

<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 potentially contaminated with protein soils.
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>● Measuring range for the test is zero (0) µg/mL to 30 µg/mL</li> <li>● 15 Protein Reagent Vials</li> <li>● 15 Pipettes</li> <li>● 15 Zipper Bags</li> <li>● Interpretation Chart</li> <li>● Cardboard Cuvette Holder</li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	Store ProChek®-W reagent vials in closed packaging in a cool place 2- to 25 °C (35.6- to 77 °F). 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, and zipper bag.
<b>Shelf Life</b>	Eighteen (18) months from manufacturing date. See package for expiration date.



<b>Instructions for Using Product</b>	
<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 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, 10 cc or larger syringe. Slip-tip style syringes are 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; align-items: center;"> <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 3



Figure 4



Figure 5



Figure 6

ProChek-W™ Semi-Quantitative Protein Test Interpretation Guide  
PF-02-001-G0

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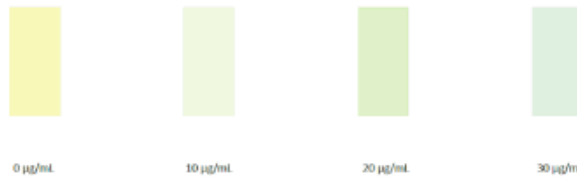


Figure 6A

Color of the solution when there is zero (0) µg, 10 µg, 20 µg, 30 µg of protein per 1 mL of 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 zipper 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 of the lumened device).</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 pre-packaged water.</li> <li>6. Flush the lumen with 10 mL of pre-packaged water.</li> <li>7. Refill the syringe with air and flush the lumen.</li> <li>8. Collect the water in the provided zipper bag.</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. 1).</b></li> <li>11. Pipette 1 mL of sample from the zipper bag. <b>(Fig. 2).</b></li> <li>12. Add 1 mL of sample to a ProChek®-W vial. <b>(Fig. 3).</b></li> <li>13. Replace the cap on the ProChek®-W vial. <b>(Fig. 4).</b></li> <li>14. Mix the contents in the vial by shaking at least five times. <b>(Fig. 5).</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. 6, 6A).</b></li> </ol> <p><b>(Note: The color interpretation chart shows the color of the solution when there is zero (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 with 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 indicates the presence of residual protein in the extract solution.</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>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	N/A
<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> </ul>

	<ul style="list-style-type: none"> <li>• Quality of Water for Testing: <ul style="list-style-type: none"> <li>▪ It is recommended to use pre-packaged water that is chlorine free.</li> <li>▪ For effective testing, care should be taken not to contaminate after opening to avoid creating the opportunity for false-positive test results.</li> </ul> </li> </ul>
<b>Related Healthmark Products</b>	ProChek®, HemoCheck™, ChannelCheck™
<b>Other Product Support Documents</b>	N/A
<b>Reference Documents</b>	N/A
<b>Customer Service Contact</b>	Healthmark, A Getinge company 18600 Malyn BLVD Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com