

Instructions for Use: ChannelCheck™

Brand Name of Product	ChannelCheck™
Generic Name of Product	3 – in – 1 residual soil test for lumened devices
Product Code Number(s)	UCC-101, UCC-101CP
Range of Applications for Product	Any lumened device coming into contact with protein, blood and/or carbohydrate during clinical use.
Key Specifications of Product	<ul style="list-style-type: none"> ○ Sensitivity of Reagent Pads <ul style="list-style-type: none"> ▪ Carbohydrate \geq 210 ug/ml ▪ Protein \geq 120 ug/ml ▪ Hemoglobin \geq 0.25 ug/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 Conditions	<ul style="list-style-type: none"> ● 2 bottles of 50 each test strips ● 2 control tests
Shelf Life	<ul style="list-style-type: none"> ● Note the expiration date on the bottle, which is for the test strips (2 years unopened) and the expiration date on the packaging for the control soil (18 months from the manufacturing date). Do not use if either date is expired. ● The test-strips are best used by 90 days, once opened and the seal on the test-strip bottle has been broken. After 90 days, the pads MAY change color, before use, indicating a false-positive. IF THE PADS CHANGE 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 box is the storage life of the test-strips; use the earlier date of the control and the strips for the expiration date. Please note that once opened, the 90 days of use should still be prior to the EXPIRATION DATE. ● Optional pre-filled syringes have a 2year shelf life from date of manufacture.

Instructions for Using Product	
Preparation for Use	<ul style="list-style-type: none"> ● Testing is typically conducted after cleaning prior to disinfection/sterilization. ● New, 10cc or larger syringe. Slip-tip style syringe is preferred. (Healthmark offers pre-filled syringes with 10ml sterile water sold separately). The Convenience Pack will contain 50 prefilled 10ml sterile water syringes. ● 10cc or more of commercially available pre-packaged sterile water. (i.e., sterile water for irrigation). ● 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 will insure that the reagent in each of the test pads has remained active after shipment. This is only done once per bottle and only 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. <ol style="list-style-type: none"> 1. Re-hydrate Soil: To re-hydrate, unscrew the cap from the vial, then add exactly 1ml of water to the vial. Screw the cap back on the vial, being sure 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.

	<ol style="list-style-type: none"> 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. 																
Diagrams (drawings, pictures)	<table border="1" style="width: 100%; text-align: center;"> <tr> <td data-bbox="565 317 808 621"></td> <td data-bbox="808 317 1052 621"></td> <td data-bbox="1052 317 1295 621"></td> <td data-bbox="1295 317 1539 621"></td> </tr> <tr> <td data-bbox="565 621 808 653"><i>Figure 1</i></td> <td data-bbox="808 621 1052 653"><i>Figure 2</i></td> <td data-bbox="1052 621 1295 653"><i>Figure 3</i></td> <td data-bbox="1295 621 1539 653"><i>Figure 4</i></td> </tr> <tr> <td data-bbox="565 653 808 957"></td> <td data-bbox="808 653 1052 957"></td> <td data-bbox="1052 653 1295 957"></td> <td data-bbox="1295 653 1539 957"></td> </tr> <tr> <td data-bbox="565 957 808 989"><i>Figure 5</i></td> <td data-bbox="808 957 1052 989"><i>Figure 6</i></td> <td data-bbox="1052 957 1295 989"></td> <td data-bbox="1295 957 1539 989"></td> </tr> </table>					<i>Figure 1</i>	<i>Figure 2</i>	<i>Figure 3</i>	<i>Figure 4</i>					<i>Figure 5</i>	<i>Figure 6</i>		
																	
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Steps for Use of Product	<ol style="list-style-type: none"> 1. Fill Syringe with Water: Using at least a 10ml syringe, fill with 10ml of commercially available pre-packaged sterile water (i.e., sterile water for irrigation). 2. Flush the Water Through Channel: This is done by flushing the channel(s) of the instrument with 10mL of water. This is then followed by flushing the channel with 10ml of air. (If using pre-filled syringe with sterile 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) 3. Recapture Water in the Zip-Lock Bag: Recapture the water in a clean, container, such as the supplied zip-lock bag (see zip-lock 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, being sure 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. 																
Interpretation of Results	<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: Should the color 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 Residue” pads. 																
Contraindications of Test Results	<p>Oxidizing agent like chlorine or hypochlorite (present in some disinfecting agents and detergents) will give a color change on the blood pad. In this case the test cannot be used to detect blood residues.</p>																
Documentation	<p>Record Results: On a log sheet, record the results of each pad.</p>																
Special Warnings and Cautions	<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 reagent in anyone 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 indicates 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>Quality of Water for Testing;</p> <ol style="list-style-type: none"> It is recommended to use prepackaged sterile water, such as sterile water for irrigation. For effective testing, it is not necessary that the water remain sterile, but care should be taken not to contaminate after opening to avoid creating the opportunity for false positive test results. Be sure to recap the bottle after each use. <p>Zip-Lock 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 ¾ 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 being 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 Channel Check™ 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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