

HemoCheck™ Sample Policy

SUBJECT: Detection of blood residue on various surfaces

DEPARTMENT: Central Service

APPROVED BY:

EFFECTIVE:

REVISED: 05/2018

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:

"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."

One such problem is 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.

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

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.

“Many types of soil could be present on reusable medical devices, but dried blood is especially difficult to clean. As a liquid, blood tends to flow over and into joints, hinges, grooves, and other difficult-to-clean locations. It then coagulates and dries to create a significant challenge to cleaning.”⁵

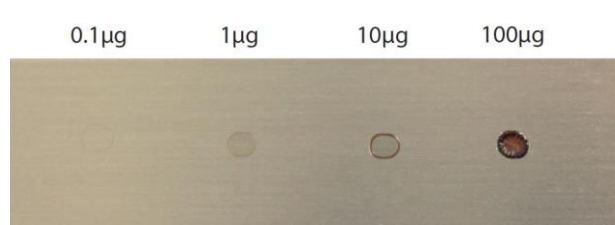
“Blood is composed primarily of water-soluble proteins. If blood remains on an instrument after the wash phase of a mechanical cleaning equipment cycle, the water-soluble proteins will be denatured in any subsequent heated process, such as the hot disinfection phase of a washer-disinfector or washer-sterilizer cycle or a steam sterilization process. Denaturing proteins creates a soil that is much harder to clean the next time through the washing process. It is imperative that all traces of blood, body fluids, and debris be removed during the wash phase of a mechanical cleaning equipment cycle. Failure to do so could result in undetected bioburden that could pose a risk to employee health or result in a patient infection.”⁶

“...Visual detection alone does not allow one to detect residual bioburden that may remain on cleaned devices...”⁷

“...16% of the loaner instruments tested positive for blood....”⁸

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; one needs to understand what that stain is to improve their process. Technicians who are processing medical devices are looking for a fast and effective test they can perform in their work space that will provide them feedback and give them assurance they are doing their reprocessing of the medical devices properly.

Since the current standard is visually clean, it is assumed that you can see dirt or the stain (bioburden) on a medical device and then re-clean it. The real goal is to detect a level low enough, so one can be certain 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 .⁹



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

Some of the areas that can be tested on a medical device are: the flat surface of any medical devices, box lock (hinge) area, inside a lumen or cannulated area of a device, the distal tip area of a robotic arm, the ECRP elevator wire on the distal tip, these are just some of the areas you can test with the HemoCheck™. Anywhere you suspect that a medical device might not be clean you should swab and test to ensure your process is doing what it should “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 (residual bioburden) suspected to be blood is an important function of any Infection Control program. Testing stains with the **HemoCheck™** and recording results in a log is one such system.

Examples of area to test on medical devices

Distal tip area of robotic arms



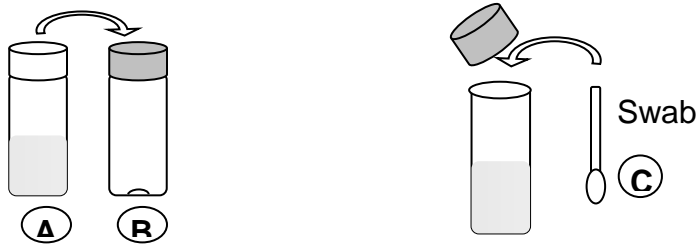
Other Areas of a medical device



PROCEDURE FOR USING THE HEMOCHECK™:

1. 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) and C: cotton swab.
2. 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, (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) or the distal tip of a robotic arm. Any areas that you think are hard to clean and should be tested for cleanliness. If a lumen is going to be checked; you swab the inner channel vigorously back and forth. 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. Open the indicator vial (A transparent cap) and transfer the liquid into the activator vial (B green cap).
4. Place the sample swab (C) into the vial (head down into the liquid) and shake at least 5 times. If using a longer type swab was used for testing lumens, cut the tip off into the vial with a clean scissor.
5. 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.
6. 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.



A: Indicator-vial (transparent cap), B: activator-vial (green cap) and C: cotton 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 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**TM 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:
 100µg, 10µg, 1µg, 0.1µg, Blind control

HemoCheck™ Test Log

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.

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

¹ ANSI/AAMI ST 35 – 2003: 9.1-General Rationale;9.2 – Quality Process; 9.2e Documentation of Decontamination processing parameters.

² http://www.healthmark.info/CleaningVerification/HemoCheck/Study_on_HemoCheck_and_EndoCheck.pdf

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 Page 55; ANSI/AAMI ST79:2010 & A1 & A2 & A3 & A4

⁶ Mechanical cleaning ANSI/AAMI ST79:2010/A3:2012-7.5.3.3; page 58

⁷ <http://www.accessdata.fda.gov/ScienceForums/forum06/B-48.htm>

⁸ AORN Journal; March 2007, Volume 85, #3; page 566

⁹ TOSI@man’s Best, No. 9, Vol. 1/February 2007(www.pereg.de)