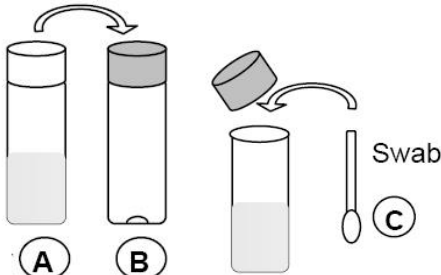





<b>Brand Name of Product</b>	HemoCheck™-S
<b>Generic Name of Product</b>	Blood residue test
<b>Product Code Number(s)</b>	HC-101, Swab-110, Swab-200, Swab-270, Swab-350, Swab-420, Swab-470
<b>Intended Use</b>	To test for blood (hemoglobin) residue on a surgical instrument and other medical devices prior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

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

Instructions for Using Product	
<b>Description of Use (s)</b>	HemoCheck™-S the test kit for detection of blood residue on surfaces.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>In case of refrigerated storage condition, let the test warm up to room temperature before use.</li> <li>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.</li> <li>Keep test away from sunlight.</li> </ol>
<b>Diagrams (drawings, pictures)</b>	  <p style="text-align: center;"><b>Picture is of a Positive Test Result from Right to Left</b></p>
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>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.</li> <li>Open the solution vial (A transparent cap) and transfer the liquid into -vial (B green cap).</li> <li>Place the sample-swab (C) into the vial (head down into the liquid) and shake at least 5 times.</li> <li>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.</li> </ol>
<b>Interpretation of Results</b>	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.
<b>Contraindications of Test Results</b>	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.
<b>Documentation</b>	Record test results on <a href="#">log sheet</a> located on hmark.com
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Evaluate the result immediately — late color changes are not valid.</li> <li>• If a positive result (blue-green) report that result immediately.</li> <li>• A positive result is proof of remaining blood residue in the tested area only and the device should be reprocessed.</li> <li>• 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.</li> <li>• Stains negative for blood may still represent a danger to patients and staff. If staining is common occurrence, further testing should be considered.</li> </ul>
<b>Disposal</b>	Since it is possible that blood is present, it is recommended to dispose of the HemoCheck™-S in a biohazard container.

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

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

2018-05-22 Ralph J Basile