

Instructions for Use: Flexible Endoscope Sampling Kit

Brand Name of Product	Flexible Endoscope Sampling Kit (FESK)
Generic Name of Product	Endoscope Culture Sample Kit
Product Code Number(s)	FESK-200-200, FESK-230-400, FESK-230-600, FESK- 230-900,
Intended Use	The Flexible Endoscope Sampling Kit provides items to collect a sample from the instrument channel of an endoscope and ship it to Nelson Labs® for further testing for presence of microorganisms. If present, the organisms will be quantified, and two (2) organisms will be identified. Additional organism identification, if needed/desired, can be conducted for an additional fee. This test does not assure the suitability of the flexible endoscope for patient use.
Range of Applications for Product	For bacterial surveillance testing of flexible endoscopes that do not have an elevator mechanism.
Key Specifications of Product	<ul style="list-style-type: none"> • Sample Collection Container (Clicktainer™) • Clicktainer™ Label • Scissors • WarmMark® • Shipping Box (shipping label included) • Two (2) Ice Packs • Ice Blanket • Two (2) 30 mL Syringes • Instrument channel brush • Alcohol Wipe • DE Broth • 95 kPa transport bag • Absorbent pad • One (1)-Packaging tape.

Shipping & Storage	
Shipping Conditions & Requirements	<ol style="list-style-type: none"> 1. Sample <i>must</i> be shipped the same day it is captured. 2. The included shipping label is for weekday, next day delivery. 3. This sample needs to be taken and shipped Monday–Thursday to Nelson Labs®.
Storage Conditions	<ul style="list-style-type: none"> • Lay ice packs and Ice blanket flat (without any folds). Must be frozen prior to use. • WarmMark® can be stored in a freezer or a refrigerator. This allows for preconditioning, so the indicator doesn't begin wicking immediately in room temperature where the products are packaged.
Packaging Conditions	Follow instructions below for proper packaging.
Shelf Life	Six (6) months from the date of manufacture.

Instructions for Using Product	
Description of Use(s)	Collect a sample from flexible endoscope and send out to Nelson Labs® for further testing for presence of microorganisms. If present, organisms will be identified and quantified and up to two (2) organisms will be identified.
Preparation for Use	<ol style="list-style-type: none"> 1. Upon receiving the kit, remove the ice packs and ice blanket that are around the DE Broth. 2. Store the WarmMark® in the freezer or a refrigerator. 3. Freeze the ice packs and ice blanket laid flat (without any folds) in a freezer at least eight (8) hours before use. 4. Store the DE Broth in the refrigerator two (2) °C to eight (8) °C (35.6 °F to 46.4 °F) immediately after receipt. 5. When ready to test, enter on the provided Clicktainer™ label the date, personnel initials, model, and serial numbers for the scope. 6. Supplies to be provided by the facility include:

- Disinfecting wipe
- One (1)-sterile pad/drape (large enough to have an endoscope to be placed flat on it for testing).
- Forty (40) mL of sterile water.
- Appropriate PPE for two (2) people: a) fluid resistant sterile gown, b) fluid resistant face and eye protection, c) sterile gloves, and d) bouffant caps for hair.
- A countertop or table long enough to lay the scope out.\ for visual inspection.

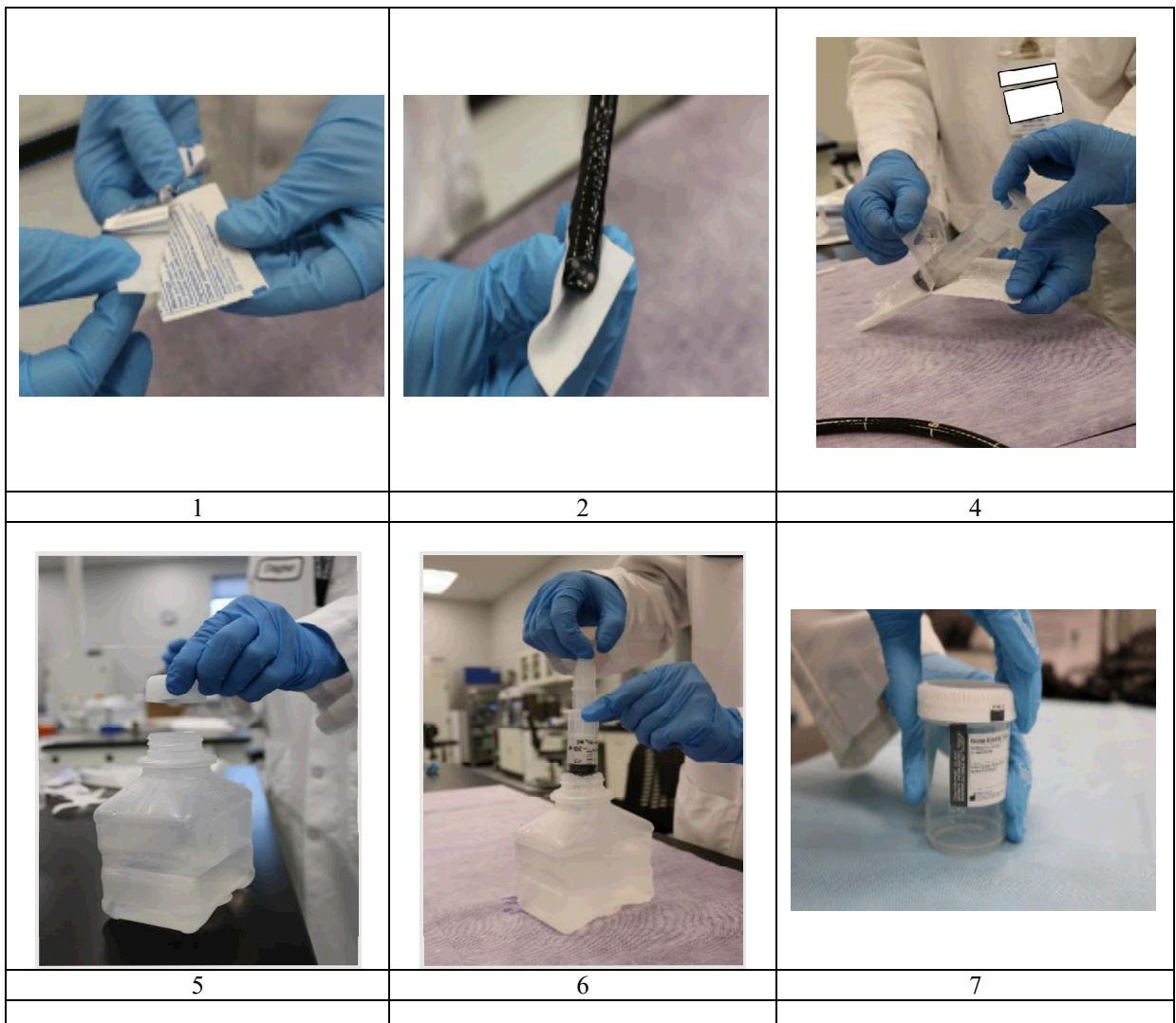
7. Prepare test area:

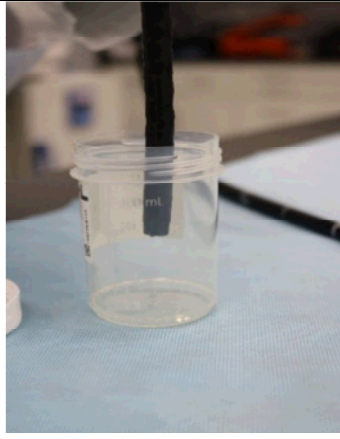
- After referencing the IFU about the disinfecting wipe first, wipe down the counter with the disinfecting wipe.
- Place a sterile pad/drape on counter/surface.
- Don PPE.

8. Sampling test area:

- Allow enough space for the tested flexible endoscope to lie flat on the sterile pad/drape.
- Visually inspect the distal end for debris or other concerns. (NOTE: If debris is present notify appropriate staff per facility policy.)
- Two (2) people (a Sampler and a Facilitator) are necessary for sampling.
 - The [Sampler](#) maintain aseptic handling and conducts brushing steps.
 - The [Facilitator](#) open the packages and handles unsampled portions of the endoscope.

**Diagrams
(drawings,
pictures)**





7A



8



9



10



10A



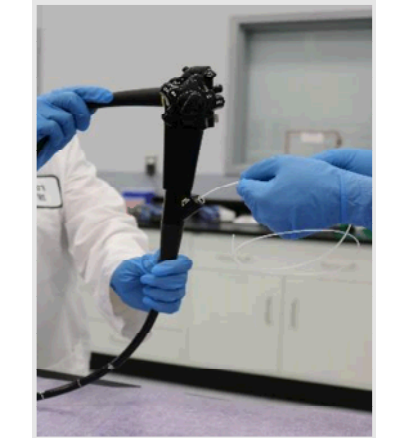
12



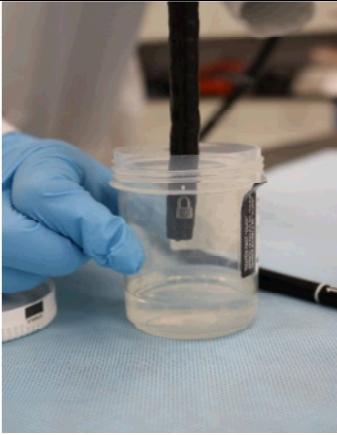
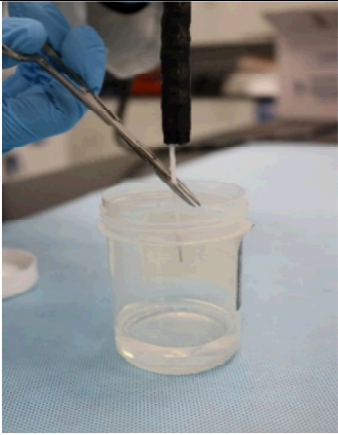





13



14



15

			
	16	18	21
			
	22	23	24
			
	24	25	26

Steps for Use of Product

Sampling the Instrument Channel

1. Facilitator open and presents alcohol wipe to the Sampler in an aseptic manner.
2. Sampler wipe around the distal tip of the endoscope without contacting any internal areas of the distal end.
3. Facilitator open the packages for two (2) 30 mL syringes.
4. Sampler remove each syringe from the packaging.

5. [Facilitator](#) open the sterile water bottle.
6. [Sampler](#) fill each syringe with 20 mL of sterile water.
7. [Sampler](#) hand one of the two sterile water filled syringes to the facilitator, then holds the distal end of the endoscope over the sample collection container.
8. [Facilitator](#) flush the instrument channel with the syringe filled containing 20 mL of sterile water, which the [Sampler](#) captures in the sample collection container.
9. [Facilitator](#) fill 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 instrument channel, the [Sampler](#) may cap the sample collection container and place it on the sterile drape.
11. [Facilitator](#) place the endoscope on the sterile drape.
12. [Facilitator](#) open scissor package containing an instrument channel brush.
13. [Sampler](#) remove the instrument channel brush from the packaging.
14. [Facilitator](#) hold the endoscope vertically while the [Sampler](#) inserts the instrument channel brush into the biopsy port.
15. Once the brush has been inserted about three (3) inches into the biopsy port, the [Sampler](#) transfer the brush handle to the facilitator.
16. [Sampler](#) hold 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](#) continue to push the brush through the instrument channel until the brush head exits the distal tip.
18. [Sampler](#) use 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. [Facilitator](#) pull the remainder of the brush out of the endoscope from the biopsy port.
20. Repeat the above sampling steps (1–9) for an additional fluid flush, with the second syringe holding 20 mL of sterile water, to be added to the collection container.

Addition of neutralizer solution and transport preparation:

21. Before use of the DE Broth, wipe the neutralizer bottle and the lid with an alcohol wipe.
22. [Facilitator](#) open and presents alcohol wipe to the [Sampler](#) in an aseptic manner.
23. [Sampler](#) wipe around the DE Broth bottle.
24. [Sampler](#) wipe around the lid.
25. [Sampler](#) add the provided neutralizer (DE Broth) 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.
 - DE Broth is added to facilitate outgrowth of microbes that have been potentially damaged by the reprocessing process.
26. [Sampler](#) tightly closes the lid of the 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. Ensure the label is properly filled out and adhere the label to the sample collection container. (**Fig. 1**).



Figure 1

2. Wrap the sample collection container with the frozen ice blanket. (**Fig. 2**).



Figure 2

3. Wrap the absorbent material around the sample collection container and ice blanket. (**Fig. 3**).



Figure 3

4. Place the wrapped sample collection container in the compliant 95 kPa transport bag and seal. (**Fig. 4**).



Figure 4

5. Place the frozen ice pack at the bottom of the culture kit foam cooler. (**Fig. 5**).



Figure 5

6. Place the above packaging in the provided cubed foam insert.
 - a. Place the foam cell insert (**Fig. 6**) on top of the ice pack (**Fig. 5**). Ensure the appropriate number of foam cubes are removed from the foam cell insert. (**Fig. 6a**).

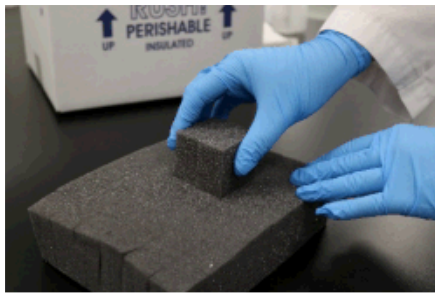


Figure 6

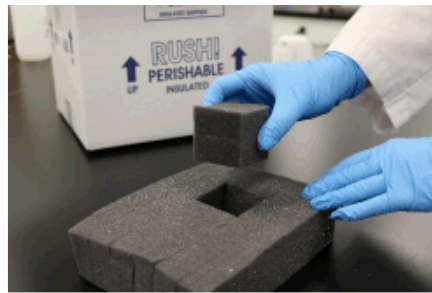


Figure 6a

- b. Place sample collection container into the empty section (where foam cubes were removed). (**Fig. 7**).



Figure 7

- c. Make sure the sample collection container's base is in complete contact with the bottom ice pack. (**Fig. 8**).



Figure 8

7. Place the second frozen ice pack on top of the compliant 95 kPa transport bag. (**Fig. 9**).



Figure 9

8. Fill out the provided sample submission form. (**Fig. 10**).

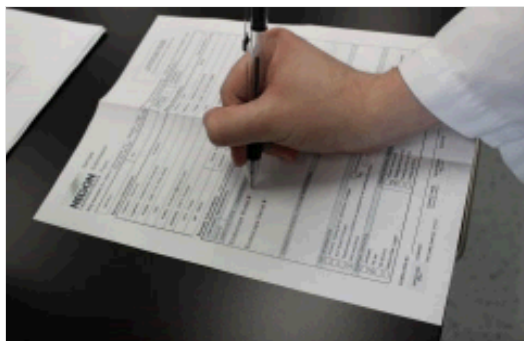


Figure 10

9. Insert the sample submission form into the envelope attached to the top of the insulated foam lid. (**Fig. 11**).



Figure 11

10. Remove the WarmMark® eight (8) °C / 12-hour indicator from the refrigerator and place on the inside of the culture kit cooler lid.
11. Activate the indicator by folding up and then pulling the activation tag. (**Fig. 12, 12a, 12b, 12c**).



Figure 12



Figure 12a



Figure 12b



Figure 12c Inactivated vs. Activated temperature indicator

12. Place the lid on the culture kit cooler.
 - a. Peel the backing off the adhesive of the WarmMark®. (**Fig. 13**).
 - b. Place the WarmMark® on the lid of culture the kit cooler. (**Fig. 13a**).

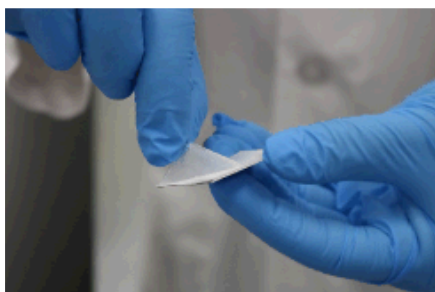


Figure 13

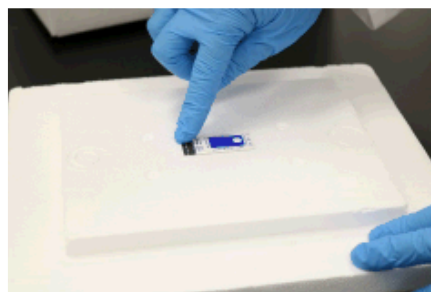


Figure 13a

13. Seal the culture kit in the shipping box with the provided packaging tape. (**Fig. 14**).



Figure 14

14. Immediately take boxed culture kit 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).

Interpretation of Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A

Special Warnings and Cautions	This test should be shipped Monday–Thursday OVERNIGHT to Nelson Labs®.
Disposal	N/A

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	The kit includes species identification for two (2) species. To ID additional species greater than two (2) organisms, an additional fee will be added. The facility will be contacted for authorization to conduct further speciation.

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