



Instructions for Use: ChannelCheck™

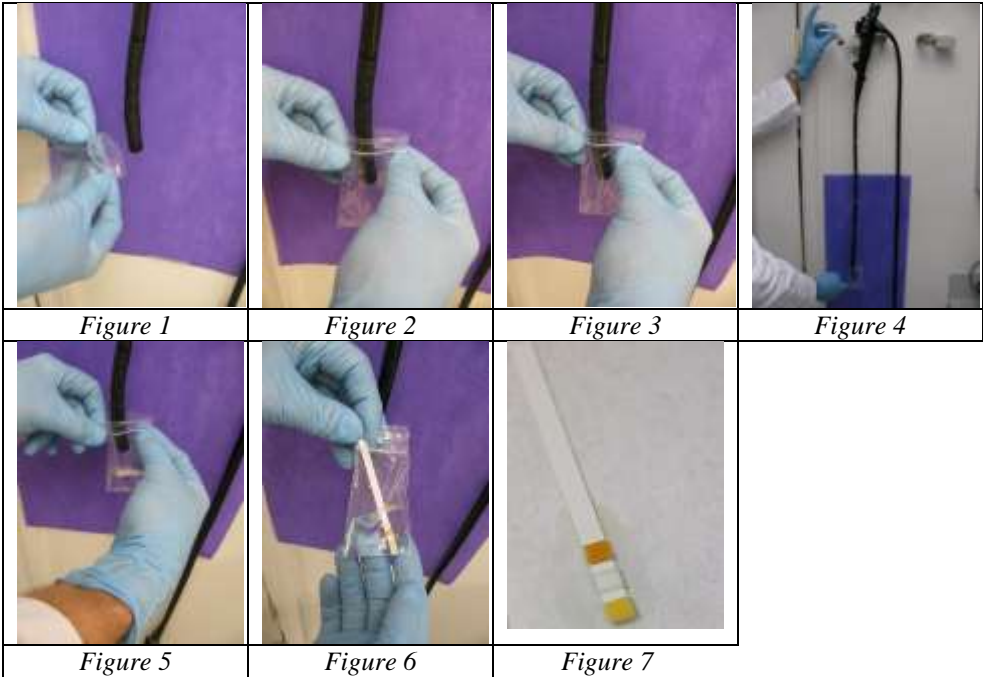
Brand Name of Product	ChannelCheck™
Generic Name of Product	3-in-1 Residual Soil Test for Internal Channels
Product Code Number(s)	UCC-222
Range of Applications for Product	Any internal channel encountering protein, hemoglobin and/or carbohydrate during clinical use.
Key Specifications of Product	Sensitivity of Reagent Pads: <ul style="list-style-type: none"> • Carbohydrate ≥ 25 µg/mL • Protein ≥ 30 µg/mL • Hemoglobin ≥ 0.25 µg/mL

Shipping & Storage	
Shipping Conditions & Requirements	Avoid direct sunlight.
Storage Conditions	<ul style="list-style-type: none"> • Bottles should be tightly capped. • Keep in a cool, dry place out of direct sunlight.
Packaging Contents	<ol style="list-style-type: none"> 1. 2 Bottles of 50 (each) Test Strips 2. 2 Control Tests 3. 2 Interpretation Guides 4. 100 Zipper Bags
Shelf Life	<ul style="list-style-type: none"> • The expiration date for the test strips is two years, if unopened, from the date of manufacturer) • The expiration date for the control soil is 18 months from the date of manufacturing date. Do not use if either date is expired. • Once opened (e.g., the seal is broken), the test strips are best used within 90 days. <ul style="list-style-type: none"> ○ After 90 days, the pads may change color before use, indicating a false positive. ○ IF THE PADS CHANGED COLOR, THEY SHOULD NOT BE USED. ○ If the color on the pads remains unchanged the test strips can still be used. • The expiration date printed on the side of the box will match the expiration date with the item that expires first within the kit. Note: Once opened, the 90 days of use should still be prior to the expiration date.

Instructions for Using Product	
Preparation for Use	<p>Testing is conducted after cleaning and prior to disinfection/sterilization. Use 10 mL of commercially available pre-packaged chlorine-free water.</p> <p>Control Test: The first step when opening a new bottle of ChannelCheck™ residual soil test strips is to check the performance of the lot with the included vial of control soil. This is to be done once per bottle and 2 control vials (1 per bottle) are included. To test, remove the vial of dehydrated test soil from the box. The test vial holds enough lyophilized test soil to create a single milliliter of test soil.</p> <ol style="list-style-type: none"> 1. Rehydrate Soil: To rehydrate, unscrew the cap from the vial, then add exactly 1 mL of pre-packaged chlorine-free water to the vial. Screw the cap back on the vial ensuring a tight seal. 2. Shake Vigorously: Shake the vial vigorously for at least 1-minute. Check the vial to make sure the soil has been completely rehydrated. 3. Retrieve a Single Test Strip: Retrieve a single ChannelCheck™ test strip from the pack. 4. Dip Test Strip into Vial: Dip the test into the vial for 5 seconds making sure to completely immerse all 3 test pads into the solution.

5. **Dab Side of Test Strip on Absorbent Pad:** After 5 seconds, remove the test strip and dab the side of the moistened test pad on a clean, dry absorbent pad to wick off excess water.
6. **Wait 5 Minutes:** The reagents in the test pads require time to interact with the residual soil. Wait a complete 5 minutes before reading the results.
7. **Compare Results to Control Color Chart:** After 5 minutes, compare the results to the Control Result Color Chart. The colors of each test pad should closely approximate the colors on the Control Color Chart found on the Interpretation Guide.
8. **Record Results:** On a log sheet, record the results of each pad.

Diagrams (drawings, pictures)



Steps for Use of Product

1. **Fill Syringe with Water:** Using at least a 10 mL syringe, fill with 10 mL of commercially available pre-packaged chlorine-free water.
2. **Flush the Water Through Channel:** Flush the channel(s) of the instrument with 10 mL of pre-packaged chlorine-free water, followed by flushing the channel with 10 mL of air. (If using pre-filled syringe with water, simply remove the cap and place the slip tip at the channel to be tested and use the plunger-rod to deliver the water to sample the channel. Refill with air to finish the sampling procedure.) **(Fig 4)**
3. **Recapture Water in the Zipper Bag:** Recapture the water in a clean container, such as the supplied zipper bag (see “Zipper Bag Sample Collection” instructions below in the **Additional Information** section). **(Fig 5)**
4. **Dip Test Strip into Water:** Dip the test strip into the recaptured water ensuring all 3 pads are completely immersed. Keep test strip immersed for 5 seconds. **(Fig 6)**
5. **Dab Side of Test Strip:** Remove test strip from the water. Dab the side of the test strip on a clean, absorbent surface to wick away excess water.
6. **Wait 90 Seconds:** The reagents in the test pads require time to interact with the residual soil. Wait a complete 90 seconds before reading the results. **(Fig 7)**

Interpretation of Results

1. **Compare to Color Chart:** Compare test strip to the No Residue Color Chart found on the Interpretation Guide to interpret results.
2. **Interpret Results:** If the color on any pad deviates from the No Residue Color Chart, this indicates a dirty instrument. It should be re-cleaned and re-tested until test results match the No Residue Color Chart.

Contraindications of Test Results

- Residual peracetic acid-based disinfectants may interfere with the carbohydrate and hemoglobin pads of the ChannelCheck™.
- Oxidizing agent, such as chlorine or hypochlorite, may give a color change on the hemoglobin pad. In this case, the test cannot be used to detect hemoglobin residues.

	<ul style="list-style-type: none"> Excess residual Intercept® (brand of Cantel Medical) detergent can cause color change (false positive for protein) on the protein pad. Rinsing is advised to remove any excess detergent prior to testing with ChannelCheck™. Sterile water with adhered foil lids should not be used because of the possibility of a positive reaction with the carbohydrate pad.
Documentation	Record Results: On a log sheet, record the results of each pad.
Special Warnings and Cautions	<ul style="list-style-type: none"> Perform rinsing after manual cleaning to remove residual contaminants and detergent prior to performing the ChannelCheck™. Use the color chart that comes with the ChannelCheck™ that is included in this package. ChannelCheck™ does not ensure that an item is safe for use or free of contamination. It is to be a one-step quality process implemented by the healthcare facility to verify the cleaning process. Do not swirl the strip when dipping the water. Swirling can cause color to run off the pad and change the results. It is important: that the test strips are protected from ambient moisture, light and heat to protect against altered reagent activity and deterioration. It is possible some of the reagent in any one of the pads may be released when immersed in water, slightly coloring the water. This is normal and will not adversely affect the performance of the test.
Disposal	It is recommended to dispose the used test strips in a suitable 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	<p>Quality of Water for Testing:</p> <ol style="list-style-type: none"> It is recommended to use pre-packaged chlorine-free water. Care should be taken not to contaminate the water after opening to avoid creating the opportunity for false positive test results. Be sure to recap the bottle after each use. Sterile water with adhered foil lids should not be used because of the potential for a possible reaction with the carbohydrate pad. <p>Zipper Bag Sample Collection:</p> <ol style="list-style-type: none"> Open the plastic bag by gently pushing from the side of the bag (Fig 1). This will help create a wide enough opening, so the clean plastic bag can be placed over the distal tip of the item. Push the distal tip halfway down into the clean plastic bag. (Fig 2) <ol style="list-style-type: none"> Once the tip is halfway into the clean plastic bag, seal the bag by pushing the sides together. Close the seal about three-quarters of the way (up to the distal tip), then stop. This will provide enough of a seal to capture the sample without the bag falling off during the sampling process. (Fig 3) Follow the instructions in “Steps for Use of Product”.

Related Healthmark Products	ATS-2015
Other Product Support Documents	Cleaning Verification Brochure, Cleaning Verification Price List, ChannelCheck™ Specification Sheet, ChannelCheck™ Bottle Label, ChannelCheck™ Packaging Insert,

	ChannelCheck™ Validation Study, Instructions for Residual Soil Tests, Sample Policy with competency for ChannelCheck™, MSDS ChannelCheck™ UCC-222.
Reference Documents	<ul style="list-style-type: none"> ● ALFA MJ, DEGAGNE P, AND OLSON N. WORST-CASE SOILING LEVELS FOR PATIENT-USED FLEXIBLE ENDOSCOPES BEFORE AND AFTER CLEANING. AM J INFECT CONTROL, 27:392–401, 1999. ● ALFA MJ, DEGAGNE P, AND OLSON N. VALIDATION OF ATS AS AN APPROPRIATE TEST SOIL. ZENTR STERIL, 13(6):387–402, 2005. ● ALFA MJ, OLSON N, DEGAGNE P, AND JACKSON M. A SURVEY OF REPROCESSING METHODS, RESIDUAL VIABLE BIOBURDEN AND SOIL LEVELS IN PATIENT-READY ENDO-SCOPIC RETROGRADE CHOLIANGIOPANCREATOGRAPHY DUODENOSCOPES USED IN CANADIAN CENTERS. INFECT CONTROL HOSP EPIDEMIOL, 23:198–206, 2002.
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com

2021-06-08 Ralph J Basile