

## Instructions for Use: ProChek<sup>TM</sup>-W Semi-Quantitative Protein Test for Robotic Arms

Brand Name of Product	ProChek <sup>TM</sup> -W Protein Test for Robotic Arms
Generic Name of Product	Protein Test for Robotic Arms
Product Code Number(s)	PT-SQ-001
Intended Use	Testing for residual protein remaining on robotic arms after cleaning.
Range of Applications for Product	Robotic arms likely to be contaminated with protein soils during clinical use.
Key Specifications of Product	<ul> <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 Zip lock Bags</li> <li>1 Interpretation Chart</li> </ul>
	Customer will supply the syringe and prepackaged sterile water

Shipping & Storage		
Shipping Conditions &		
Requirements		
Storage Conditions	Room temperature	
Packaging Conditions		
Shelf Life		

Instructions for Using Product	
Description of Use(s)	To test for residual protein that remain on robotic arms after cleaning.
Preparation for Use	<ul> <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> </ul>
	Customer will supply the syringe and prepackaged sterile water.
Diagrams of Use(s)	Figure 1 Figure 2



Figure 3



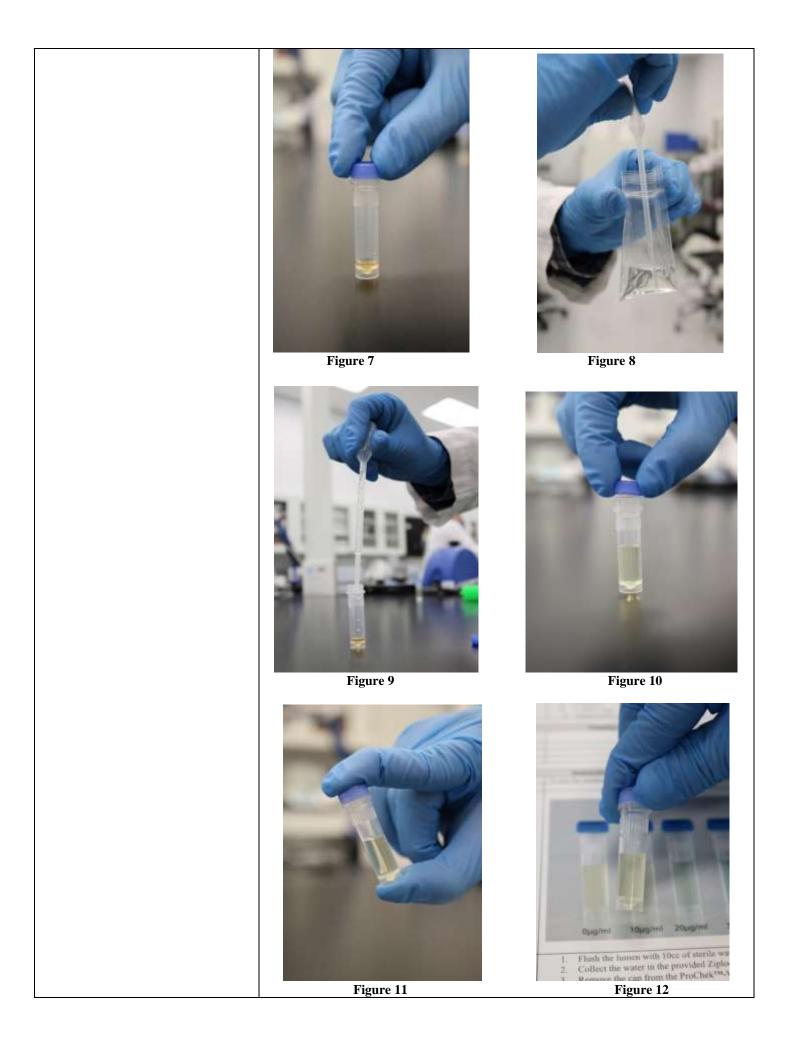
Figure 4



Figure 5



Figure 6



	ProCheb W <sup>ac</sup> Sand-Quantitative Problem Yest Interprolation Guide.  If SQ 201-5D  Interpretation of the Committee of the Comm
	Opegfool to pagfool to pagfool Mopagfool
	Color of the solution when there is 0 $\mu g$ ,10 $\mu g$ , 20 $\mu g$ , 30 $\mu g$ of protein per 1 ML of the extract.
	Note: For color accuracy please compare vials to printed interpretation guide included with the ProChek-W.
Steps for Use of Product	<ol> <li>Wear clean gloves.</li> <li>Place zip lock bag on distal tip and secure it to ensure it does not fall off.</li> <li>Fill syringe with 6 mL of sterile water. Fig. 1</li> <li>With syringe, flush the lumen through Port 1. Fig. 2</li> <li>Draw the water back out with the same syringe. Fig. 3</li> <li>Gently eject the water into the supplied zip lock bag. Fig. 4</li> <li>Make sure water comes in contact with entire area of distal tip and gently swish the distal tip in the recaptured water in the same zip lock bag for 10 seconds. Fig. 5</li> <li>Remove the robotic arm from the zip lock bag. Fig. 6</li> <li>Unscrew the cap to the ProChek<sup>TM</sup>-W vial. Fig. 7</li> <li>With supplied pipette, draw up 1 mL of recaptured water from the zip lock bag. Fig. 8</li> <li>From the pipette, add 1 mL of water to a ProChek<sup>TM</sup>-W vial. Fig. 9</li> <li>Replace the cap on the ProChek<sup>TM</sup>-W vial. Fig. 10</li> <li>Mix the contents in the vial by shaking at least five times. Fig. 11</li> <li>Wait 5 minutes.</li> <li>Place the ProChek 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. Fig. 12</li> <li>The color interpretation chart shows the color of the solution when there is</li> </ol>
Interpretation of Results	<ul> <li>0 μg, 10 μg, 20 μg, 30 μg of protein per 1 ML of the extract.</li> <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> </ul>
Contraindications of Test Results	For an accurate semi-quantitative result, wait the full 5 minutes.  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.
Documentation	Record test results on log sheet located at www.hmark.com
Special Warnings and Cautions	<ul> <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 proof of remaining protein residue in the tested area</li> </ul>
Disposal	• In case of a positive test result, the device should be reprocessed.  Since it is possible that organic soil is present, it is recommended to dispose all components of the ProChek <sup>TM</sup> -W test kit in a biohazard container.

Reprocessing Instructions		
Point of Use		
<b>Preparation for Decontamination</b>		
<b>Disassembly Instructions</b>		
Cleaning – Manual		
Cleaning - Automated		
Disinfection		

Drying	
Maintenance, Inspection, and	
Testing	
Reassembly Instructions	
Packaging	
Sterilization	
Storage	
Additional Information	<ul> <li>Lot control test results (Statement of Conformance) are available from Healthmark upon request.</li> <li>Quality of Water for Testing: 1. It is recommended to use pre-packaged sterile water, such as sterile water for irrigation. 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> </ul>
Related Healthmark Products	EndoCheck <sup>TM</sup> , ProChek <sup>TM</sup> , HemoCheck <sup>TM</sup> , ChannelCheck <sup>TM</sup>
Other Product Support Documents	ProFormance™ Brochure, ProFormance™ Price List
Reference Documents	
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc.
	33671 Doreka
	Fraser, MI 48026
	1-586-774-7600
	healthmark@hmark.com
	hmark.com

2019-06-01 Suzanne Latta

Rev. B