








Instructions for Use: ChannelCheck™ Convenience Pack

Brand Name of Product	ChannelCheck™ Convenience Pack
Generic Name of Product	3-in-1 Residual Soil Test Kit
Product Code Number(s)	UCC-101CP
Intended Use	To check lumened devices for residual protein, blood and carbohydrates.
Range of Applications for Product	Any lumened device that comes in contact with protein, blood and/or carbohydrate during clinical use.
Key Specifications of Product	Sensitivity of Reagent Pads: <ul style="list-style-type: none"> • Carbohydrate ≥ 210 ug/ml • Protein ≥ 120 ug/ml • Hemoglobin ≥ 0.25 ug/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 Conditions	<ol style="list-style-type: none"> 1. 50 UCC-101 Test Strips (individually packaged) 2. 1 ATS Control 3. 50 Ziplock Bags for collection 4. 50 Pre-filled 10 ml Water Syringes 5. 1 UCC Color Chart 6. 1 IFU
Shelf Life	Convenience Pack has a shelf life of 18 months.

Instructions for Using Product	
Description of Use (s)	
Preparation for Use	<ul style="list-style-type: none"> • Testing is typically conducted after cleaning and prior to disinfection/sterilization. • 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. This will ensure that the reagent in each of the test pads has remained active after shipment. This is only done with one of the individually packaged test strips and 1 ATS control vial that is included in the Convenience Pack. To test, remove the vial of dehydrated test soil from the package. 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, then add exactly 1 ml of water to the vial. Screw the cap back on the vial ensuring you have a tight seal. 2. Shake Vigorously: Shake the vial vigorously for at least one minute. Check the vial to make sure the soil has been completely re-hydrated. 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, making sure to completely immerse all three test pads into the solution. 5. Swish Test Strip: Swish the test strip in the vial for 10 seconds. 6. Dab Side of Test Strip on Absorbent Pad: After 10 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. 7. Wait 5 Minutes: The reagents in the test pads require time to interact with the residual soil, so wait a complete 5 minutes before reading the results. 8. 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 found on the Control Color Chart. 9. Record Results: On a log sheet, record the results of each pad.

<p>Diagrams (drawings, pictures)</p>	<p style="text-align: center;">ChannelCheck™ Convenience Pack</p>   <p style="text-align: center;">Figure 1</p>  <p style="text-align: center;">Figure 2</p>  <p style="text-align: center;">Figure 3</p>  <p style="text-align: center;">Figure 4</p>  <p style="text-align: center;">Figure 5</p>  <p style="text-align: center;">Figure 6</p>
<p>Steps for Use of Product</p>	<ol style="list-style-type: none"> 1. Uncap Pre-filled 10 ml Water Syringe. 2. Flush the Water Through Channel: This is done by flushing the channel(s) of the instrument with the 10 ml pre-filled syringe of water followed by the 10 ml of air to facilitate flushing. 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. 3. Recapture Water in the ziplock Bag: Recapture the water in a clean ziplock bag (see ziplock bag collection instructions below in the Additional Information section). 4. Dip Test Strip into Water and Swish: Dip the test strip into the recaptured water, ensuring that all three pads are completely immersed. Swish the test strip for 10 seconds. 5. Dab Side of Test Strip: Then remove it 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, so wait a complete 90 seconds before reading the results.
<p>Interpretation of Results</p>	<ol style="list-style-type: none"> 1. Compare to Color Chart: Compare test strip to the “No Residues” color chart to interpret results. 2. Interpret Results: If the colors on any pad deviate from the “No Residues”, this indicates a dirty instrument and it should be re-cleaned and re-tested until test results match the “No Residues” pads.
<p>Contraindications of Test Results</p>	<p>Oxidizing agents like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a color change on the blood pad. These residues, however, should not remain after a properly rinsed device.</p>
<p>Documentation</p>	<p>Record Results: On a log sheet, record the results of each pad.</p>
<p>Special Warnings and Cautions</p>	<ul style="list-style-type: none"> ● It is IMPORTANT that the test strips be protected from ambient moisture, light and heat to guard against altered reagent activity and deterioration.

	<ul style="list-style-type: none"> 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	A positive test result indicated that residual organic soil remains and also is on the surface of the test strip. It is recommended to dispose of the used test strip in a suitable 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	<p>Ziplock Bag Sample Collection:</p> <ol style="list-style-type: none"> Open the plastic bag by gently pushing from the side of the bag. (Figure 1) (This will help create a wide enough opening, so the clean plastic bag can be placed over the distal tip of the scope.) Push the distal tip halfway down into the clean plastic bag. (Figure 2) Once the tip is halfway into the clean plastic bag, seal the bag by pushing the sides together. Close the seal about $\frac{3}{4}$ 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. (Figure 3) Once the clean plastic bag is secure, begin to flush the channel according to Steps for Use of Product above. (Figure 4) After you have recaptured the sample in the clean plastic bag, gently pull the clean plastic bag off the distal tip. (Figure 5) Dip the test strip into the recaptured sample (water). Make sure that all three pads are completely immersed. Swish the test strip for ten seconds inside the clean plastic bag. (Figure 6)
Related Healthmark Products	ATS
Other Product Support Documents	ProFormance™ Brochure, ProFormance™ 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-101
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.
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