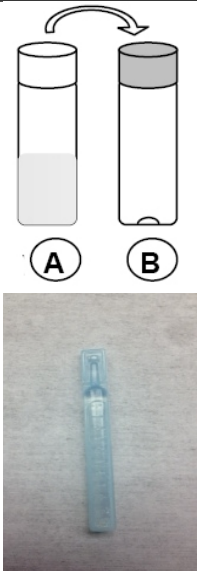
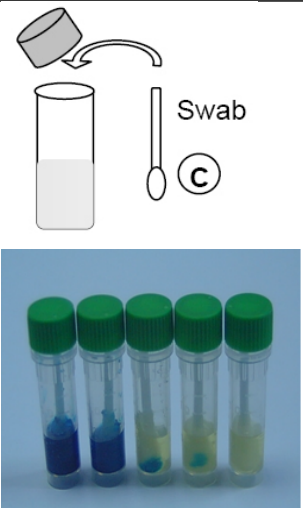



Instructions for Use: RoboticArmCheck™

Brand Name of Product	RoboticArmCheck™
Generic Name of Product	Test for residual blood inside the channel of a robotic arm.
Product Code Number(s)	RAC-001
Intended Use	To test for blood (hemoglobin) residue inside a robotic surgical arm prior to sterilization/disinfection process.
Range of Applications for Product	Robotic surgical arms with an internal channel that can accommodate a 1.75mm minimum diameter swab.
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. • RAC-001 Tip size: 1.38mm

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Store RoboticArmCheck™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat. Do not allow to freeze.
Packaging Conditions	<ul style="list-style-type: none"> • 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 ○ Prepackaged, chlorine-free water vial ○ Scissors
Shelf Life	<ul style="list-style-type: none"> • The reagent expires 18 months from date of manufacture. • The Included prepackaged, chlorine-free water vial expires 2 years from date of manufacture. • See package for expiration date.

Instructions for Using Product	
Description of Use(s)	To test for blood (hemoglobin) residue inside a robotic arm prior to sterilization/disinfection process.
Preparation for Use	<ol style="list-style-type: none"> 1. In case of refrigerated storage condition, let the test warm up to room temperature before use. 2. Open the protective pouch of the RoboticArmCheck™ test kit. 3. Included are: <ol style="list-style-type: none"> A. Solution vial (transparent cap) B. Vial B (green cap) C. Collection swab, vial of prepackaged chlorine-free water and scissors 4. Keep test away from sunlight.

<p>Diagrams (drawings, pictures):</p>		 <p>Image is of a Positive Results (from right to left)</p>	
<p>Steps for Use of Product</p>	<ol style="list-style-type: none"> 1. Open the test kit. Included are: solution vial (transparent cap), vial (green cap), and wire with cotton swab at one end. 2. Testing of the port “1” channel is done after cleaning and before the sterilization/disinfection process. 3. Open the vial (B, green cap) and place the vial into the holder provided. Open the vial (A, transparent cap), and transfer the liquid into the vial (B, green cap). 4. Moisten the swab with a drop of clean water. Do not use chlorinated water. 5. Insert the swab end of the wire into the port marked “1”. 6. If there is any resistance to the swab, do not force the swab; gently remove the swab from the channel (this indicates the channel is not wide enough to accept the swab). 7. If there is no resistance to the swab, push it all the way to the end of channel. 8. Once the end of the channel is reached, do not force the swab any further. 9. Remove the swab from the channel. 10. Cut the swab end off the wire with scissors directly into the vial. Do not touch the swab. 11. Recap the activator vial and shake at least five times. 12. The yellow color change after activation is a normal reaction and does not indicate residue. 13. Check the swab over a period of 30 seconds for a color change to blue-green, which will indicate blood residues in the tested channel. 		
<p>Interpretation of Results</p>	<p>If the test solution and/or any surface area of the swab changes to blue/green within 30 seconds, this indicates the presence of hemoglobin. The bluer and darker the color, the greater the amount of hemoglobin is present.</p>		
<p>Contraindications of Test Results</p>	<p>Oxidizing agents like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a blue-green color change. In this case, the test cannot be used to detect blood residues.</p>		
<p>Documentation</p>	<p>Record test results on log sheet located on hmark.com</p>		
<p>Special Warnings and Cautions</p>	<ul style="list-style-type: none"> • Evaluate the result immediately after 30 seconds — late color changes are not valid. • If a positive result (blue-green) is present, report that result immediately. • A positive result is proof of remaining blood residue in the tested area only and the device should be reprocessed. 		
<p>Disposal</p>	<p>Since it is possible that blood is present, it is recommended to dispose all components of the RoboticArmCheck™ test kit in a biohazard container.</p>		

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	HemoCheck™
Other Product Support Documents	Proformance Brochure, Proformance Price List, RoboticArmCheck™ Policy, RoboticArmCheck™ Specification Sheet, Instruction for Residual Soil Tests, Validation Study of HemoCheck™
Reference Documents	
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com