


Instructions for Use: EndoCheck™ for Protein

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| Brand Name of Product | EndoCheck™ |
| Generic Name of Product | Test for residual protein inside a flexible endoscope |
| Product Code Number(s) | EDP-110, EDP-200, EDP-270, EDP-350, EDP-420, EDP-470 |
| Intended Use | To test for protein residue inside a flexible endoscope prior to sterilization/disinfection. |
| Range of Applications for Product | Any flexible endoscope likely to be contaminated with blood after clinical use. |
| Key specifications of Product | <ul style="list-style-type: none"> • MEASURING RANGE: The test kit can detect down to 1 µg of insoluble protein by showing a blue-green spot. • Tip Sizes: (See Flexible Endoscope General Diameter Guide for size and color reference.) <ul style="list-style-type: none"> ○ EDP-110 1.0-1.5mm (White) ○ EDP-200 1.6-2.4mm (Purple/Blue) ○ EDP-270 2.5-3.2mm (Green/Yellow) ○ EDP-350 3.3-3.9mm (Orange) ○ EDP-420 4.0-4.6mm (Orange) ○ EDP-470 4.7-5.0mm (Uncolored) |

| Shipping & Storage | |
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| Shipping Conditions & Requirements | |
| Storage Conditions | Store EndoCheck™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat and do not allow to freeze |
| Packaging Conditions | <ul style="list-style-type: none"> • 12 single use tests for detection of protein in flexible endoscopes. • Each test kit consists of: <ul style="list-style-type: none"> - vial with indicator solution - protein-free swab - prepackaged water vial - scissors |
| Shelf Life | 18 months from date of manufacturer. See package for expiration date. |

| Instructions for Using Product | |
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| Description of Use (s) | Test for residual protein inside flexible endoscopes. |
| 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 EndoCheck™ test kit. Included are: Indicator-vial (purple cap); collection swab; vial of prepackaged water and scissors. Keep test away from sunlight. 3. Gloves must be worn throughout the test procedure to avoid contamination of the test. |
| Diagrams (drawings, pictures) |  |
| Steps for Use of Product | <ol style="list-style-type: none"> 1. Open the test kit. Included are: indicator vial and wire with protein-free swab at one end. 2. Testing of the biopsy channel is done after cleaning and before the sterilization/disinfection process. 3. Open the indicator vial, place the vial into the Holder provided. 4. Moisten the appropriate sized swab for the channel to be tested with a drop of |

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| | <p>prepackaged water.</p> <ol style="list-style-type: none"> 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 vial and shake at least five times. 8. Check the swab over a period of 300 seconds (5 minutes) for a color change to blue-green, which will indicate protein residues in the tested scope. |
| Interpretation of Results | <ol style="list-style-type: none"> 1. In case of soluble proteins, there will be an immediate color change. In the case of denatured proteins (often the case with instruments subjected to reprocessing) color change can take up to 5 minutes. 2. In the presence of large amounts of soluble protein, the whole indicator solution will change blue-green. |
| Contraindications of Test Results | Contact to alkaline substances (larger amount of alkaline detergent) can trigger color change. Quaternary ammonium salts (used in some disinfectants) will give a false positive result. Contact to bare hands can transfer protein particles onto the swab and may give a false positive result. |
| Documentation | Record test results on log sheet located on hmark.com |
| Special Warnings and Cautions | <ul style="list-style-type: none"> • Evaluate the result immediately after 300 seconds (5 minutes) — late color changes are not valid. • If a positive result (blue-green) report that result immediately. • A positive result is proof of remaining protein residue in the tested area only and the device should be reprocessed. |
| Disposal | Since it is possible that organic soil is present, it is recommended to dispose all components of the EndoCheck™ test kit in a biohazard container. |

| Reprocessing Instructions | |
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| Point of Use | |
| Preparation for Decontamination | |
| Disassembly Instructions | |
| Cleaning – Manual | Clean the scissors in between each test with an alcohol wipe. |
| Cleaning – Automated | |
| Disinfection | |
| Drying | |
| Maintenance, Inspection, and Testing | |
| Reassembly Instructions | |
| Packaging | |
| Sterilization | |
| Storage | |
| Additional Information | <ul style="list-style-type: none"> • Lot control test results (Statement of Conformance) are available from Healthmark upon request. |

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| Related Healthmark Products | EndoCheck™ for Blood Detection, Hemocheck™ |
| Other Product Support Documents | ProFormance™ Brochure, ProFormance™ Price List, EndoCheck™ Results Log Sheet, EndoCheck™ Sample Policy, EndoCheck™-Protein Specification Sheet, Instructions for Residual Soil Tests, Support for Monitoring the Cleaning of Endoscopes, Validation Study of ProChek® -II and EndoCheck™ |
| Reference Documents | |
| Customer Service Contact | Healthmark Industries Company, Inc 18600 MayIn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com |