Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

---

NOTE: This document is an example of a policy that may be instituted in a health-care facility of the ProChek-II® for the detection of protein residue on various surfaces and medical devices. 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 on various surfaces and other items

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED*:* January 2021

PURPOSE: To test for detection of protein residue on surfaces and "cleaning implements that could pose potential health risks to personnel." [1]

POLICY: The ProChek-II® test detects protein residues on various surfaces and medical devices. Random testing of various surfaces is to be done according to the manufacturer's guidelines to ensure that the cleaning process is being done properly. Test for residues of protein-based test soils on: Chamber walls of automatic washers, Ultrasonic cleaner, Operating room tables, work bench surfaces, flexible scopes or any surgical instrument, even lumen type devices are all areas that can be tested for protein residues.

RATIONALE: One such problem is protein residue on any surface (including medical devices) in the Central Service and Operating room settings. It is often difficult to distinguish between protein and other types of stains. A stain left on a surface that has been cleaned is never good, but if that stain is protein the implications can be very serious. Also testing a lumen or channel of any medical device can also be done with the ProChek-II® but a longer swab might be needed to test the area.

Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

STANDARDS AND PROFESSIONAL SOCIETY RECOMMENDATIONS:

1. "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]

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 salt [3]. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate. [4,5]

3. Since blood is found on almost all used medical devices understanding how important it is to be removed from the device as soon as possible is important. Many types of soil could be present on reusable medical devices. As a liquid, blood tends to flow over and into joints, hinges, grooves, and difficult-to-clean locations. It then coagulates and dries to create a challenge to cleaning. However, other body fluids, fats, carbohydrates, and in particular, prion-contaminated tissue might be equally or significantly more challenging. The amount of residue that remains on an instrument will vary depending on the conditions of use of the cleaning agents, the specific component materials of the reprocessed devices, and the methods used to reduce residuals before reuse. Any organic material or residual cleaning agents remaining on an item can inactivate chemical disinfectants or sterilants as well as protect microorganisms from destruction. In addition, debris could become dislodged and could cause potential health risks, such as a foreign-body reaction or a breeding place for infection.[6]

4. Protein is the marker most commonly used to evaluate cleaning efficacy. 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, < 6.4µg/cm2; carbohydrate, < 1.8µg/cm2; hemoglobin, < 2.2µg/cm2; sodium ion, < 1µmole/cm2; and endotoxin, < 2.2 EU/cm2 in the biopsy/suction channel (Alfa, et al., 2002, 2012b, 2013)"[7]. Protein left on any medical device or surface can be an issue and should be detected.

5. 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. So, testing for this marker (protein) if left on a medical device or surface is important, it is a sign that something is not clean.[8]

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, CRE, and HIV. The procedures for sterilizing instruments are based on years of scientific testing of clean instruments. If surgical instruments are not clean, the procedures are ineffective. Dried protein on instruments or surfaces is hazardous to the employees of the hospital and to the next patient. If it is not clean it cannot be High level disinfected or sterilized.

7. It should be noted that "Any disinfectants that have a mode of action associated with protein cross-linking (e.g., formaldehyde, glutaraldehyde, ortho-phthalaldehyde [OPA] and alcohol) should not be used because of the risk of fixing prions to device surfaces, which can then remain infectious over time."[9] Medical devices surfaces (internal and external) if not properly cleaned can leave denatured protein behind on the device thus using a protein-based test can help identify the type of stain left on the device or surface.

8. The ProChek-II® 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. The detection limit of 1µg is low enough and necessary for a safe test result. Medical devices must be completely free of residue! Compared to other tests like the OPA method, the Ninhydrin test or the Biuret test, the ProChek-II® Test is more sensitive and selective in performance and is considered according to the EN ISO 15883 standards[10].

9. The use of a protein type test is supported in the AORN Recommended Practices and Guidelines as well as AAMI ST 79. Protein detection by chemical reaction is described in Annex D of ST79.

10. "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*"*[11]

11. "Protein detection by chemical reaction interpreted as a visible color change or a quantitative measure of residue (utilizing a color chart [semi-quantitative] or photometric device. Samples may be collected by swabbing, flushing, or direct application of reagent."[12]

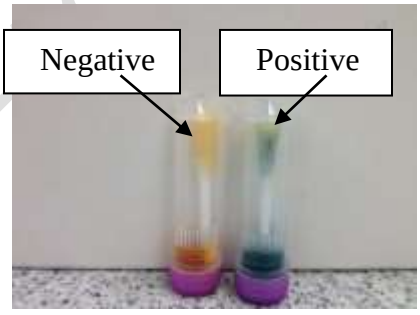
12. A quality improvement system that monitors stains suspected to be protein is an important function of any Infection Control program. As noted in AAMI ST 79, "...for verification of routine cleaning processes, users should incorporate test methods that verify the functionality of the mechanical cleaning 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…"[13]

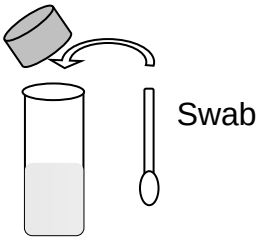
13. Testing stains with the ProChek-II$^{T®}$ and recording results in a log is one such system.[14]

PROCEDURE FOR INSPECTION:

ProChek-II® Instructions for use

Protein **R**esidue **I**nstrument **A**ssay:
The test kit for detection of protein residue on surfaces.





1. Gloves must be worn throughout the test procedure to avoid contamination of the test. Surfaces are swabbed with the supplied protein-free premoistened swab.

2. Swab the sample thoroughly. Concentrate swabbing action on difficult to clean areas like joints, crevices, (signs of visible spots or discolorations). Also, the ECRP elevator wire on the distal tip, any distal tip of a scope such as the air water channel (jet). Any areas that you think are hard to clean and should be tested for cleanliness. **Note: Swabs come in various sizes and lengths. This allows you to test varies surface and the inner lumens of many devise like a flexible scope, suction and almost any lumen medical device.**

3. Unscrew cap of the vial. Do not touch the swab. Place the swab into the vial. Cut the swab end off into the vial with the supplied scissors. Place cap back on the vial and tighten. 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.

4. 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. If other swabs not supplied with the ProChek-II® test are used, a negative and positive control needs to be performed to exclude interferences, and protein free swab and water should be used.

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

RANGE OF APPLICATION: 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.

Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

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

INTERFERENCES: Contact to alkaline substances (larger amount of alkaline detergent) can trigger color 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: 15 single use tests for detection of protein residue on surfaces and inside hollow instruments.

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

SHELF LIFE: See IFU

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

Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

- Record the Color Change for ProChek-II® Result

- A color change to blue-green, which will indicate protein residues on the tested surface.

ProChek-II® Test Log

Test Date	Tester Initials	Item Tested	ProChek-II™ Result	Action Taken	Comments	

Comments:

_____
_____
_____
_____
_____
_____

Sample Competency for using the ProChek-II® for detection of protein residue on various surfaces and other items.

Follow Hospital Policy on the cleaning medical devices both manually and with automatic cleaning equipment like a sonic cleaner, automatic washer, cart washer… Remember to always follow manufactures guidelines on cleaning that specific medical devices that is being tested.

Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

Name:_____

Competency Statement: Complies with policy and procedure for cleaning and testing medical devices for protein.

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 medical devices along with the IFU of the ProChek-II® test			
Describes the purpose of cleaning and decontamination of medical devices			
Selects and wears the appropriate personal protective equipment for this task			
Gather appropriate supplies to perform test on the medical devices (ProChek-II®…)			
Select the medical device to be tested for protein			
Gloves must be worn throughout the test procedure to avoid contamination of the test.			
Open the test kit. Included are: one indicator vial and a test swab. Place the vial in the holder provided. Unscrew cap of the vial**.**			
Surfaces (area to be tested) are swabbed with either the supplied protein-free pre-moistened swab or a protein free swab that is moistened with sterile water before testing the device. **Do not use chlorinated water.**			
Swab the sample area thoroughly. Concentrate swabbing action on difficult to clean areas like joints, crevices, (signs of visible spots or discolorations). You can also sample the ECRP			

Example of a ProChek-II® Policy for the detection of protein residue on various surfaces and medical devices

elevator wire on the distal tip of a scope, any distal tip of a scope such as the air water channel (jet). Any areas that you think are hard to clean and should be tested for cleanliness. Note: Swabs come in various sizes and lengths. This allows you to test varies surface and the inner lumens of many devise like a flexible scope, suction and almost any lumen medical device.			
Once you have swabbed the desired area (sampling) Do not touch the swab. Place the swab into the vial. Cut the swab end off into the vial with a clean scissors (if a scissors is supplied use that one). Place cap back on the vial and tighten. Invert the vial a few times to ensure that the solution has mixed well with the swab. Place the vial back in the holder. Now watch for a color change over time.			
If protein is present, color change of the liquid and/or on the swab to blue-green will occur (this is recorded as a positive test result) within the 5minute time frame. In case of soluble proteins, there usually will be an immediate color change (usually in 1 minute or less). In the case of denatured proteins (often the case with instruments subjected to reprocessing) color change can take up to 5 minutes.			
Check the liquid and the swab for a color change to blue-green often within 5 minutes time frame but stop at the 5minute mark. If no color change has taken place 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. If you have a positive test result re-clean the medical device and retest same area after the cleaning process is complete. Repeat until you get a negative result. Record all results.			
NOTE: Positive controls can be used for verification and training purposes. If other swabs not supplied by Healthmark or with the ProChek-II®-Test are used, a negative and positive control needs to be performed to exclude interferences, to ensure that protein free swab and water are being used.			

References:

[1] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Section 7.6.4.2 Manual cleaning; page 45
[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] AORN Journal; July 1995, Vol62, NO1; DesCoteaux, Poulin, Julien, Guidoin
[5] AORN Journal; March 2007, Volume 85, #3; page 566
[6] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Annex P; page 171
[7] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Annex D D.3 Cleaning verification tests for users; page 128
[8] 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
[9] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Annex C C.1; page 123
[10]http://www.healthmark.info/CleaningVerification/ProCheck/white_pages__pyrmol_info_updated_1_19_2012.pdf
[11] Page 449; Recommendation quality XXII-a.2; AORN 2011 Perioperative Standards and Recommended Practices
[12] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Annex D D.3 Cleaning verification test for users; page 128
[13] ANSI/AAMI ST79:2107 Comprehensive guide to steam sterilization and sterility assurance in health care facilities- Annex D D.3 Cleaning verification tests for users; page 128
[14] Page 449; Recommendation quality XXII-a.2; AORN 2011 Perioperative Standards and Recommended Practices