Example of a HemoCheck™ Policy for the Detection of Blook Residue on Various Surfaces

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NOTE: This document is an example of a policy that may be instituted in a health-care facility for the HemoCheck™ for the detection of blood residue on various surfaces. The actual policy in a facility must be based on variables, logistics, and risk-assessments that are specific to your facility.

Subject: Detection of blood residue on various surfaces

Department: Central Service

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter date when this will take effect]

Revised: August 2021

Purpose: To test for detection of blood residue on surfaces and to help ensure proper cleaning and reduce risk to personnel or patients. [1]

Policy: The HemoCheck™ test detects blood residues on various surfaces. 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.[2] Test for residues of blood-based test soils on: Chamber walls of automatic washers, Ultrasonic cleaner, Operating room tables, work bench, surfaces of surgical instruments (both surface and lumen area) are all areas that can be tested for blood residues.

Rationale: ". . . Risk analysis is a means to involve a cross-functional team in an activity to set policies to identify the potential risk of sterilization failures and other defects in reprocessing practice. It allows identification and implementation of procedures for risk avoidance or mitigation actions to be put in place that can reduce the overall likelihood of a risk. It is also important because sterilization assurance is a probability function, and, therefore, it is assumed that at some time a failure will occur. . . ."[3]

One such risk/problem is the possibility of blood residue on any surface in the Central Service and Operating Room settings. It is often difficult to distinguish between blood and other types of stains. A stain left on a surface that has been cleaned is never good, but if that stain is blood the implications can be very serious.

Standards and Professional Society Recommendations:

1. 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 [4]. Residual organic debris on processed surgical instruments is a concern and visual inspection is not a 100% accurate. [5]

It is important to test any surface that is suspect of blood residue. The danger of unclean surfaces in a hospital or of handling instruments contaminated with blood is obvious in this age of hepatitis, CJD, 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 blood on instruments is hazardous to the employees of the hospital and to the next surgical patient upon which the instruments are used.

2. "For verification of routine cleaning processes users should incorporated 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. Hemoglobin detection by chemical reaction. Interpreted as a visible color change or a quantitative measure of residues. Samples may be collected by swabbing or flushing." [6]

3. "A cold water rinse and the use of a pretreatment product will help prevent coagulation of blood onto the device and help remove blood, tissue, and gross debris from device lumens, joints, and serrations. Precleaning solutions can interfere with subsequent cleaning steps. Mechanical washers are programmed for specific cycles with specific cleaning agents. Introducing a presoak spray or gel can interfere with the function of these preprogrammed cycle steps and the cleaning agents used. If the spray or gel is not rinsed off during manual cleaning it can interfere with the subsequent steps in the cleaning process." [7]

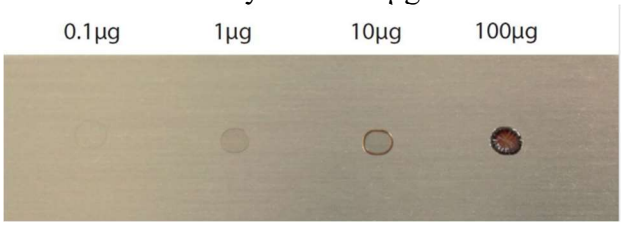
4. "Hot water can denature blood proteins, which makes them more difficult to remove. Cool water can help to prevent coagulation of blood on instruments and can help remove gross soil form lumens, and crevices. Rinsing with cool water can wash away water-soluble blood proteins and prevent denaturing." [8]

5. "…Visual detection alone does not allow one to detect residual bioburden that may remain on cleaned devices…" [9]

6. **". . . 16% of the loaner instruments tested positive for blood. . . ." [10]**

Stains come in all sizes, shapes, and intensity. Sometimes a stain can appear quite benign or not be easily detected by the human eye. Finding a stain on an instrument—which has gone through reprocessing—is never good. Gaining understanding about stains leads to improved process. Technicians who are processing medical devices are looking for a fast and effective test to implement in their workspace that will give them feedback/ assurance that their reprocessing of the medical devices is being done properly.

7. Since the current standard is *visually clean*, it is assumed that if you can see dirt or stain (bioburden) on a medical device, then you reclean it (or not use it until it is cleaned). The absolute goal is to detect a level low enough that the item tested is clean in case nothing is visually detected. A stain the size of only 1µg is visible to the naked eye on an instrument and no one would even consider using an instrument on the next patient with a stain that size. As a result, the detection limit to be achieved needs to be at least around this visibility limit of 1µg.[11]



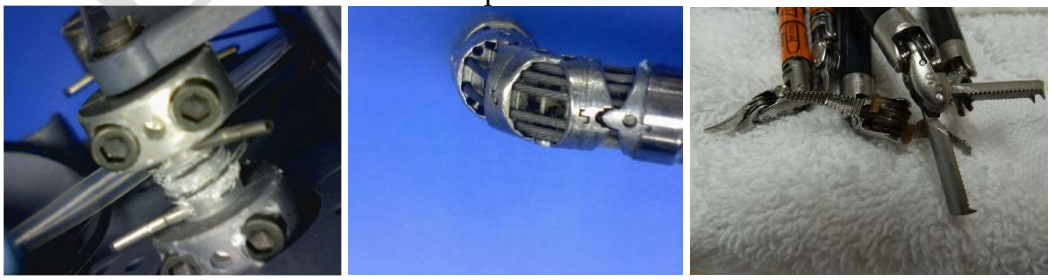
Use of a surface detection test like the HemoCheck™ is supported in the AORN Recommended Practices and Guidelines as well as AAMI ST 79. The HemoCheck™ is a product that helps you verify your process for cleaning is working properly.

Some of the areas that can be tested on a medical device are: the flat surface, box lock (hinge) area, inside a lumen or cannulated area of a device, the distal tip area of a robotic arm, and the ERCP elevator wire on the distal tip. These are just some of the areas you can test with the HemoCheck™. Anywhere you suspect a medical device might not be clean, you should swab and test to ensure your process is doing what it should, which is "getting medical devices clean." Special swabs (various sizes and lengths) for these areas are available to test for residual bioburden (stains).

A quality improvement system that monitors stains suspected to be blood is an important function of any Infection Control program. One such system is testing stains with the HemoCheck™ and recording the results in a log.

Examples of area to test on medical devices:

Distal tip area of robotic arms



Other Areas of a medical device

Procedure:

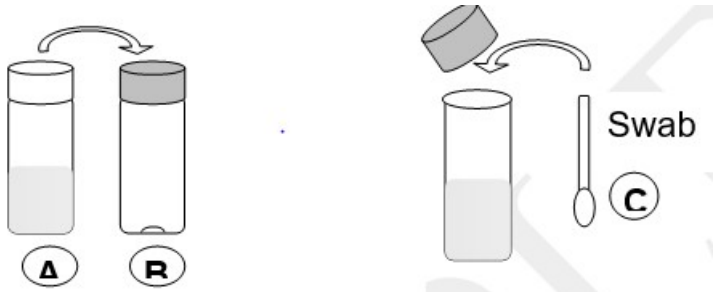
Gloves must be worn throughout the test procedure to avoid contamination of the test. Open the protective pouch of the HemoCheck™ test kit. Included are:

- A): Indicator-vial (transparent cap)
- B): Activator-vial (green cap)
- C): Cotton swab.

Areas to inspect:

- Wet surfaces are swabbed with the dry cotton swab
- Dry surfaces are swabbed by moistening the swab with a drop of clean water ***(Do not use chlorinated water)***
    - Swab the sample area thoroughly and vigorously (on a hard surface like an instrument)
    - Concentrate swabbing action on difficult to clean areas like:
        - Joints
        - Crevices
        - Stains (signs of visible spots or discolorations)
- The ECRP elevator wire on the distal tip:
    - Scope (i.e., such as the air water channel [jet])
    - Robotic arm
- Any areas considered difficult to clean and should be tested for cleanliness
- If a lumen is going to be checked, swab the inner channel vigorously back-and-forth

Note: *Swabs come in various sizes and lengths. This allows you to test various surfaces and the inner lumens of many devices like a flexible scope, suction and almost any lumen medical device.*



A: Indicator-vial (transparent cap)	B: Activator-vial (green cap)	C: Cotton swab

1. Open the indicator vial (A) and transfer the liquid into the activator vial (B green cap).

2. Place the sample swab (C) into the vial (head down into the liquid) and shake at least five times. If using a longer type of swab for testing lumens, cut the tip off into the vial with clean scissors.

3. Check the swab for an immediate color change to blue green, which will indicate blood residues on the tested surface. In the presence of large amount of blood, the whole indicator solution will change to dark blue. Record your results immediately since a small amount of blood residue will not form a stable color. The used test liquid may change to a light blue green after several hours, which does **not** indicate residues.

4. Record results of all tests on Quality form and report results to the appropriate person.

Note: In case of jointed surgical instruments blood residues are most common inside joints, which can be sampled with a swab. Longer narrower swabs can be used for checking inside cannulated instruments.

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. One µg of blood in the test will already give a dark blue color.

Interferences: Oxidising agents like chlorine or hypochlorite (present in some disinfecting agents and detergents) will also produce a color change. In this case, the test cannot be used to detect blood residues.

Storage: Store HemoCheck™ 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 and for assuring initiation, completion, and analysis of the monitoring assessment activity for testing of blood residuals on various surfaces.

Result of the HemoCheck™ Test

Amount of blood (shown from left to right): 100 µg, 10 µg, 1 µg, 0.1 µg, (Blind control).

- Record the color change for HemoCheck™ result
- A color change to blue green, which will indicate blood residues on the tested surface from a HemoCheck™ test

HemoCheck™ Test Log

Test Date	Tester Initials	Item Tested	HemoCheck™ Result	Action Taken	Comments

References:

[1] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Section 13
[2]http://www.healthmark.info/CleaningVerification/HemoCheck/Study_on_HemoCheck_and_EndoCheck.pdf
[3] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Section 14.3.2.1
[4] 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
[5] AORN Journal; July 1995, Vol62, NO1; DesCoteaux, Poulin, Julien, Guidoin
[6] 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
[7] ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities-7.6.1 Cleaning, page 43
[8] AORN Guidelines 2016; page 784
[9] http://www.accessdata.fda.gov/ScienceForums/forum06/B-48.htm
[10] AORN Journal; March 2007, Volume 85, #3; page 566
[11] TOSI®man's Best, No. 9, Vol. 1/February 2007(www.pereg.de)