



**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>	FESK-200-200, FESK-230-400, FESK-230-600, FESK- 230-900
<b>Intended Use</b>	The Flexible Endoscope Sampling Kit provides items to collect a sample from the instrument channel of an endoscope and ship to Nelson Labs for further testing for presence of microorganisms. If present, the organisms will be quantified, and two organisms will be identified. Additional identifications, if needed/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 bacterial surveillance testing of flexible endoscopes that do not have an elevator mechanism.
<b>Key Specifications of Product</b>	<ol style="list-style-type: none"> <li>1. Sample Collection Container</li> <li>2. Scissors</li> <li>3. Temperature Monitor</li> <li>4. Shipping Box (shipping label included)</li> <li>5. 2 Ice Packs</li> <li>6. (2) 30 mL Syringes</li> <li>7. Labels</li> <li>8. Instrument Channel Brush</li> <li>9. Alcohol Wipe</li> <li>10. DNP neutralizing agent</li> <li>11. Absorbent Pad with zipper bag</li> <li>12. 1 Packaging Tape</li> </ol>

<b>Shipping &amp; Storage</b>	
<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>	<ul style="list-style-type: none"> <li>• Ice packs and temperature monitor must be frozen until prior to use.</li> <li>• DNP neutralizing agent store at room temperature at a range of 59 °F-77 °F.</li> </ul>
<b>Packaging Conditions</b>	Follow instructions below for proper packaging.
<b>Shelf Life</b>	Two years from the date of manufacture

<b>Instructions for Using Product</b>	
<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. Additional identifications, if needed/desired, can be conducted for additional purchase.
<b>Preparation for Use</b>	<ol style="list-style-type: none"> <li>1. Upon receiving the kit, remove the ice packs that are around the DNP neutralizing agent.</li> <li>2. Store the DNP neutralizing agent at room temperature.</li> <li>3. Remove temperature monitor from the zipper bag.</li> <li>4. Freeze the <b>ice packs and temperature monitor in a freezer</b> for a minimum of 8 hours before use. Ensure the ice packs are laid flat in the freezer.</li> <li>5. When ready to test, enter on the provided label the date, personnel initials, model, and serial numbers of the scope.</li> <li>6. Supplies to be provided by the facility include: <ul style="list-style-type: none"> <li>○ Disinfecting wipe</li> </ul> </li> </ol>

- 1 sterile pad/drape (large enough to have an endoscope to be placed flat on it for testing).
- 40 mL of sterile water
- Appropriate PPE for 2 people: fluid resistant sterile gown, fluid resistant face and eye protection, sterile gloves, bouffant caps for hair
- A countertop or table long enough to lay the scope out.
- 10x Magnifier


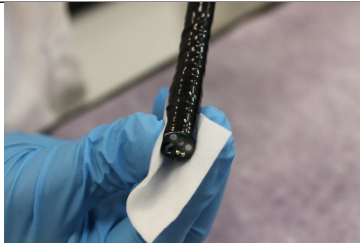

7. Prepare test area:

- Wipe down the counter with the disinfecting wipe (referencing the IFU for the wipe).
- Place a sterile pad/drape on counter/surface.
- Don PPE.

8. Sampling test area:

- Allow enough space for the flexible endoscope that is to be tested to lie flat on the sterile pad/drape.
- Place endoscope flat on the pad/drape.
- Using a 10x magnifier, perform a visual inspection of the distal end for debris or other concerns. If debris is present notify appropriate staff per facility policy.
- Two people (a Sampler and a Facilitator) will be needed to do the sampling:
  - The sampler maintains aseptic handling and conducts brushing steps.
  - The facilitator opens the packages and handles unsampled portions of the endoscope.

**Diagrams  
(drawings,  
pictures)**

		
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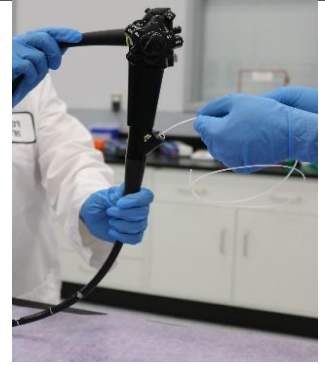
			
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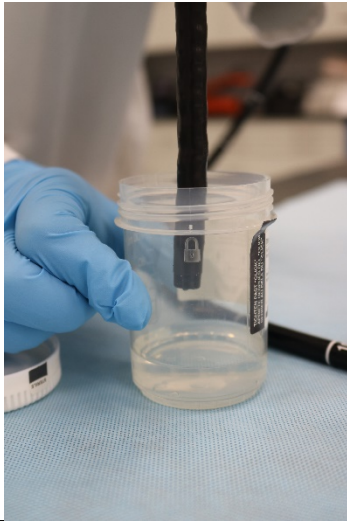
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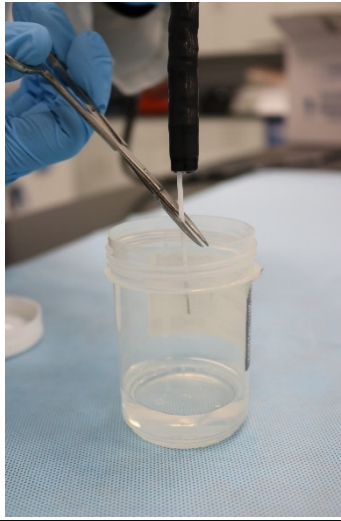
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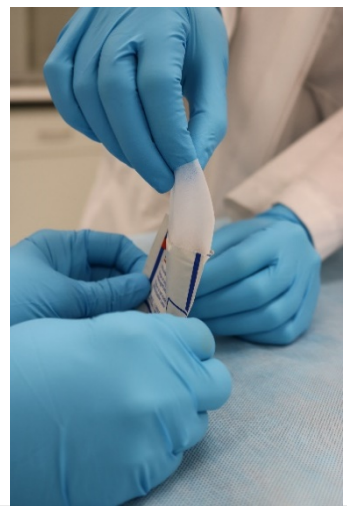
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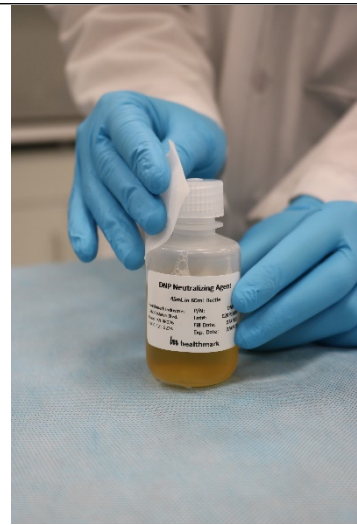
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**Steps for Use of Product**

**Sampling the Instrument Channel**

1. Facilitator open and present alcohol wipe to the Sampler in an aseptic manner.
2. Sampler wipes around the distal tip of the endoscope without contacting any internal areas of the distal end.
3. Facilitator opens the packages for two 30 mL syringes.
4. Sampler removes each syringe from the packaging.
5. Facilitator opens the sterile water bottle.
6. Sampler fills each syringe with 20 mL of water.
7. Sampler hands a syringe to the facilitator and holds the distal end of the endoscope over the sample collection container.
8. Facilitator flushes the instrument channel with 20 mL of sterile water, which the sampler captures in the sample collection container.
9. Facilitator fills the syringe with air and flushes air into the instrument channel. Any residual fluid is captured in the sample collection container.
10. After the air has been flushed into the channel, the sampler may cap the sample collection container and place it on the sterile drape.
11. Facilitator places the endoscope on the sterile drape.
12. Facilitator opens scissors package.
13. Sampler removes the instrument channel brush from the packaging.
14. Facilitator holds the endoscope vertically while the sampler inserts the instrument channel brush into the biopsy port.
15. Once the brush has been inserted about 3 inches, the sampler transfers the brush handle to the facilitator.
16. Sampler holds the collection container and with the distal end of the endoscope placed in the container to capture any fluid that exits the channel with the brush, making sure not to touch the distal end.
17. Facilitator continues to push the brush through the instrument channel.
18. After the brush head exits the distal tip, the sampler uses the scissors to cut the entire head of the bristled portion of the brush while keeping it in the container and places it into the sample collection container.
19. The remainder of the brush should be pulled out of the endoscope from the biopsy port.
20. Repeat the above sampling steps (1-9) for an additional fluid flush to be added to the collection container.

**Addition of neutralizer solution and transport preparation:**

21. Before use of the DNP neutralizing agent, wipe the neutralizer bottle and the lid with an alcohol wipe.

22. Facilitator open and present alcohol wipe to the Sampler in an aseptic manner.
23. Sampler wipes around the DNP neutralizing agent bottle.
24. Sampler wipes around the lid.
25. Add the provided neutralizer (DNP neutralizing agent) to the sample.
  - Do not allow the endoscope to contact the neutralizer solution in the sample container.
  - Accidental immersion of any part of the endoscope distal end into the neutralizer solution necessitates complete reprocessing.
  - DNP neutralizing agent is added to facilitate outgrowth of microbes that have been potentially damaged by the reprocessing process.
26. Tightly close lid of sample container by turning the cap clockwise on the bottle, the cap should click to insure a secure close.

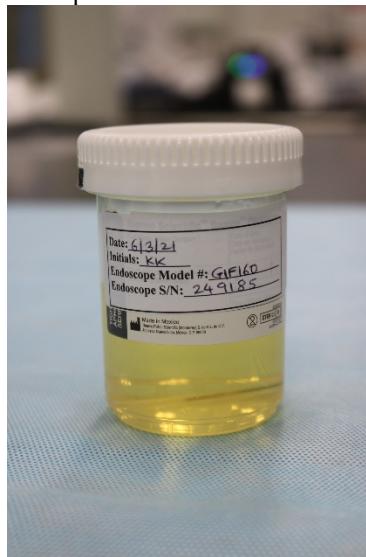
#### **Sampling of additional channels**

Healthcare facilities may also choose to sample additional channels in endoscopes, such as the air/water and suction channels by flushing those channels with sampling fluid (sterile water).

The volume of flush solution will vary depending on the channel dimensions, and endoscope model-specific connectors may be required for flushing different channels.

#### **Package for Shipment**

1. Adhere the label to the sample collection container. **Fig 1**



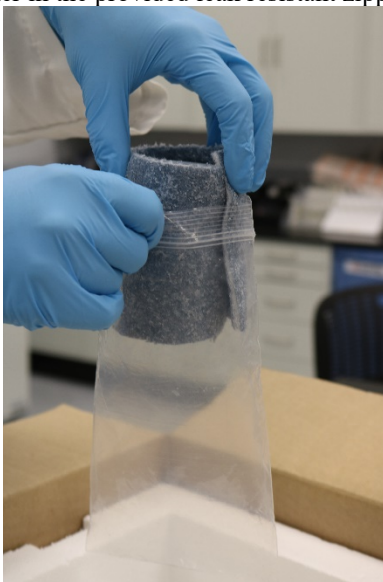
**Fig 1**

2. Ensure the label is properly filled out.
3. Wrap the absorbent material around the sample container. **Fig 2**



**Fig 2**

4. Place the sample container in the provided leak resistant zipper bag. **Fig 3**



**Fig 3**

5. Place the above packaging in the provided cubed foam insert. **Fig 4**



**Fig 4**



6. Place the frozen ice pack in the bottom of the shipping box. **Fig 5**



**Fig 5**

7. Place the foam with sample collection container on top of the ice pack. Press the container down so that the bottom of the container is in contact with the frozen ice pack. **Fig 6**



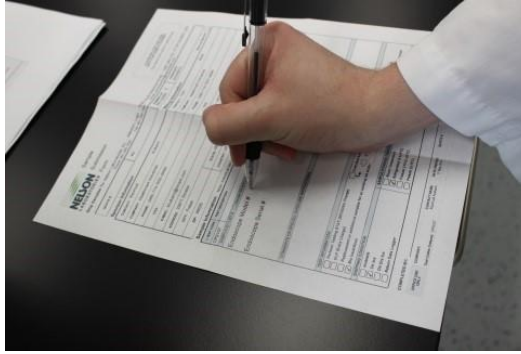
**Fig. 6**

8. Place the other frozen ice pack on top of the sample container. **Fig. 7**



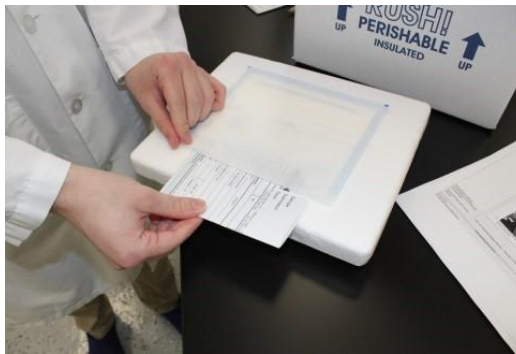
**Fig 7**

9. Fill out the provided sample submission form. **Fig 8**



**Fig 8**

10. Insert the sample submission form into the envelope attached to the top of the insulated foam lid. **Fig 9**



**Fig 9**

11. Activate the temperature monitor by pressing in the clear button. **Fig 10**



**Fig 10**

12. Adhere the instrument to the underside of the insulated foam lid. **Fig 11**



**Fig 11**

13. Close the lid of the shipping box with the included packaging tape. **Fig 12**



**Fig 12**

14. Immediately take to the shipping department or a FedEx pick-up location for shipment to Nelson Labs for next day morning delivery (prepaid shipping label is already on the shipping box).

15. Follow the endoscope manufacturer's IFU for high level disinfection and preparation for storage (including drying steps).

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

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	N/A
<b>Preparation for Decontamination</b>	N/A
<b>Disassembly Instructions</b>	N/A
<b>Cleaning – Manual</b>	N/A
<b>Cleaning – Automated</b>	N/A
<b>Disinfection</b>	N/A
<b>Drying</b>	N/A
<b>Maintenance, Inspection, and Testing</b>	N/A
<b>Reassembly Instructions</b>	N/A
<b>Packaging</b>	N/A
<b>Sterilization</b>	N/A
<b>Storage</b>	DNP neutralizing agent store at room temperature at a range of 59 °F-77 °F.
<b>Additional Information</b>	To ID an additional species that have more than two organisms, an additional charge will be added.

<b>Related Healthmark Products</b>	Duodenoscope Sampling Kit, ChannelCheck™, FlexiCheck™
<b>Other Product Support Documents</b>	N/A
<b>Reference Documents</b>	ProFormance™ Brochure, ProFormance™ Price List
<b>Customer Service Contact</b>	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a> hmark.com

2021-07-08 Ralph J Basile