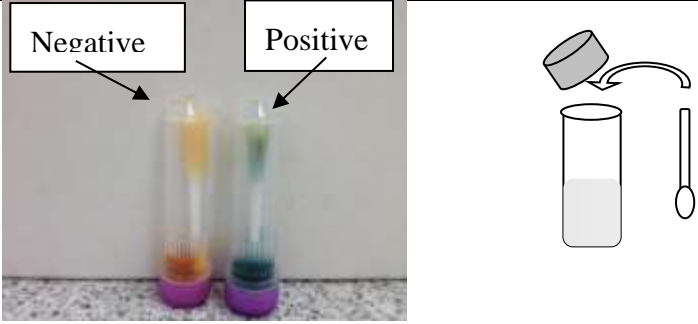


<b>Brand Name of Product</b>	ProChek®-II
<b>Generic Name of Product</b>	Protein Test
<b>Product Code Number(s)</b>	PT-202, PT-201-12
<b>Intended Use</b>	To test for residual protein remaining on surfaces after cleaning prior to further processing.
<b>Range of Applications for Product</b>	Any items likely 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 1µg of insoluble protein by showing a blue-green spot.</li> <li>● PT-202 – (3651 DW SC) swabs that come with product are approximately 5.286 mm 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 Contents</b>	<ul style="list-style-type: none"> <li>● 12 single-use tests.</li> <li>● Each test kit consists of:               <ul style="list-style-type: none"> <li>- Vial with indicator solution</li> <li>- Premoistened protein-free swab with a breakpoint.</li> </ul> </li> </ul>
<b>Shelf Life</b>	18 months from date of manufacture. See package for expiration date.

<b>Instructions for Using Product</b>	
<b>Description of Use(s)</b>	To test for residual protein remaining on items 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) and collection swab. (Keep test away from sunlight.)</li> <li>3. Gloves should 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 schematic drawing of the test kit components: a vial with a purple cap and a collection 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.</li> <li>2. Testing is to be done after cleaning, prior to further processing steps.</li> <li>3. Open the indicator vial and place the vial into the holder provided.</li> <li>4. Swab the suspect stain or target area of the item for testing.</li> <li>5. Break the swab end off at the breakpoint directly into the vial.</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 residue on the tested item.           <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 the case of soluble proteins, there will be an immediate color change.</li> <li>2. In the case of denatured proteins (often the case with items subjected to reprocessing), color change can take up to 5 minutes.</li> </ol>

	3. In the presence of large amounts of soluble protein, the whole indicator solution will change blue-green.
<b>Contraindications of Test Results</b>	<ul style="list-style-type: none"> <li>● Contact to alkaline substances can trigger color change.</li> <li>● Quaternary ammonium salts may give a false positive result.</li> <li>● Contact by 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 hmark.com
<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) is indicated, report that result immediately.</li> <li>● A positive result is indicative of remaining protein residue in the tested area and the device should be reprocessed.</li> <li>● No matter the test result, visible soil or staining on the item should be considered contamination. Follow the item's IFU for further steps.</li> <li>● If staining is a common occurrence, further investigation is warranted.</li> <li>● ProChek®-II does not ensure that an item is safe for use or free of contamination. It is to be a step in a total quality process implemented by the healthcare facility to verify the cleaning process.</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 Sampling Kits
<b>Other Product Support Documents</b>	ProFormance™ Brochure, ProFormance™ Price List, ProChek®-II Specification Sheet, Instructions for Residual Soil Tests, Results Log sheet, Validation Study of ProChek®-II
<b>Reference Documents</b>	
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. 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>

2020-09-15 Ralph J Basile