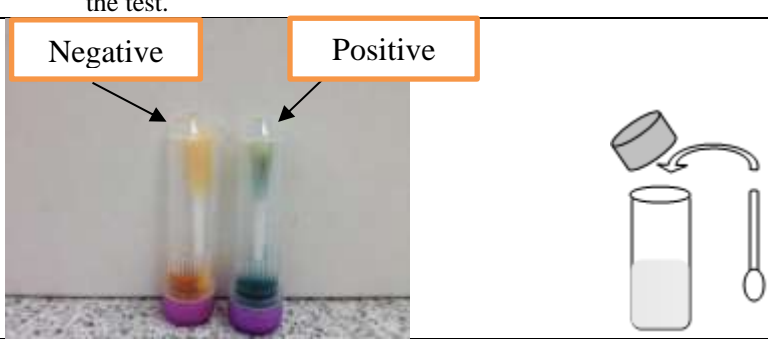


## Instructions for Use: ProChek-II

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| <b>Brand Name of Product</b>             | ProChek®-II   |
| <b>Generic Name of Product</b>           | Protein Test  |
| <b>Product Code Number(s)</b>            | PT-313  |
| <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>• <b>MEASURING RANGE:</b> The test kit can detect down to 1µg of insoluble protein by showing a blue-green spot.</li> <li>• PT-313 – (HC-SWAB) swabs that come with product are approximately 5.286 mm in diameter at the widest point.</li> </ul> |

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| <b>Shipping &amp; Storage</b>                 |   |
| <b>Shipping Conditions &amp; Requirements</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>Storage Conditions</b>                     |   |
| <b>Packaging Contents</b>                     | <ul style="list-style-type: none"> <li>• Each test kit consists of:           <ul style="list-style-type: none"> <li>- Vial with indicator solution</li> <li>- Non-premoistened swabs</li> <li>- 3 mL water vials</li> <li>- Vial holder</li> </ul> </li> </ul> |
| <b>Shelf Life</b>                             | 18 months from date of manufacture. See package for expiration date.  |

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| <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 image shows two test vials. 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 is a diagram of a vial with a purple cap being inverted, with a swab inside, illustrating the step of observing the color change on the 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. Moisten the swab with the 3mL water vial that is provided.</li> <li>3. Testing is to be done after cleaning, prior to further processing steps.</li> <li>4. Open the indicator vial and place the vial into the holder provided.</li> <li>5. Swab the suspect stain or target area of the item for testing.</li> <li>6. Place the swab in the reagent vial.</li> <li>7. Recap the vial and shake at least five times.</li> <li>8. 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 Test 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>   |

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|  | 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>            |   |
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| <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.<br>18600 Malyn Blvd.<br>Fraser, MI 48026<br>1-586-774-7600<br><a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a><br>hmark.com |

2021-01-11 Suzanne Latta