



**Instructions for Use: Flexible Endoscope Sampling Kit**

<b>Brand Name of Product</b>	Flexible Endoscope Sampling Kit
<b>Generic Name of Product</b>	Endoscope Culture Sample Kit
<b>Product Code Number(s)</b>	CK-250, CK-374
<b>Intended Use</b>	The Flexible Endoscope Sampling Kit provides items to collect a sample and ship to Nelson Labs for further testing for presence of microorganisms. If present, the organisms will be quantified and 2 organisms will be identified. Additional identifications, if need/desired, can be conducted for additional purchase. This test does not assure the suitability of the flexible endoscope for patient-use.
<b>Range of Applications for Product</b>	For testing of flexible endoscopes.
<b>Key specifications of product</b>	<ol style="list-style-type: none"> <li>1. Sample Collection Container</li> <li>2. Sterile Scissors</li> <li>3. Thermometer</li> <li>4. Shipping Box (shipping label included)</li> <li>5. Ice Packs</li> <li>6. 2 30cc Syringes</li> <li>7. 1 5cc Syringes</li> <li>8. Labels</li> <li>9. Tween</li> <li>10. Filter Disc</li> <li>11. Instrument channel brush (240cm long)</li> <li>12. Distal tip brush</li> <li>13. Alcohol Wipe</li> <li>14. Two 1 ML pipettes</li> </ol>

**Shipping & Storage**

<b>Shipping Conditions &amp; Requirements</b>	<ol style="list-style-type: none"> <li>1. Sample must be shipped same day it is captured.</li> <li>2. The included shipping label is for weekday, next day delivery.</li> <li>3. This sample needs to be taken and shipped Monday - Thursday to Nelson Labs.</li> </ol>
<b>Storage Conditions</b>	Ice packs and thermometer must be frozen until prior to use.
<b>Packaging Conditions</b>	Follow instructions below for proper packaging.
<b>Shelf Life</b>	

**Instructions for Using Product**

<b>Description of Use (s)</b>	Collect a sample and send to Nelson Labs for further testing for presence of microorganisms. If present, up to 2 organisms will be identified and quantified.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. Upon receiving the kit remove the ice packs and temperature monitor.</li> <li>2. Freeze the provided ice packs and temperature monitor a minimum of 8 hours before use. Ensure the ice packs are laid flat.</li> <li>3. When ready to test, enter on the provided label the date, personnel initials, model and serial numbers of the scope.</li> <li>4. Supplies to be provided by the facility include             <ul style="list-style-type: none"> <li>o Disinfecting wipe</li> <li>o 1 sterile pad/drape (large enough to have an endoscope to be placed flat on the pad/drape for testing).</li> <li>o 51cc of sterile water</li> <li>o Appropriate PPE for 2 people</li> <li>o Sterile gloves (6 pair)</li> </ul> </li> <li>5. Prepare test area:             <ul style="list-style-type: none"> <li>o Disinfect the counter with the disinfecting wipe.</li> <li>o Place a sterile pad/drape on counter/surface.</li> <li>o Don PPE in the proper order for endoscope reprocessing (i.e., gown and face shield or mask with eye-protection devices, sterile gloves).</li> </ul> </li> <li>6. Arrange the testing area             <ul style="list-style-type: none"> <li>o Allow enough space for the flexible endoscope that is to be tested to lie flat on the sterile pad/drape</li> </ul> </li> </ol>

- Aseptically open and remove and place on the sterile pad/drape:
  - Scissor
  - 2 pipettes
  - 2 30cc syringes
  - Instrument channel brush (240cm long)
  - Distal tip brush
  - Sample collection container
- Draw up 25cc of sterile water into each 30cc syringe
- 7. 2 people will be needed to do the sampling:
  - The first person is the person who does not handle non-sterile items.
  - The second person is the person who will be picking up the scope to do the various testing on the scope. This person will hold the scope in a manner that will allow them to flush, and brush the scope while holding it during the testing

**Diagrams  
(drawings,  
pictures):**



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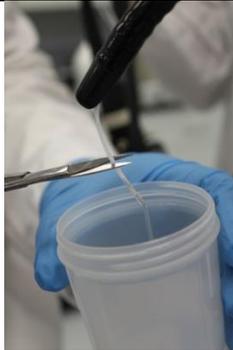
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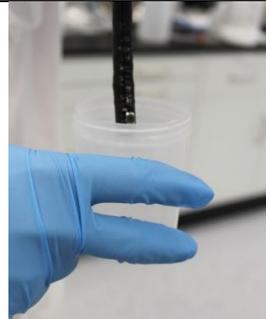
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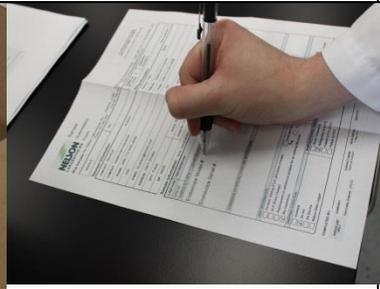
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**Steps for Use of Product**

**Sampling the Instrument Channel**

1. (Second person) Open and present alcohol wipe to the first person in an aseptic manner.
2. (First person) Wipe around the distal tip of the endoscope without contacting the elevator mechanism or any internal areas of the distal end.
3. (Second person) Pick up the scope and then pick up one of the filled sterile syringes needed for flushing
4. (First person) will hold the supplied sample collection container under endoscope to collect the extraction sample.
5. (Second person) Flush 25cc of sterile water through the endoscope instrument channel at the biopsy port using a syringe.
6. (Second person) Draw up 30cc of air.
7. (Second person) Purge the instrument channel with the 30cc of air.
8. (Second person) Pick up the instrument channel brush
9. Feed the brush the full length of the instrument channel.
10. (First person) Holding the sample collection container, cut off the brush part end into the container with the sterile scissors, making sure not to come in contact with the distal tip of the scope.
11. (Second person) Remove the rest of the brush shaft from the endoscope and discard according to facility policy of biohazardous waste.
12. (Second person) Flush the channel with 25cc of sterile water.
13. (Second person) Draw up 30cc of air.
14. (Second person) Purge with the 30cc of air.
15. (First person) Collect the flushed sample water in the sample collection container.
16. Lay scope flat on the sterile pad/drape.

**Collecting Sample from the Distal Tip**

17. (First and second person) Don fresh sterile gloves.
  18. (Second person) Adjusts the position of the elevator lever during this procedure.
  19. (Second person) Place the elevator lever in the 45 degree position.
  20. (First person) Draw up 0.5cc of sterile water into a sterile pipette.
  21. (First person) Hold the sample collection container.
  22. (Second person) Hold the distal tip over the sample collection container.
  23. (First person) Apply the water in and around the elevator lever.
  24. (First person) Draw up the sample water from the distal tip with the same pipette.
  25. (First person) Add sample water to the instrument channel sample water in the sample collection container.
  26. (First person) Moisten the supplied distal tip brush by dipping in sterile water.
  27. (First person) Brush in and around the elevator lever with the elevator in 3 different positions: 1) fully lowered; 2) raised to 45 degrees; 3) fully raised
  28. (First person) Place the entire brush in the sample container.
  29. (Second person) Position the elevator lever at 45 degrees.
  30. (First person) Draw up 0.5cc of sterile water.
  31. Apply the water in and around the elevator lever.
  32. (First person) Draw up the sample water from the distal tip with the same pipette.
  33. (First person) Add sample water to the instrument channel sample water in the sample collection container.
  34. Remove the scope from the area.
- Addition of Tween to Sample Water
35. (First person) Don fresh sterile gloves.
  36. (Second person) Open container of Tween.
  37. (Second person) Present the 5cc syringe in a manner that the first person can withdraw aseptically.
  38. (First person) Extract 5cc syringe from package.
  39. (First person) Draw up 5cc of Tween into the syringe.
  40. (Second person) Present the filter in a manner that the first person can attach the filter to the syringe in an aseptic manner
  41. (First person) Attach the provided filter disc to the luer-lock end of the syringe
  42. (First person) Dispense the solution through the filter into the sample collection container.
  43. (First person) Close the lid of the sample collection container.
  44. (First person) Swirl container for 5 seconds to mix sample solution.

**Package for Shipment**

45. Adhere the label to the sample collection container.
46. Ensure the label is properly filled out.
47. Place the bottle in the provided cubed foam insert.
48. Place one frozen ice pack in the bottom of the shipping box.
49. Place the foam with sample collection container on top of the ice pack.
50. Place the second frozen ice pack on top of the sample collection container.
51. Fill out the sample submission form.
52. Insert the sample submission form into the envelope attached to the top of the insulated foam lid.
53. Activate the thermometer by pressing in the clear button.
54. Adhere the thermometer to the underside of the insulated foam lid.
55. Close the lid of the shipping box with the included packing tape.
56. Immediately take to the shipping department or a Fedex pick-up location for shipment to Nelson Labs for next day delivery (shipping label is already on the shipping box).
57. Follow the endoscope manufacturer's IFU for drying procedures of the flexible endoscope.

<b>n of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation</b>	
<b>Special Warnings and Cautions</b>	<b>This test should be shipped Monday - Thursday OVERNIGHT to Nelson Labs.</b>
<b>Disposal</b>	

<b>Reprocessing Instructions</b>	
<b>Point of use:</b>	
<b>Preparation for decontamination:</b>	
<b>Disassembly Instructions:</b>	
<b>Cleaning – Manual:</b>	
<b>Cleaning – Automated:</b>	
<b>Disinfection:</b>	
<b>Drying:</b>	
<b>Maintenance, inspection, and testing:</b>	
<b>Reassembly Instructions:</b>	
<b>Packaging:</b>	
<b>Sterilization:</b>	
<b>Storage:</b>	
<b>Additional Information:</b>	

<b>Related Healthmark Products</b>	EndoCheck™ for Blood, EndoCheck™ for Protein, ChannelCheck™, FlexiCheck™
<b>Other Product Support Documents</b>	
<b>Reference Documents</b>	ProFormance Brochure, ProFormance Price List
<b>Customer Service contact:</b>	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com

2017-07-03 Ralph J Basile