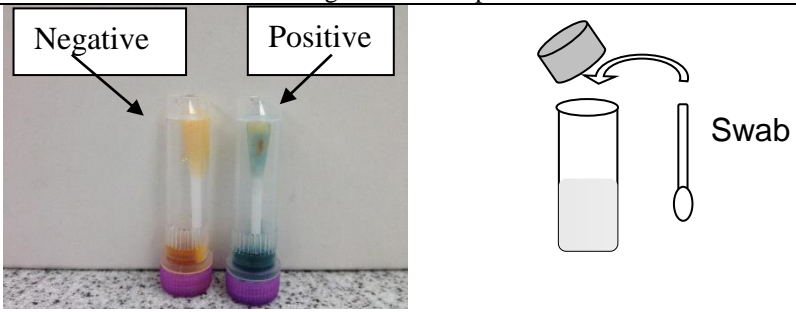


Brand Name of Product	ProChek-II™
Generic Name of Product	Test for residual protein on surgical instruments and other medical devices, prior to any sterilization/disinfection process.
Product Code Number(s)	PT-202
Intended Use	To test for protein residue on a surgical instrument and other medical devices
Range of Applications for Product	Any medical device likely to be 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-202 – (3651) swabs that come with product are approximately 5.286mm in diameter at the widest point.

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	Store ProChek-II™ in closed packaging in a cool place 2°C- 25°C. Keep away from light and heat and do not allow to freeze
Packaging Conditions	<ul style="list-style-type: none"> • 15 single use tests. • Each test kit consists of: <ul style="list-style-type: none"> - vial with indicator solution - protein-free swab
Shelf Life	18 months from date of manufacturer. See package for expiration date.

Instructions for Using Product	
Description of Use (s)	To test for residual protein remaining on a surgical instrument or other medical devices likely to be soiled with protein residue during clinical use.
Preparation for Use	<ol style="list-style-type: none"> 1. In case of refrigerated storage condition, let the test warm up to room temperature before use. 2. Open the protective pouch of the ProChek-II™ test kit. Included are: indicator vial (purple cap); collection swab; and scissors. Keep test away from sunlight. 3. Gloves must 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"> 1. Open the test kit. Included are: indicator vial and protein-free swab. (If swab is not pre-moistened, then moisten with sterile water. 2. Testing is to be done prior to any sterilization/disinfection process. 3. Open the indicator vial, place the vial into the holder provided. 4. Swab the suspect stain, or target area of the device for testing (i.e., box locks). 5. Cut the swab end off with a scissors directly into the vial. Do not touch the swab. 6. Recap the vial and shake at least five times. 7. Check the swab and liquid over a period of 300 seconds (5 minutes) for a color change to blue-green, which will indicate protein residues on the tested device. <ol style="list-style-type: none"> a. Inverting the vial will improve observation of color change on the swab.
Interpretation of Results	<ol style="list-style-type: none"> 1. In case of soluble proteins, there will be an immediate color change. 2. In the case of denatured proteins (often the case with instruments subjected to reprocessing) color change can take up to 5 minutes. 3. 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 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. • Contact to 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) — late color changes are not valid. • If a positive result (blue-green) report that result immediately. • A positive result is proof of remaining protein residue in the tested area only and the device should be reprocessed.
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:	
Preparation for decontamination:	
Disassembly Instructions:	
Cleaning – Manual:	
Cleaning – Automated:	
Disinfection:	
Drying:	
Maintenance, inspection, and testing:	
Reassembly Instructions:	
Packaging:	
Sterilization:	
Storage:	
Additional Information:	

Related Healthmark Products	Swab-110-12, Swab-200-12, Swab-270-12, Swab-350-12, Swab-470-12, EndoCheck™ for Protein Detection, Hemocheck™
Other Product Support Documents	Performance Brochure, Performance Price List, ProChek-II™ Specification Sheet, Endocheck™ Sample Policy, Endocheck™-Protein Specification Sheet, Instructions for Residual Soil Tests, Results Log sheet, Validation Study of ProChek-II™ and Endocheck™
Reference Documents	
Customer Service contact:	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2017-12-21 Ralph J Basile