



Instructions for Use: HemoCheck™

Brand Name of Product	HemoCheck™-S
Generic Name of Product	Blood residue test
Product Code Number(s)	HC-101, Swab-110, Swab-200, Swab-270, Swab-350, Swab-420, Swab-470
Intended Use	To test for blood (hemoglobin) residue on a surgical instrument and other medical devices prior to sterilization/disinfection process.
Range of Applications for Product	Any medical device likely to be contaminated with blood during clinical use.
Key Specifications of Product	<ul style="list-style-type: none"> MEASURING RANGE: The test kit can detect 0.1 µg of blood with a blue-green color change either on the swab and/or in the liquid. HC-101 swabs that come with product are approximately 5.286mm in diameter.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Store HemoCheck™-S in closed pouches in a cool place 2°C- 25°C. Keep away from light and heat
Packaging Conditions	12 single use tests. Each test kit consists of: <ul style="list-style-type: none"> - vial with solution A (transparent cap) - vial B (green cap) - swab
Shelf Life	18 months from date of manufacturer. See package for expiration date

Instructions for Using Product	
Description of Use (s)	HemoCheck™-S the test kit for detection of blood residue on surfaces.
Preparation for Use	<ol style="list-style-type: none"> In case of refrigerated storage condition, let the test warm up to room temperature before use. Open the protective pouch of the HemoCheck™-S test kit. Included are: A: Solution vial (transparent cap), B: vial (green cap) and C: cotton swab. Keep test away from sunlight.
Diagrams (drawings, pictures)	<div style="display: flex; align-items: center;"> <div style="flex: 1;"> </div> <div style="flex: 1;"> </div> </div> <p style="text-align: center;">Picture is of a Positive Test Result from Right to Left</p>
Steps for Use of Product	<ol style="list-style-type: none"> 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 vigorously. Open the solution vial (A transparent cap) and transfer the liquid into -vial (B green cap). Place the sample-swab (C) into the vial (head down into the liquid) and shake at least 5 times. 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.
Interpretation of Results	If the test solution and/or any surface area of the swab changes to blue/green record the

	results immediately, which indicates the presence of hemoglobin. The bluer and darker the color, the greater the amount of hemoglobin is present.
Contraindications of Test Results	Oxidising agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a color change too. In this case the test cannot be used to detect blood residues.
Documentation	Record test results on log sheet located on hmark.com
Special Warnings and Cautions	<ul style="list-style-type: none"> • Evaluate the result immediately — late color changes are not valid. • If a positive result (blue-green) report that result immediately. • A positive result is proof of remaining blood residue in the tested area only and the device should be reprocessed. • In case of jointed surgical instruments blood residues are most common inside joints which cannot be sampled with a swab. Long swabs can be used for checking inside cannulated instruments. • Stains negative for blood may still represent a danger to patients and staff. If staining is common occurrence, further testing should be considered.
Disposal	Since it is possible that blood is present, it is recommended to dispose of the HemoCheck™-S in a biohazard container.

Reprocessing Instructions	
Point of Use	
Preparation for Decontamination	
Disassembly Instructions	
Cleaning – Manual	
Cleaning – Automated	
Disinfection	
Drying	
Maintenance, Inspection, and Testing	
Reassembly Instructions	
Packaging	
Sterilization	
Storage	
Additional Information	

Related Healthmark Products	EDH-xxx (EndoCheck™ for Hemoglobin), RAC-001 (Robotic Arm Check)
Other Product Support Documents	HemoCheck™ Log Sheet, HemoCheck™ User Guide, PB-Reagent Tests, QA Tray Policy,
Reference Documents	Improving the Quality of Surgical Trays, Kovach; Loaner Instrumentation – Processing the Unknown, AORN Journal; Study on HemoCheck™ and EndoCheck™, Pfiefer
Customer Service Contact	<p>Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com</p> <p>Manufacturer: PEREG GmbH Porsche Str. 12 D-84478 Waldkraiburg www.pereg.de</p>

2018-05-22 Ralph J Basile