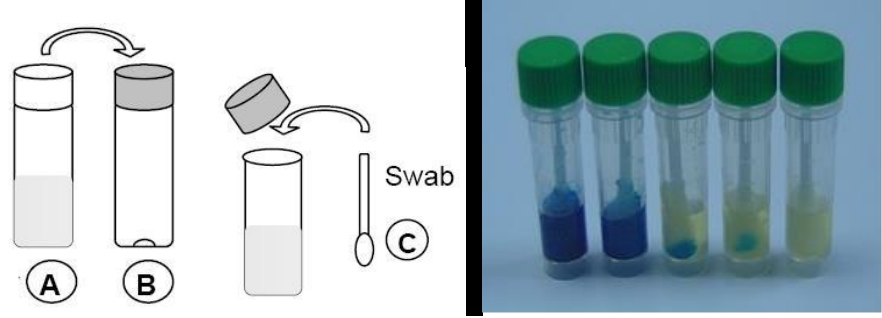


Brand Name of Product	HemoCheck™
Generic Name of Product	Hemoglobin detection test
Product Code Number(s)	HC-101
Intended Use	To test for hemoglobin residue on items after cleaning.
Range of Applications for Product	Any item likely to be contaminated with blood during clinical use.
Key Specifications of Product	<ul style="list-style-type: none"> • MEASURING RANGE: The test kit can detect down to 0.1 µg of hemoglobin with a blue-green color change either on the swab and/or in the liquid • HC-101 swabs are approximately 5 mm in diameter

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	Store HemoCheck™ in closed pouches in a cool place 2 °C - 25 °C. Keep away from light and heat.
Packaging Contents	<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
Shelf Life	18 months from the date of manufacture. See package for expiration date.

Instructions for Using Product	
Description of Use(s)	HemoCheck™- is a test kit for detection of hemoglobin on surfaces.
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 HemoCheck™ test kit. Included are: <ol style="list-style-type: none"> a. A: Solution Vial (transparent cap) b. B: Vial (green cap) c. C: Swab 3. Keep test away from sunlight.
Diagrams (drawings, pictures)	 <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"> 1. Wet surfaces are swabbed with the dry swab. Dry surfaces are swabbed by moistening the swab with a drop of pre-packaged chlorine-free water. Swab the target area of the item. 2. Open the Solution Vial A (transparent cap) and transfer the liquid into Vial B (green cap) 3. Place the Swab (C) into the vial (head down into the liquid) and shake at least five times 4. Check the swab at 30 seconds for a color change to blue-green, which will indicate hemoglobin residues on the tested surface. In the presence of a large amount of hemoglobin, 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 (which indicates the presence of hemoglobin), record the results immediately. The bluer and darker the color, the greater the amount of hemoglobin was detected.
Contraindications of Test Results	<ul style="list-style-type: none"> • Oxidizing agents such as chlorine or hypochlorite can produce a color change • Betadine can cause a false positive test if it remains on the item after cleaning
Documentation	Record test results on log sheet located on hmark.com
Special Warnings and Cautions	<ul style="list-style-type: none"> • Evaluate the results immediately (~30 seconds) • If a positive result (blue-green) is observed, report immediately • A positive result indicates remaining hemoglobin residue in the tested area only. It does not detect other contaminants that could be present • Visible soil or staining on the item should be considered contamination. Follow the item's IFU for further steps • Visible stains (negative for hemoglobin) may still represent a danger to patients and staff and may require reprocessing • If staining is a common occurrence, further investigation is warranted • HemoCheck™ does not ensure that an item is safe for use, or free of contamination. It is to be a single step in the total quality process implemented by the healthcare facility to verify the cleaning process
Disposal	Since it is possible that hemoglobin is present, it is recommended to dispose of the HemoCheck™ in a biohazard container.

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

Related Healthmark Products	Long swabs (available from Healthmark) can be used for checking cannulated items.
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™, Pfiefer
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2021-09-09 Ralph J Basile