

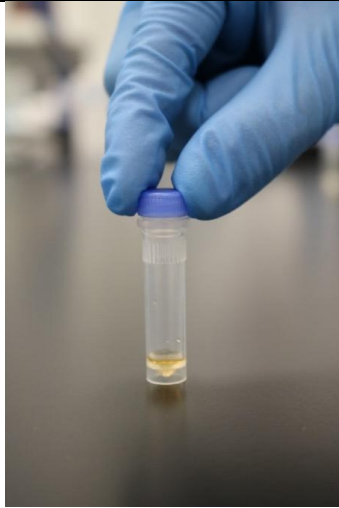


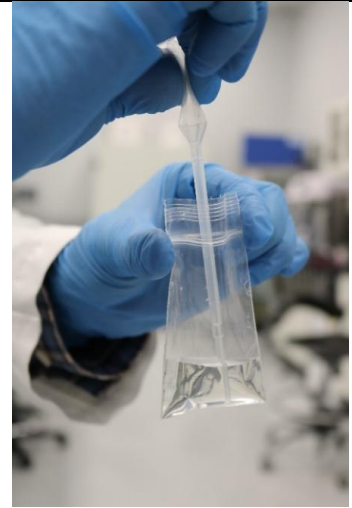
<b>Brand Name of Product</b>	ProChek®-W Protein Test for Robotic Arms
<b>Generic Name of Product</b>	Protein Test for Robotic Arms
<b>Product Code Number(s)</b>	PT-SQ-001
<b>Intended Use</b>	Testing for residual protein remaining on robotic instruments after cleaning and prior to disinfection/sterilization.
<b>Range of Applications for Product</b>	Robotic instruments potentially contaminated with protein soils during clinical use.
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• Measuring range for the test is zero (0) µg/ml–30 µg/ml.</li> <li>• 15 Protein Reagent Vials</li> <li>• 15 Pipettes</li> <li>• 15 Zipper Bags</li> <li>• One (1)-Interpretation Chart</li> <li>• Cardboard Cuvette Holder.</li> </ul> <p>(NOTE: Customer will supply the syringe and pre-packaged sterile water.)</p>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	N/A
<b>Storage Conditions</b>	Room temperature and away from light.
<b>Packaging Contents</b>	<ul style="list-style-type: none"> <li>• 15 single-use tests.</li> <li>• Each kit consists of: Protein Reagent Vial, Pipette, and Zipper Bag.</li> </ul>
<b>Shelf Life</b>	Eighteen (18) months from manufacturing date. See packaging for expiration date.

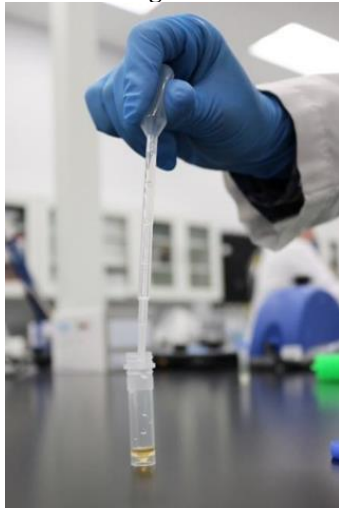
<b>Instructions for Using Product</b>	
<b>Description of Use(s)</b>	To test for residual protein that remains on robotic instruments after cleaning.
<b>Preparation for Use</b>	<ul style="list-style-type: none"> <li>• Testing is typically conducted after cleaning; prior to disinfection/sterilization.</li> <li>• Clean gloves.</li> <li>• New 6 cc or larger syringe with blunt nose that fits the ports of robotic arms.</li> <li>• Customer will supply the syringe and pre-packaged sterile water.</li> </ul>
<b>Diagrams of Use(s)</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>



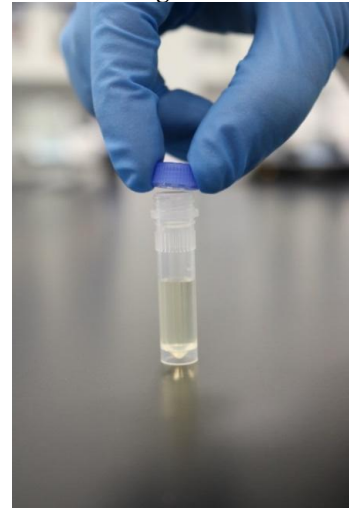
**Figure 3**



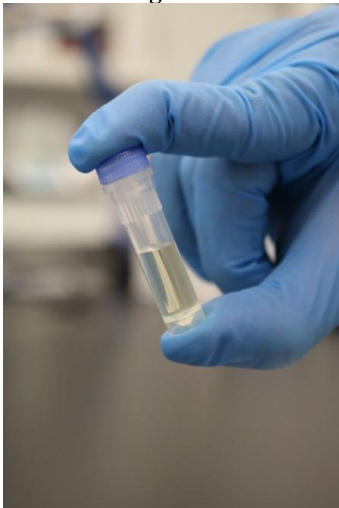
**Figure 4**



**Figure 5**



**Figure 6**

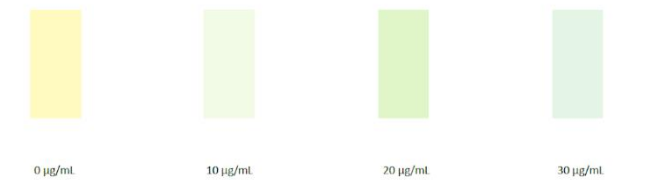


**Figure 7**



**Figure 8**

1. Flush the lumen with 10cc of sterile wa
2. Collect the water in the provided Ziplo
3. Remove the cap from the ProChek™.Y

	<p style="text-align: center;">ProChek-W™ Semi-Quantitative Protein Test Interpretation Guide PT-SQ-001-G0</p> <p style="text-align: right;">healthmark HMARK.COM   800.527.4224</p>  <p style="text-align: center;"><b>Figure 9</b> <b>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> <b>(Note: For color accuracy please compare vials to printed interpretation guide included with the ProChek®-W.)</b></p>
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Wear clean gloves.</li> <li>2. Place zipper bag on distal tip and secure it to ensure it does not fall off.</li> <li>3. Fill syringe with 6 mL of sterile water. <b>(Fig. 1)</b>.</li> <li>4. With syringe, flush the lumen through Port 1.</li> <li>5. Draw the water back out with the same syringe.</li> <li>6. Gently eject the water into the supplied zipper bag. <b>(Fig. 2)</b>.</li> <li>7. Make sure water comes in contact with the entire area of distal tip and gently swish the distal tip in the recaptured water in the same zipper bag for 10 seconds. <b>(Fig. 3)</b>.</li> <li>8. Remove the robotic distal end from the zipper bag. <b>(Fig. 4)</b>.</li> <li>9. Unscrew the cap to the ProChek®-W vial. <b>(Fig. 3)</b>.</li> <li>10. With supplied pipette, draw up 1 mL of recaptured water from the zipper bag. <b>(Fig. 4)</b>.</li> <li>11. From the pipette, add 1 mL of water to a ProChek®-W vial. <b>(Fig. 5)</b>.</li> <li>12. Replace the cap on the ProChek®-W vial. <b>(Fig. 6)</b>.</li> <li>13. Mix the contents in the vial by shaking at least five times. <b>(Fig. 7)</b>.</li> <li>14. Wait 5 minutes.</li> <li>15. Place the ProChek®-W vial in between the colors on the chart, which will allow you to compare the color of the solution to the provided color interpretation chart. <b>(Fig. 8)</b>.</li> </ol> <p>(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>(Fig. 9)</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 instruments 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>	<ul style="list-style-type: none"> <li>• Contact with alkaline substances (larger amount of alkaline detergent) can trigger color change.</li> <li>• Quaternary ammonium salts (used in some disinfectants) will give a false positive result.</li> </ul>
<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) — <i>late color changes are not valid.</i></li> <li>• Report a positive test result immediately.</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> <li>• Quality of Water for Testing: <ol style="list-style-type: none"> <li>1. It is recommended to use pre-packaged sterile water, such as sterile water for irrigation.</li> <li>2. For effective testing, it is not necessary that the water remain sterile, but 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>	N/A
<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