



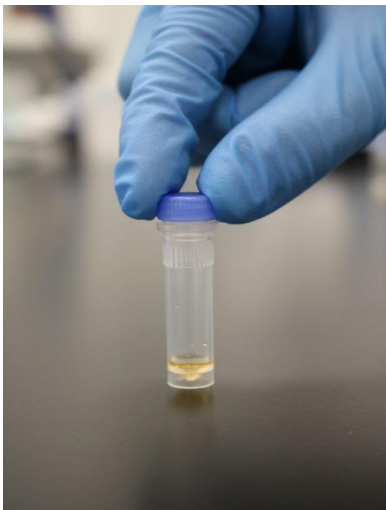
<b>Brand Name of Product</b>	ProChek®-Semi Quantitative Protein Test
<b>Generic Name of Product</b>	Protein Test
<b>Product Code Number(s)</b>	PT-SQ-001
<b>Intended Use</b>	Testing for residual protein in lumens.
<b>Range of Applications for Product</b>	Any lumened item likely to be contaminated with protein soils.
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• Measuring range for the test is 0 µg/mL-30 µg/mL</li> <li>• 15 Protein Reagent Vials</li> <li>• 15 Pipettes</li> <li>• 15 Ziplock Bags</li> <li>• Interpretation Chart</li> <li>• Cardboard Cuvette Holder</li> </ul>

Shipping & Storage	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	Store ProChek®-W reagent vials 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>	15 single-use tests. Each kit consists of protein reagent vial, pipette, Ziplock bag.
<b>Shelf Life</b>	18 months from manufacturing date. See package for expiration date.

Instructions for Using Product	
<b>Description of Use(s)</b>	To test for residual protein in lumens.
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>• Testing is typically conducted after cleaning prior to disinfection/sterilization.</li> <li>• Clean gloves must be worn throughout the test procedure to avoid contamination of the test.</li> <li>• New, 10cc or larger syringe. Slip-tip style syringe is preferred. (Healthmark offers prefilled syringes with 10 mL water sold separately.)</li> </ul>
<b>Diagrams (drawings, pictures)</b>	<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p><b>Figure 1</b></p> </div> <div style="text-align: center;">  <p><b>Figure 2</b></p> </div> </div>



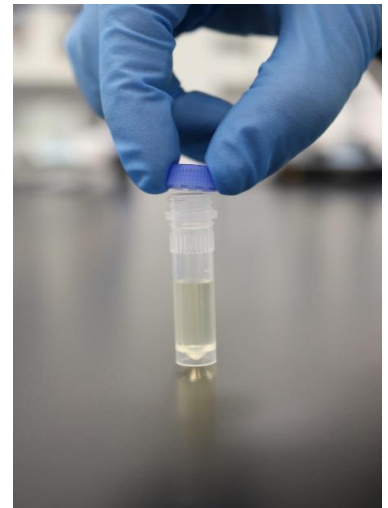
**Figure 4**



**Figure 3**



**Figure 5**



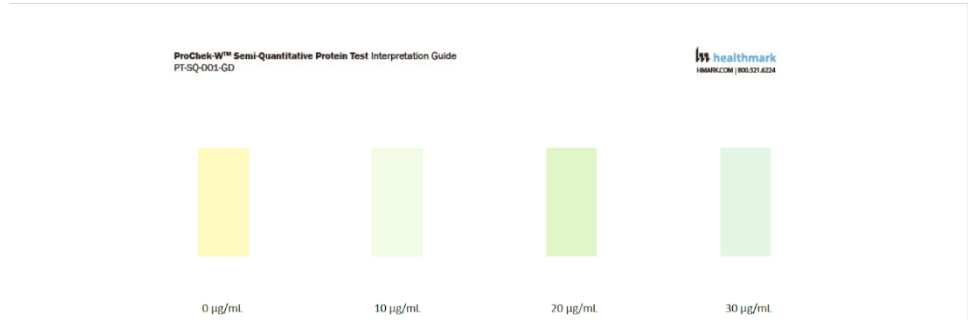
**Figure 6**



**Figure 7**



**Figure 8**



**Figure 8A**  
Color of the solution when there is 0 µg, 10 µg, 20 µg, 30 µg of protein per 1 mL of the extract.

**Note: For color accuracy, please compare vials to printed interpretation chart included with the ProChek®-W.**

<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Wear clean gloves.</li> <li>2. Open the Ziplock bag by gently pushing from the side of the bag (this will help create a wide enough opening, so the clean plastic bag can be placed over the distal tip).</li> <li>3. Push the distal tip halfway down into the clean plastic bag.</li> <li>4. Once the tip is halfway into the clean plastic bag, seal the bag by pushing the sides together. Close the seal about ¾ of the way (up to the distal tip) and then stop. This will provide enough of a seal to capture the sample without the bag falling off during the sampling process.</li> <li>5. Fill syringe with 10 mL of prepackaged water.</li> <li>6. Flush the lumen with 10 mL of prepackaged water. <b>Fig. 1</b></li> <li>7. Refill the syringe with air and flush the lumen.</li> <li>8. Collect the water in the provided Ziplock bag. <b>Fig. 2</b></li> <li>9. After you have recaptured the sample in the clean plastic bag, gently pull the clean plastic bag off the distal tip.</li> <li>10. Unscrew the cap to the ProChek®-W vial. <b>Fig. 3</b></li> <li>11. Pipette 1 mL of sample from the Ziplock bag. <b>Fig. 4</b></li> <li>12. Add 1 mL of sample to a ProChek®-W vial. <b>Fig. 5</b></li> <li>13. Replace the cap on the ProChek®-W vial. <b>Fig. 6</b></li> <li>14. Mix the contents in the vial by shaking at least five times. <b>Fig. 7</b></li> <li>15. Place sample into holder.</li> <li>16. Wait 5 minutes.</li> <li>17. Compare the color of the solution to the provided color interpretation chart to determine the amount of protein extracted. <b>Fig. 8, 8A</b></li> </ol> <p><b>Note: The color interpretation chart shows the color of the solution when there is 0 µg, 10 µg, 20 µg, 30 µg of protein per 1 mL of the extract.</b></p>
<b>Interpretation of Results</b>	<ul style="list-style-type: none"> <li>• In the case of soluble proteins, there will be an immediate color change.</li> <li>• In the case of denatured proteins (often the case with items subjected to reprocessing), color change can take up to 5 minutes.</li> <li>• For an accurate semi-quantitative result, wait the full 5 minutes.</li> </ul>
<b>Contraindications of Test Results</b>	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.
<b>Documentation</b>	Record test results on log sheet located at <a href="http://www.hmark.com">www.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>• Report a positive test result immediately.</li> <li>• A positive result is indicative of remaining protein residue in the recaptured extract solution.</li> <li>• If positive, the item should be reprocessed.</li> </ul>
<b>Disposal</b>	Since it is possible that organic soil is present, it is recommended to dispose of all components of the ProChek®-W 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>	<ul style="list-style-type: none"> <li>● Lot control test results (Statement of Conformance) are available from Healthmark upon request.</li> <li>● Quality of Water for Testing: <ol style="list-style-type: none"> <li>1. It is recommended to use prepackaged water that is chlorine free.</li> <li>2. For effective testing, care should be taken not to contaminate after opening to avoid creating the opportunity for false positive test results.</li> </ol> </li> </ul>
<b>Related Healthmark Products</b>	ProChek®, HemoCheck™, ChannelCheck™
<b>Other Product Support Documents</b>	ProFormance™ Brochure, ProFormance™ Price List
<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> hmark.com

2020-12-04 Suzanne Latta