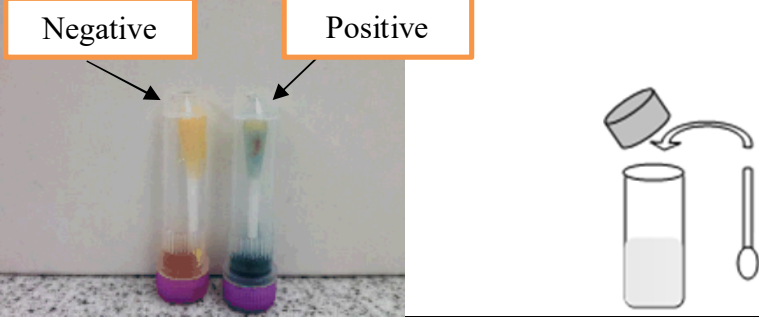



Brand Name of Product	ProChek®-II
Generic Name of Product	Protein Test
Product Code Number(s)	PT-313, PT-201-12
Intended Use	To test for residual protein remaining on surfaces after cleaning and prior to further processing.
Range of Applications for Product	Any items potentially contaminated with protein soils during clinical use.
Key Specifications of Product	<ul style="list-style-type: none"> Measuring Range: The test kit can detect down to 1 µg of insoluble protein by showing a blue-green spot. PT-313 – (HC-SWAB) swabs that come with product are approximately 5.286 mm in diameter at the widest point. PT-201-12 – No swab included. Will need to supply your own swab.

Shipping & Storage	
Shipping Conditions & Requirements	<ul style="list-style-type: none"> Store ProChek®-II in closed packaging in a cool place 2- to 25 °C (35.6- to 77 °F). Keep away from light and heat. Do not allow to freeze.
Storage Conditions	
Packaging Contents	Each test kit consists of: <ul style="list-style-type: none"> Vial with indicator solution Non-premoistened swabs (for PT-313) 3 mL water vials Vial holder.
Shelf Life	Eighteen (18) months from date of manufacture. (NOTE: See package for expiration date.)

Instructions for Using Product	
Description of Use(s)	To test for residual protein remaining on items potentially soiled with protein residue during clinical use.
Preparation for Use	<ol style="list-style-type: none"> Open the protective pouch of the ProChek®-II test kit. Included are: <ol style="list-style-type: none"> Indicator vial (purple cap). Collection swab. (NOTE: Keep test away from sunlight.) Gloves should be worn throughout the test procedure to avoid contamination of the test.
Diagrams (drawings, pictures)	
Steps for Use of Product	<ol style="list-style-type: none"> Open the test kit. Moisten the swab with the 3 mL water vial provided. Open the indicator vial and place the vial into the holder provided. Swab the target area of the item for testing. Place the swab in the reagent vial. Recap the vial and shake at least five (5) times. Check the swab and liquid over a period of 300 seconds (5 minutes) for a color change to blue green. <ol style="list-style-type: none"> Indicative of protein residue on the tested item. Inverting the vial will improve observation of color change on the swab.

Interpretation of Test Results	<ul style="list-style-type: none"> • In the case of soluble proteins, there will be an immediate color change. • In the case of denatured proteins (often the case with items subjected to reprocessing), color change can take up to 5 minutes. • In the presence of large amounts of soluble protein, the whole indicator solution will change blue green.
Contraindications of Test Results	<ul style="list-style-type: none"> • Contact with alkaline substances can trigger color change. • Quaternary ammonium salts may give a false-positive result. • Contact by bare hands can transfer protein particles onto the swab and may give a false positive result.
Documentation	Record test results on log sheet located on hmark.com
Special Warnings and Cautions	<ul style="list-style-type: none"> • Evaluate the result immediately after 300 seconds (5 minutes) — <i>late color changes are not valid.</i> • If a positive result (blue green) is indicated, report that result immediately. • A positive result is indicative of remaining protein residue in the tested area. • ProChek®-II does not ensure an item is safe for use or free of contamination. • ProChek®-II is intended to be part of a comprehensive quality process implemented by the healthcare facility.
Disposal	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.

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	N/A
Cleaning – Automated	N/A
Disinfection	N/A
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	N/A
Storage	N/A
Additional Information	N/A
Related Healthmark Products	Swab Sampling Kits
Other Product Support Documents	N/A
Reference Documents	N/A
Customer Service Contact	Healthmark, A Getinge company 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com