

SUBJECT: Detection of Blood residue inside the biopsy channel of a scope

DEPARTMENT: Central Service/ Endoscopy

APPROVED BY:

EFFECTIVE:

REVISED: 12/2009

PURPOSE: To test for detection of blood residue inside the biopsy channel of a scope and to help ensure proper cleaning *and reduce risk to personnel and patients*

POLICY: The EndoCheck test detects blood residues inside the various channels of a scope. The random testing of various scope channels like the biopsy is to be used 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".(9)

One such problem is blood residual inside the biopsy channel of a scope.

Detection of blood residues inside the biopsy channel of a scope is very important and distinguishing between blood and other types of residues can be very confusing. Finding any blood 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 (7). Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate (8).

Testing any surface that is suspect of blood 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 blood of patients infected with hepatitis, CJD, HIV, etc.

The procedures for disinfecting/sterilizing flexible endoscopes are based on years of scientific testing on completely clean instrument surfaces. If endoscopes are not clean, the procedures are ineffective. Dried blood is hazardous to the employees and to the next surgical patient upon which the instruments are to be used. Scopes especially the biopsy channel that come in contact with patients need to be free from blood residuals. Looking inside a biopsy channel is nearly impossible without damaging it. The EndoCheck™ does allow you to test specifically for blood residue inside the biopsy channel by swabbing this specific channel surface.

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

The use of the EndoCheck 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 is done properly. The frequency of testing (i.e. after each cleaning, daily, weekly, etc.) of the scopes various channels like the biopsy channels should be done at least weekly. All results should be documented.

PROCEDURE:

EndoCheck™: The test kit for detection of blood residue inside the biopsy channel of a scope.

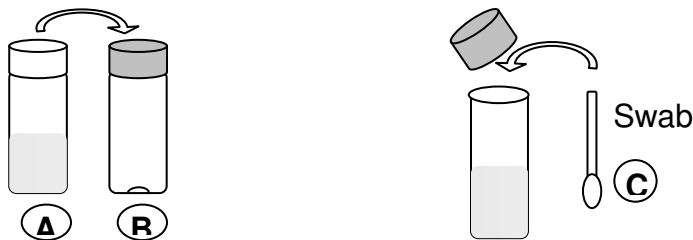
IMPORTANT: This testing must be done after cleaning and before disinfection/sterilization.

Note: A positive result is proof of remaining blood residue in the tested area only.



1. If the test has been refrigerated, allow it to come to room temperature before using.
2. Open the test kit. Included are: indicator vial (transparent cap), activator vial (green cap), and wire with cotton swab at one end.

3. Testing of the biopsy channel is done after cleaning and before the sterilization/disinfection process.
4. Open the indicator vial (A, transparent cap) and transfer the liquid into the activator vial (B, green cap).
5. Moisten the cotton swab with a drop of clean water. Do not use chlorinated water.
6. Insert the swab end of the wire into the scope/biopsy channel. Push it all the way through one (1) time. (Done post-cleaning – pre-disinfection/sterilization)
7. Cut the swab end off the wire with scissors. Do not touch the swab.
8. Place the swab into the activator vial and shake at least five times.
9. Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested scope. In the presence of large amount of blood residue the entire indicator solution will become dark blue.
10. Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue.
11. If a positive result (blue-green) report that result immediately and clean the scope again according to policy and after cleaning retest the scope until you get a negative result. Sterilizing or high level disinfecting a scope that is dirty can comprise the sterilization process.



A: Indicator-vial (transparent cap), B: activator-vial (green cap) and C: cotton tip swab.

Please Note the following

PRINCIPLE

Due to the high content of Peroxidases in blood an enzymatic reaction is used for detection of blood residues.

MEASURING RANGE

The test kit can detect 0,1 µg of blood by showing a slight blue-green spot. 1 µg of blood in the test will already give a dark blue colour.

INTERFERENCES

Oxidising agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a colour change too. In this case the test cannot be used to detect blood residues

STORAGE

Store EndoCheck in closed pouches in a cool place 2°C- 25°C. Keep away from light and heat

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 Cleaning of Scopes

Name: _____

Competency Statement: Complies with policy and procedure for cleaning and testing scopes (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: _____

Learner: _____

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 (EndoCheck, brushes...)			
Leak test the Scope			
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 (Air)			
Check channel with EndoCheck after cleaning is done If the test has been refrigerated, allow it to come to room temperature before using.			
Open the test kit. Included are: indicator vial (transparent cap), activator vial (green cap), and wire with cotton swab at one end.			

Open the indicator vial (A, transparent cap) and transfer the liquid into the activator vial (B, green cap).			
Moisten the cotton swab with a drop of clean water. 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. (Done post-cleaning – pre-disinfection/sterilization)			
Cut the swab end off the wire with scissors. Do not touch the swab.			
Place the swab into the activator vial and shake at least five times.			
Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested scope. In the presence of large amount of blood residue the entire indicator solution will become dark blue.			
Record the result immediately—late color changes are not valid. The yellow color change after activation is a normal reaction and does not indicate residue			

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

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

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. All orientation, on-the-job, and in-service training should be documented....” (Section 4.3.1)
 - Regarding verification of the cleaning process: “...Sterile 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)

3. Excerpts from published articles:
 - *57% of centers that process scopes were not in compliance with basic national standards.ⁱ*

 - *“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.”ⁱⁱ*

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

 - *“Company blames bronchoscope infections on poor cleaning.”^{iv}*

- 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.^v
- “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 scopes--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.”^{vi}
- 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.^{vii}

4. Technical sources

EndoChek™ information

<http://www.healthmark.info/proformance.html>

5. Blood as a Soil on Surgical Instruments ; Cleaning Profile, Cleaning , Detection; M.Pfeifer, Zentr Steril 1998;6 (6);381-385

6. Standardized Test Soil Blood 1 : Composition, Preparation, Application ; M.Pfeifer, Zentr Steril 1998;6 (6);304-310

7. *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*

8. *AORR Journal; July 1995, Vol62, NO1; DesCoteaux, Poulin, Julien, Guidoin*

9. ANSI/AAMI-ST 79;2006

10. <http://www.proformance-test.com>

ⁱ Infection Control and Hospital Epidemiology ; Volume 23 ; 2002

ⁱⁱ Kampf G, Bloss, Martiny H; Surface fixation of dried blood by glutaraldehyde and peracetic acid; JHI; June 2004; 57(2): 139-143

ⁱⁱⁱ Endonurse 12/6

^{iv} 3/7/02; http://www.hpnonline.com/dailyupdates/march_02.html

^v <http://www.gov.mb.ca/health/publichealth/cdc/fs/endoscopy.pdf>, page 1

^{vi} page 16; New Technologies Require thorough reprocessing; EndoNurse; August/September 2005

^{vii} *The New England Journal of Medicine* **337**, 237-240 (1997).