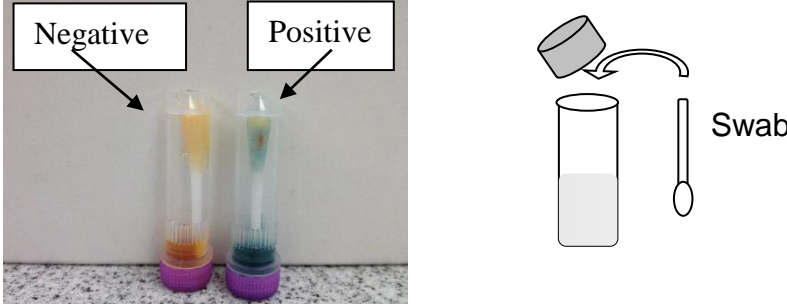


<b>Brand Name of Product</b>	ProChek-II™
<b>Generic Name of Product</b>	Test for residual protein on surgical instruments and other medical devices, prior to any sterilization/disinfection process.
<b>Product Code Number(s)</b>	PT-202
<b>Intended Use</b>	To test for protein residue on a surgical instrument and other medical devices
<b>Range of Applications for Product</b>	Any medical device likely to be contaminated with protein soils during clinical use.
<b>Key specifications of product</b>	<ul style="list-style-type: none"> <li>• MEASURING RANGE: The test kit can detect down to 1 µg of insoluble protein by showing a blue-green spot.</li> <li>• PT-202 – (3651) swabs that come with product are approximately 5.286mm in diameter at the widest point.</li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	Store ProChek-II™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat and do not allow to freeze
<b>Packaging Conditions</b>	<ul style="list-style-type: none"> <li>• 15 single use tests.</li> <li>• Each test kit consists of: <ul style="list-style-type: none"> <li>- vial with indicator solution</li> <li>- protein-free swab</li> </ul> </li> </ul>
<b>Shelf Life</b>	18 months from date of manufacturer. See package for expiration date.

<b>Instructions for Using Product</b>	
<b>Description of Use (s)</b>	To test for residual protein remaining on a surgical instrument or other medical devices likely to be soiled with protein residue during clinical use.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. In case of refrigerated storage condition, let the test warm up to room temperature before use.</li> <li>2. Open the protective pouch of the ProChek-II™ test kit. Included are: indicator vial (purple cap); collection swab; and scissors. Keep test away from sunlight.</li> <li>3. Gloves must be worn throughout the test procedure to avoid contamination of the test.</li> </ol>
<b>Diagrams (drawings, pictures):</b>	 <p>The diagram shows two vials side-by-side. The left vial is labeled 'Negative' and contains a yellow liquid. The right vial is labeled 'Positive' and contains a blue-green liquid. To the right of the vials is a diagram of a vial with a purple cap and a swab being inserted into it. The swab is labeled 'Swab'.</p>
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Open the test kit. Included are: indicator vial and protein-free swab. (If swab is not pre-moistened, then moisten with sterile water.</li> <li>2. Testing is to be done prior to any sterilization/disinfection process.</li> <li>3. Open the indicator vial, place the vial into the holder provided.</li> <li>4. Swab the suspect stain, or target area of the device for testing (i.e., box locks).</li> <li>5. Cut the swab end off with a scissors directly into the vial. Do not touch the swab.</li> <li>6. Recap the vial and shake at least five times.</li> <li>7. Check the swab and liquid over a period of 300 seconds (5 minutes) for a color change to blue-green, which will indicate protein residues on the tested device. <ol style="list-style-type: none"> <li>a. Inverting the vial will improve observation of color change on the swab.</li> </ol> </li> </ol>
<b>Interpretation of Results</b>	<ol style="list-style-type: none"> <li>1. In case of soluble proteins, there will be an immediate color change.</li> <li>2. In the case of denatured proteins (often the case with instruments subjected to reprocessing) color change can take up to 5 minutes.</li> <li>3. In the presence of large amounts of soluble protein, the whole indicator solution will change blue-green.</li> </ol>

<b>Contraindications of Test Results</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Contact to bare hands can transfer protein particles onto the swab and may give a false positive result.</li> </ul>
<b>Documentation</b>	Record test results on <a href="#">log sheet</a> located on <a href="#">hmark.com</a>
<b>Special Warnings and Cautions</b>	<ul style="list-style-type: none"> <li>• Evaluate the result immediately after 300 seconds (5 minutes) — late color changes are not valid.</li> <li>• If a positive result (blue-green) report that result immediately.</li> <li>• A positive result is proof of remaining protein residue in the tested area only and the device should be reprocessed.</li> </ul>
<b>Disposal</b>	Since it is possible that organic soil is present, it is recommended to dispose all components of the ProChek-II™ test kit in a biohazard container.

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	
<b>Cleaning – Automated:</b>	
<b>Disinfection:</b>	
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	
<b>Storage:</b>	
<b>Additional Information:</b>	

<b>Related Healthmark Products</b>	Swab-110-12, Swab-200-12, Swab-270-12, Swab-350-12, Swab-470-12, EndoCheck™ for Protein Detection, Hemocheck™
<b>Other Product Support Documents</b>	Performance Brochure, Performance Price List, ProChek-II™ Specification Sheet, Endocheck™ Sample Policy, Endocheck™-Protein Specification Sheet, Instructions for Residual Soil Tests, Results Log sheet, Validation Study of ProChek-II™ and Endocheck™
<b>Reference Documents</b>	
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> <a href="http://hmark.com">hmark.com</a>

2017-12-21 Ralph J Basile