healthmark
INDUSTRIES CO.
health care products
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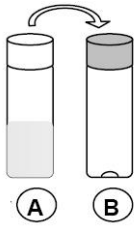
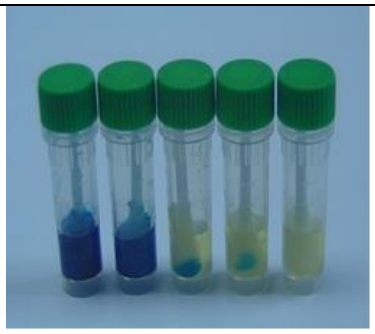
Instructions for Use: EndoCheck™ for Blood

Brand Name of Product	EndoCheck™
Generic Name of Product	Test for Residual Blood in Flexible Endoscopes
Product Code Number(s)	EDH-110, EDH-200, EDH-270, EDH-350, EDH-420, EDH-470,
Intended Use	To test for blood (hemoglobin) residue inside a flexible endoscope prior to sterilization/disinfection process.
Range of Applications for Product	Any flexible endoscope likely to be contaminated with blood after clinical use.
Key Specifications of Product	• 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. 1. Tip Sizes: (See Flexible Endoscope General Diameter Guide for size and color reference.) ○ EDH-110 1.0-1.5mm (White) ○ EDH-200 1.6-2.4mm (Purple/Blue) ○ EDH-270 2.5-3.2mm (Green/Yellow) ○ EDH-350 3.3-3.9mm (Orange) ○ EDH-420 4.0-4.6mm (Orange) ○ EDH-470 4.7-5.0mm (Uncolored)

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Store EndoCheck™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat. Do not allow to freeze.
Packaging Conditions	• 12 single use tests for detection • Each test kit consists of: ○ vial with solution A (transparent cap) ○ vial B (green cap) ○ swab C ○ sterile water vial ○ scissors
Shelf Life	18 months from date of manufacturer. See package for expiration date.

Instructions for Using Product	
Description of Use (s)	To test for blood (hemoglobin) residue inside a flexible endoscope prior to sterilization/disinfection process.
Preparation for Use	1. In case of refrigerated storage condition, let the test warm up to room temperature before use. 2. Open the protective pouch of the EndoCheck test kit. Included are: A: solution vial (transparent cap), B: vial (green cap) and C: collection swab, vial of sterile water and scissors. 3. Keep test away from sunlight.
Diagrams (drawings, pictures)	   **Picture of Positive Result from Right to Left**
Steps for Use of Product	1. Open the test kit. Included are: vial A (transparent cap), vial B (green cap), and wire with cotton swab at one end.

	2. Testing of the biopsy 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 appropriate sized swab for the channel to be tested with a drop of clean water. Do not use chlorinated water. 5. Insert the swab end of the wire into the scope/biopsy channel. Push it all the way through one (1) time. 6. Cut the swab end off the wire with scissors directly into the vial. Beware not to cut distal tip. Do not touch the swab. To remove the remaining segment of the EndoCheck, pull the wire out from the distal tip. 7. Recap the activator vial and shake at least five times. 8. Check the swab for an immediate color change to blue-green, which will indicate blood residues in the tested scope. 9. The yellow color change after activation is a normal reaction and does not indicate residue.
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	Oxidizing 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	• 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.
Disposal	Since it is possible that blood is present, it is recommended to dispose all components of the EndoCheck™ test kit 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	• Lot control test results (Statement of Conformance) are available from Healthmark upon request.

Related Healthmark Products	EndoCheck™ for Protein Detection, HemoCheck™
Other Product Support Documents	Proformance Brochure, Proformance Price List, EndoCheck™ Results Log Sheet, EndoCheck™ Sample Policy, EndoCheck™-Hemoglobin Specification Sheet, Instructions for Residual Soil Tests, Support for Monitoring the Cleaning of Endoscopes, Validation Study of HemoCheck™ and EndoCheck™
Reference Documents	
Customer Service Contact	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

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