### Instructions for Use: EndoCheck™ for Blood

<table>
<thead>
<tr>
<th>Brand Name of Product</th>
<th>EndoCheck™</th>
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<tbody>
<tr>
<td>Generic Name of Product</td>
<td>Test for Residual Blood in Flexible Endoscopes</td>
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<tr>
<td>Product Code Number(s)</td>
<td>EDH-110, EDH-200, EDH-270, EDH-350, EDH-420, EDH-470,</td>
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<tr>
<td>Intended Use</td>
<td>To test for blood (hemoglobin) residue inside a flexible endoscope prior to sterilization/disinfection process.</td>
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<tr>
<td>Range of Applications for Product</td>
<td>Any flexible endoscope likely to be contaminated with blood after clinical use.</td>
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| 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.  
   - 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

<table>
<thead>
<tr>
<th>Shipping Conditions &amp; Requirements</th>
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<tbody>
<tr>
<td>Storage Conditions</td>
<td>Store EndoCheck™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat. Do not allow to freeze.</td>
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</tbody>
</table>
| 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  
  - prepackaged 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 prepackaged water and scissors.  
3. Keep test away from sunlight.

**Diagrams (drawings, pictures)**

**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.  

![Diagram of test kit components](image-url)
2. Testing of the biopsy channel is done after cleaning and before 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
Clean the scissors in between tests with an alcohol wipe.
Cleaning – Automated
Disinfection
Drying
Maintenance, Inspection, and Testing
Reassemble Instructions
Sterilization
Packaging
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
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2018-12-13 Ralph J Basile

Rev. B