

Brand Name of Product	ChannelCheck™ Convenience Pack
Generic Name of Product	3-in-1 Residual Soil Test Kit
Product Code Number(s)	UCC-222TS, ATS-2-CTP
Intended Use	To check lumened items for residual protein, blood, and carbohydrates.
Range of Applications for Product	Lumen items that come in contact with protein, blood, or carbohydrate during clinical use.
Key Specifications of Product	Sensitivity of Reagent Pads: <ul style="list-style-type: none"> ● Carbohydrate $\geq 25 \mu\text{g/mL}$ ● Protein $\geq 30 \mu\text{g/mL}$ ● Hemoglobin $\geq 0.25 (1/4) \mu\text{g/mL}$

Shipping & Storage	
Shipping Conditions & Requirements	Avoid direct sunlight.
Storage Conditions	<ul style="list-style-type: none"> ● Box should be kept closed. ● Keep in a cool dry place out of direct sunlight.
Packaging Contents	<ol style="list-style-type: none"> 1. 100 HPC-222-P Test Strips (individually packaged) 2. One (1) ATS-2-CTP (Control Test Pack) 3. 100 Zipper Bags (2- x 3 inches) for collection 4. One (1) Interpretation Guide 5. One (1) IFU
Shelf Life	Convenience Pack has a shelf life of 12 months.

Instructions for Using Product	
Description of Use(s)	N/A
Preparation for Use	<p>Testing is conducted after cleaning and prior to disinfection/sterilization.</p> <ul style="list-style-type: none"> ● Control Test: The first step, when opening a new, individually packaged residual soil test strip, is to check the performance of the lot with the included vial of control soil—ensuring the reagent in each of the test pads has remained active after shipment. <ul style="list-style-type: none"> ● Control test is only done with <ul style="list-style-type: none"> ○ one (1) individually packaged test strip. ○ one (1) ATS control vial (included in the Convenience Pack). ● To test, remove the vial of dehydrated test soil from the package. (NOTE: The test vial holds enough lyophilized test soil to create a single milliliter of test soil.) <ol style="list-style-type: none"> 1. Rehydrate Soil: To rehydrate, unscrew the cap from the vial. Add exactly one (1) mL of water to the vial. 2. Shake Vigorously: Shake the vial vigorously for at least one-minute. 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 five (5) seconds, making sure to completely immerse all three (3) test pads into the solution. 5. Dab Side of Test Strip on Absorbent Pad: After five (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 five (5) Minutes: The reagents in the test pads require time to interact with the residual soil. Wait a complete five (5) minutes before reading the results. 7. Compare Results to Control Color Chart: After five (5) minutes, compare the results to the Control Result Color Chart. (NOTE: The colors of each test pad should closely approximate the colors found 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)



Figure 1



Figure 2

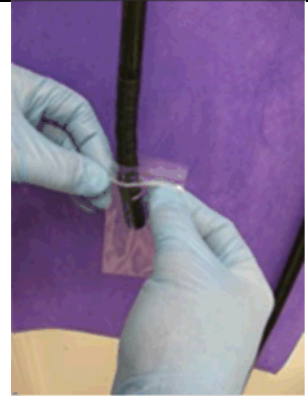


Figure 3



Figure 4



Figure 5



Figure 6



Figure 7

Steps for Use of Product

1. **Flush the Water Through Channel:** Performed by flushing the channel(s) with 10 mL of water.
 - a. Place the slip tip at the channel to be tested and use the plunger rod syringe to deliver the water to sample the channel.
 - b. Refill the syringe with air and flush with 10 mL of air to facilitate flushing (Fig. 4).
2. **Recapture Water in the Zipper Bag:** Recapture the water in a clean zipper bag (see *Zipper Bag Sample Collection* instructions below in the *Additional Information* section). (Fig. 5 above).
3. **Dip Test Strip into Water:** Dip the test strip into the recaptured water ensuring all three (3) pads are completely immersed. Keep test strip immersed for five (5) seconds, then remove it from the water. (Fig. 6).
4. **Dab Side of Test Strip:** Dab the side of the test strip on a clean, absorbent surface to wick off excess water.
5. **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 Test Results

1. **Compare to Color Chart:** Compare test strip to the “No residues” color chart found on the Interpretation Guide to interpret results.

	2. Interpret Results: If the colors on any pad deviate from the “No Residue” Color Chart, this indicates a dirty instrument, and it should be recleaned and retested until test results match the “No Residues” Color Chart.
Contraindications of Test Results	<ul style="list-style-type: none"> Residual peracetic acid-based disinfectants may interfere with the carbohydrate and blood pads of the ChannelCheck™. Oxidizing agents (e.g., chlorine or hypochlorite) may produce a color change on the hemoglobin pad. (NOTE: These residues should <i>not</i> remain on an item that has been properly rinsed). Excess residual Intercept® (brand of Cantel Medical) detergent can cause a color change (false-positive for protein) on the protein pad. (NOTE: Adequate rinsing to remove any excess detergent prior to testing with ChannelCheck™). Sterile water with adhered foil lids should not be used because of the potential reaction with the carbohydrate pad. Sani-Cloth and CaviWipes™ may cause color change in the protein pad.
Documentation	Record results of each pad on a log sheet.
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™. ChannelCheck™ does not ensure an item is safe for use or free of contamination. It is to be one step in a total quality process implemented by the healthcare facility to verify the cleaning process. Do not swirl the strip when dipping in the water. Swirling can cause color to run off the pad and change their results. IMPORTANT: Protect the test strips from ambient moisture, light, and heat to guard against altered reagent activity and deterioration. It is possible some of the reagents 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 of the used test strip 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>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), creating a wide enough opening for the clean plastic bag to be placed over the distal tip of the scope. Push the distal tip halfway down into the clean plastic bag. (Fig. 2) Once the tip is halfway into the clean plastic bag: <ol style="list-style-type: none"> Seal the bag by pushing the sides together. Close the seal about three-quarters (3/4) of the way (up to the distal tip) and 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 steps in <i>Steps for Use of Product</i>.
Related Healthmark Products	ATS2015
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 Test, Example 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 CHOLANGIOPANCREATOGRAPHY DUODENOSCOPES USED IN CANADIAN CENTERS. INFECT CONTROL HOSP EPIDEMIOL, 23:198–206, 2002
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