ST79 Section - D.2 Markers)."

Why test for protein? Because the three most predominant contaminants that are the main components of bodily fluids are protein, hemoglobin, and carbohydrates. Protein has numerous sources in clinical soil and is typically the primary marker for reusable cleaning validations by medical device manufactures. If protein is left on a surface it means something[5]. So testing for this marker if left on an item is important, it is a sign if something is clean.[6]

It is important to test any surface that is suspect of protein residue. The danger of unclean surfaces in a hospital or of handling instruments contaminated with protein is obvious in this age of hepatitis, CJD, and HIV. The procedures for sterilizing and High Level Disinfection (HLD) of medical devices (like flexible endoscopes) are based on years of scientific

testing. If medical devices are not clean, the procedures are ineffective. Dried protein on any medical device can be hazardous to the employees of the hospital and to the next patient upon which the medical device are used.

The ProCheckII™ Test is based on the formation of a protein-dye complex. This reaction detects the protein chain itself; therefore, it can still show chemically altered and denatured protein. This is mandatory for the detection of residue after chemical disinfection processes. **The detection limit of 1µg** is low enough and necessary for a safe test result. **Medical devices should be completely free of residue!** Compared to other tests like the OPA method, the Ninhydrin test or the Biuret test, the ProCheckII™ Test is more sensitive and selective in performance and is considered according to the EN ISO 15883 standards. [7]

The use of a protein type test is supported in the AORN Recommended Practices and Guidelines as well as AAMI ST 79.

"Periodic testing provides an opportunity to evaluate the performance of personnel. Manual cleaning is a learned skill and subject to human error. New instruments can pose unique challenges when cleaning. ***Protein indicators are commercially available to assist with this evaluation****"*[8]

"Protein detection by chemical reaction interpreted as a visible color change or a quantitative measure of residue (utilizing a color chart [semi-quanititative or photometric device]. Samples may be collected by swabbing, flushing, or direct application of reagent". [9]

Users must establish an appropriate cleaning policy and procedures for the resusable medical devices they process… As noted in Annex D in AAMI ST 79.

"...for verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the automated washer (if used) and the cleanliness of specific devices after manual or automated cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined….".

Testing any medical device or surface that is suspect of protein residue is important. The risk of not only having the biopsy channel cleaned but also any surface properly cleaned is significant especially when handling instruments contaminated with protein, blood and other patient secretions of patients.

Having a quality system to help monitor the channel especially the biopsy channel of an endoscope that you might suspect has not been cleaned properly and have blood/protein residue is an important function of any Infection Control program. Testing these channels with the EndoCheck™-EDP and recording results in a log is one such program.

The use of the EndoCheck™-EDP is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether cleaning is being performed properly. The frequency of testing (i.e. after each cleaning, daily, weekly, etc.) of the endoscopes various channels like the biopsy channels should be done at least weekly. All results should be documented and shared with the staff

PROCEDURE FOR INSPECTION:

Instructions for testing endoscopes for protein using EndoCheck™-EDP

Protein **R**esidue **I**nstrument **A**ssay: A test kit for the detection of protein residue in flexible endoscopes. [10]



Gloves must be worn throughout the test procedure to avoid contamination of the test.

1. The biopsy channel of a flexible endoscope is a critical component to be tested. This is performed after cleaning and before the sterilization/disinfection process.

    a. Place the vial into the holder provided unscrew cap. Make sure to moisten the cotton swab with a drop of clean water before testing the channel of the scope. Do not use chlorinated water.

b. Insert the swab end of the wire into the scope/biopsy channel. Push it all the way through one (1) time.

c. Place the swab into the vial. Cut the swab end off into the vial with the supplied scissors. Do not touch swab. Place cap back on the vial and tighten and shake at least 5 times. If protein is present, color change of the liquid and/or on the swab to blue-green will occur. In case of soluble proteins, there will be an immediate color change. In the case of denatured proteins (often the case with instruments subjected to reprocessing) color change can take up to 5 minutes.

d. To remove the remaining segment of the Endocheck, pull the wire out from the distal tip. Dispose in trash according to facility policy

e. Check the liquid and the swab for a color change to blue-green within 5 minutes and no longer. If no color changes within 5 minutes the test is negative for protein. Record the result for quality assurance. 1µg of denatured protein residue on the swab will develop a small blue-green spot. In the presence of large amounts of soluble protein the whole indicator solution will change blue-green.

NOTE: Positive controls can be used for verification and training purposes.

PRINCIPLE:

The formation of a protein-dye complex is used to detect small protein residue by means of a colour change on a swab. Swabbing is the preferred sampling technique in order to also detect insoluble residue.

RANGE OF APPLICATION:

For detection of protein residues on surfaces. Examples: Chamber walls of WD´s, Ultrasonic cleaner, work bench, surfaces of surgical instruments or inside channels of endoscopes. Test for residues of protein based test soils.

MEASURING RANGE:

The test kit can detect down to1.0 µg of insoluble protein by showing a blue-green spot.

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INTERFERENCES:

Contact to alkaline substances (larger amount of alkaline detergent) can trigger colour change. Quaternary ammonium salts (used in some disinfectants) will give a false positive result. Contact to bare hands can transfer protein particles onto the swab and may give a false positive result.

CONTENTS OF PACKAGE:

12 X single use tests for detection of protein residue on surfaces and inside hollow instruments like flexible endoscope.

STORAGE: Store EDP in a cool place at 2°C- 25°C. Keep away from light and heat and do not freeze.

SHELF LIFE: See imprint on packaging

RESPONSIBILITY:

The Central Service manager is responsible for training, assuring initiation, completion and analysis of the monitoring assessment activity for testing of blood residuals on various surfaces.

Sample Competency for Tests Endoscopes for Protein residue

Name: _____

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

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: _____

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Learner: _____

Critical Behavior	1	2	3
Review Hospital Policy on cleaning of Endoscopes			
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 (EndoCheck™-EDP, brushes…)			
Leak test the endoscope.			
Removal of all detachable parts.			
Cleaning (brush and syringing) with approved solution (irrigation of all channels) and surface cleaning. Follow manufacture guidelines for cleaning. Rinse according to manufactures guidelines.			
Dry Endoscope using air and alcohol.			
Check channel with EndoCheck™-EDP after cleaning is done.			
If the test has been refrigerated, allow it to come to room temperature before using.			
Gloves must be worn throughout the test procedure to avoid contamination of the test. Pick correct type of glove.			
At a minimum, the biopsy channel of a flexible endoscope is the most critical to be tested. This is done after cleaning and before the sterilization / disinfection process. Choose the correct type of swab to test according to channel size to be tested.			
Place the vial into the holder provided unscrew cap. Make sure to moisten the cotton swab with a drop of clean water before testing the channel of the scope. Do not use chlorinated water.			
Insert the swab end of the wire into the scope/biopsy channel. Push it all the way through one (1) time.			
Place the swab into the vial. Cut the swab end off into the vial with the supplied scissors. Do not touch swab. Place cap back on the vial and tighten and shake at least 5 times. If protein is present, color change of the liquid and/or on the swab to blue-green will occur. In case of soluble proteins, there will be an immediate color change. In the case of denatured proteins (often the case with instruments subjected to reprocessing)			

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color change can take up to 5 minutes. To remove the remaining segment of the EndoCheck™ pull the wire out from the distal tip. Dispose in trash according to facility policy.			
Check the liquid and the swab for a color change to blue-green within 5 minutes and no longer. If no color changes within 5 minutes the test is negative for protein. Record the result for quality assurance. 1µg of denatured protein residue on the swab will develop a small blue-green spot. In the presence of large amounts of soluble protein the whole indicator solution will change blue-green.			
Record results in log			
Dispose of vial according to hospital policy			

Follow Hospital Policy on the Sterilization / disinfection of the scope.

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

EndoCheck™-EDP Test Log

Test Date	Tester Initials	Channel Tested	EndoCheck EDP Result	Action Taken	Comments	Scope #

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Record the Color Change for EndoCheck™-EDP Result.

Check the liquid and the swab for a color change to blue-green within 5 minutes and no longer. If no color changes within 5 minutes the test is negative for protein. Record the result for quality assurance. 1µg of denatured protein residue on the swab will develop a small blue-green spot. In the presence of large amounts of soluble protein the whole indicator solution will change blue-green.[11]

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***REFERENCES*:**

1. A 2003 multi-society position paper states:

   "Healthcare facilities should develop protocols to ensure that users can readily identify whether an endoscope is contaminated or is ready for patient use." (*Gastrointestinal Endoscopy*, Volume 58 No.1; page 5)

2. Highlights of **AAMI ST 79**:

   - AAMI realizes that the efficacy of any high-level disinfection/sterilization process, including saturated steam, depends on a consistent system for lowering and limiting bio-burden before high-level disinfection/sterilization.
   - Staff qualifications, training, and continuing education are important: "... Personnel should receive in-service training for all new instrumentation, devices, and equipment. Orientation, education, and training provide workers with essential information to perform their assigned responsibilities. Documentation if education and training is required by accrediting agencies..." (Section 4.3.1)
   - Regarding verification of the cleaning process: "…Personnel should visually inspect each item carefully to detect any visible soil. Mechanical cleaning equipment performance should be tested each day it is used and all results should be recorded. Steam sterilization cannot be assured unless proper cleaning of the device and reduced bioburden and soil was achieved. Verification and documentation of automated processes through objective means is an important aspect of quality control. Enhanced visualization tools such as lighted magnification and video borescopes might identify residues not observable by the unaided eye…" (Section 7.6.4.5)
   - "For verification of routine cleaning presses, users should incorporate test methods that verify the functionality of the mechanical cleaning equipment (if used) and the cleanliness of specific devices after manual or mechanical cleaning is completed. These verification tests are part of continuous quality improvement to demonstrate continued compliance with cleaning benchmarks, once these benchmarks have been defined." (Section D.2 Markers)

3. Excerpts from published articles:

- *57% of centers that process endoscopes were not in compliance with basic national standards.*[12]

- "Our findings underline the potential for blood fixation, not only by glutaraldehyde, but also by peracetic acid, and support the evidence that effective cleaning should precede the chemical disinfection."13

- 53% of biopsy ports valves exhibited some form of debris or potential contamination after cleaning.[14]

- "Company blames bronchoscope infections on poor cleaning."15

- Endoscopes have been implicated in the transmission of disease (specifically nosocomial infections) when appropriate cleaning, disinfection or sterilization procedures were not employed. Of particular significance is the need to thoroughly manually clean equipment prior to any manual or automated disinfection or sterilization process.[16]
- "It is very clear that every documented case of patient infection linked to a contaminated scope is because of a breach of some of the reprocessing protocol. If you look back on the history, that is what it is – improper disinfection; you don't dry the scope; inadequate cleaning; or somebody forgot to clean the biopsy channel. It has been more human error than anything else… Rules No.1, 2 and 3 are to educate the people who are cleaning the endoscopes--how and what should be done. If I had it my way, I would have them take a test before letting them do the cleaning."[17]

- In one case two colonoscopy patients were infected with hepatitis C (HCV) from an endoscope contaminated by an earlier patient. The investigation concluded that the biopsy channel had not been properly cleaned and the disinfection failed. Only two hours had elapsed between the first patient and the last, so even if samples had been taken immediately after the first patient, traditional microbiology results would not have been available in time to prevent cross-infection. [18]

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[1] 2017 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST79:2017 Section 14.2.1
[2] 2015 Association for the Advancement of Medical Instrumentation ■ AAMI ST91:2015; Section 12.4
[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,Vol 62, NO1;DesCoteaux, Poulin, Julien, Guidoin
[5] Blood as a Soil on Surgical Instruments; Cleaning Profile, Cleaning, Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385
[6] The source for all of this information is taken from: A White Paper; The New Scope of Reusable Device Cleaning Validations-By: Patrick Kenny; Microtest-2011
[7] Standardized Test Soil Blood 1: Composition, Preparation, Application; M.Pfeifer, Zentr Steril 1998;6 (6);304-310
[8] Page 449; Recommendation quality XXII-a.2; AORN 2011 Perioperative Standards and Recommended Practices
[9] 2017 Association for the Advancement of Medical Instrumentation ■ ANSI/AAMI ST79:2017
[10] http://www.healthmark.info/CleaningVerification/EndoCheck/EndoCheck_Protein.pdf
[11] http://www.healthmark.info/CleaningVerification/EndoCheck/EndoCheck_Protein.pdf
[12] Infection Control and Hospital Epidemiology; Volume 23; 2002
[13] Kampf G,Bloss, Martiny H; Surface fixation of dried blood by glutaraldehyde and peracetic acid;JHI; June 2004; 57(2): 139-143
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[15] 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html
[16] http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf, page 1
[17] page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005
[18] *The New England Journal of Medicine* **337**, 237-240 (1997).