



Instructions for Use: Duodenoscope Sampling Kit

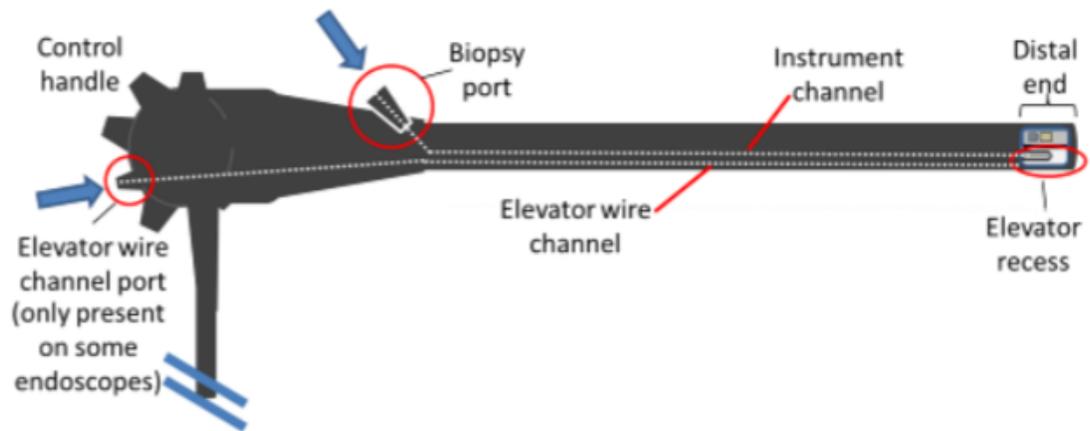
Brand Name of Product	Duodenoscope Sampling Kit
Generic Name of Product	Endoscope sampling and culturing kit
Product Code Number(s)	CK-250, CK-374
Intended Use	The Duodenoscope Sampling Kit provides items to collect a sample from a duodenoscope and ship to Nelson Labs for microorganism analysis. If present, 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.
Range of Applications for Product	For microbial surveillance testing of duodenoscopes
Key Specifications of Product	<ol style="list-style-type: none"> 1. Sample collection container 2. Scissors 3. Thermometer 4. Shipping box (shipping label included) 5. 2 Ice packs 6. (2) 30 mL syringes 7. (1) 5 mL syringe 8. Labels 9. Instrument channel extraction tool (240cm long) 10. Distal tip extraction tool 11. Alcohol wipe 12. (2) 1 mL pipettes 13. Swab 14. DNP neutralizing agent 15. Absorbent pad with zipper bag 16. 1 Packing tape

Shipping & Storage	
Shipping Conditions & Requirements	<ol style="list-style-type: none"> 1. Sample must 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	Ice packs and thermometer must be frozen until prior to use. DNP broth store at room temperature at a range of 59°F-77°F.
Packaging Conditions	Follow instructions below for proper packaging.
Shelf Life	Two years from manufacturer date.

Instructions for Using Product	
Description of Use(s)	Collect a sample and send to Nelson Labs for further testing for presence of microorganisms. If present, the organisms will be quantified and up to two organisms will be identified.
Preparation for Use	<ol style="list-style-type: none"> 1. Upon receiving the kit, remove the ice packs that are around the DNP broth. 2. Remove the thermometer. 3. Place the ice packs and temperature monitor in a freezer for a minimum of 8 hours before use. Ensure the ice packs are laid flat. 4. Store the DNP neutralizing agent at room temperature. 5. When ready to test, enter on the provided label the: date, personnel initials, model, and serial numbers of the scope. 6. Supplies to be provided by the facility include: <ul style="list-style-type: none"> ○ Disinfecting wipe ○ 1 Sterile pad/ drape (large enough to have an endoscope to be placed flat on it for testing). ○ 45 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

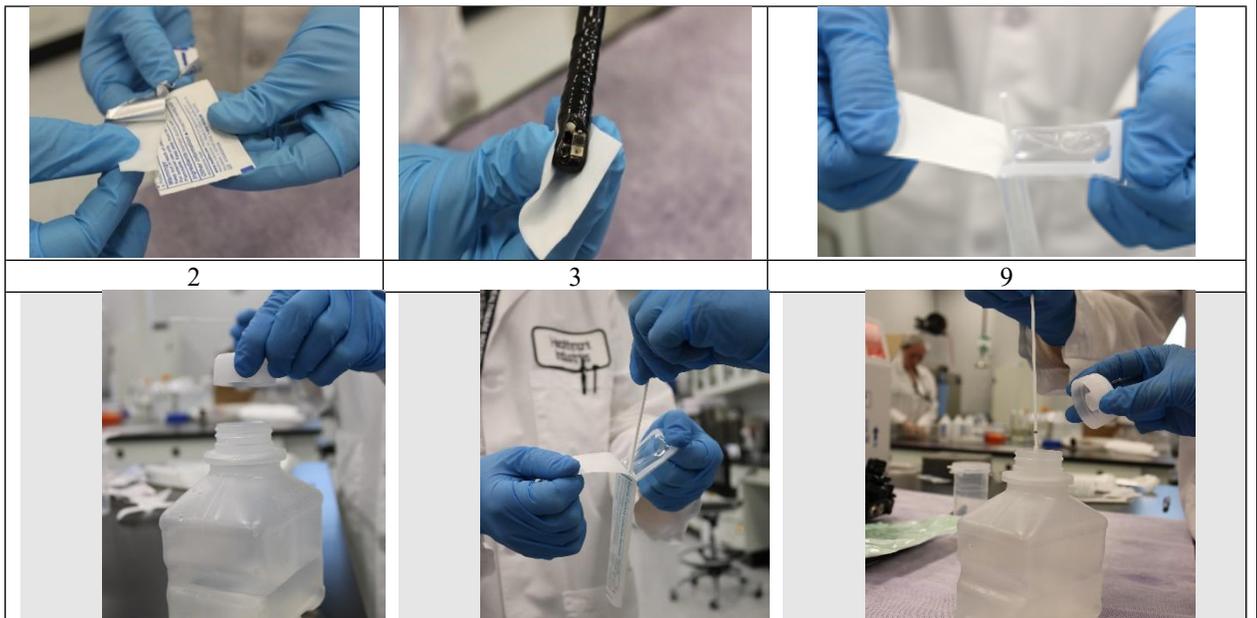
- Sterile elevator wire channel washing/flushing/cleaning tube adapter
7. Prepare test area:
- Wipe down the counter with the disinfecting wipe (reference the IFU for the wipe).
 - Place a sterile pad/drape on counter/surface.
 - Don PPE
8. Sampling Preparation:
- Allow enough space for the flexible endoscope that is to be tested to lie flat on the sterile pad/drape
 - Place duodenoscope 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.
 - 2 people (Sampler and Facilitator) will be needed to do the sampling.:
 - The [sampler](#) maintains aseptic handling and conducts brushing steps.
 - The [facilitator](#) opens packages and handles unsampled portions of the endoscope.

**Diagrams
(drawings,
pictures)**



Duodenoscope Diagram

Photos:



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<p>13</p> 	<p>14</p> 	<p>15</p> 
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19A



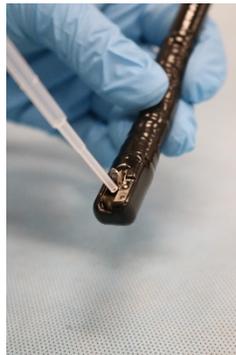
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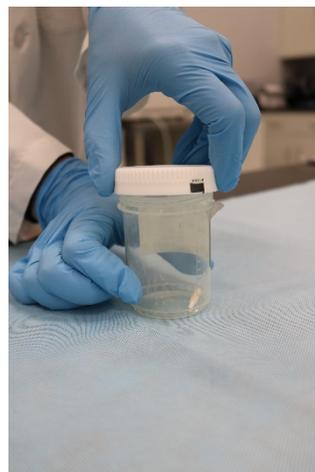
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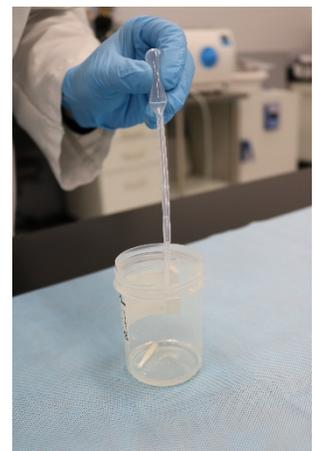
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29A



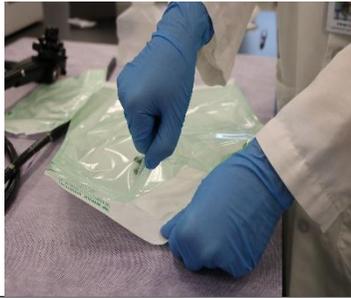
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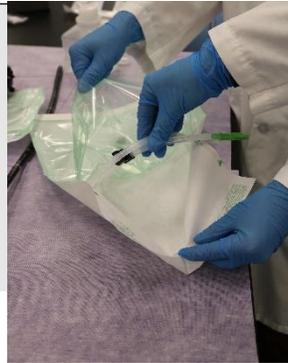
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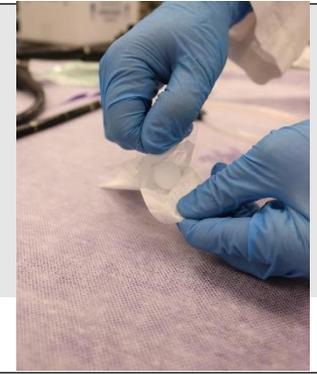
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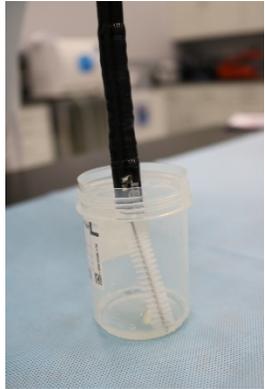
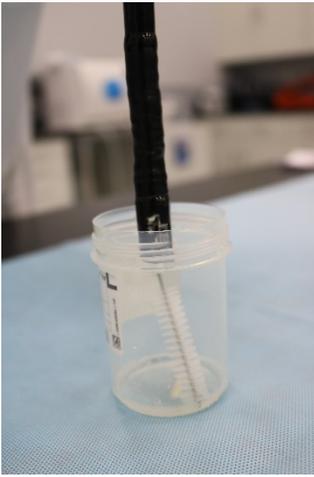
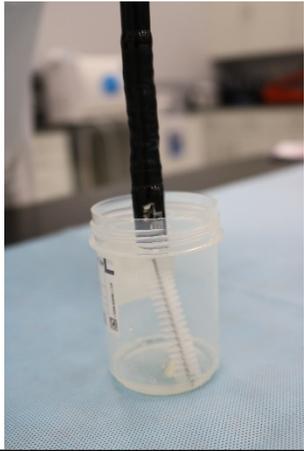
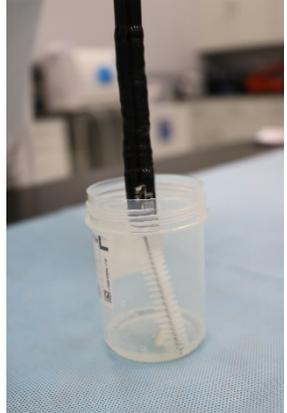
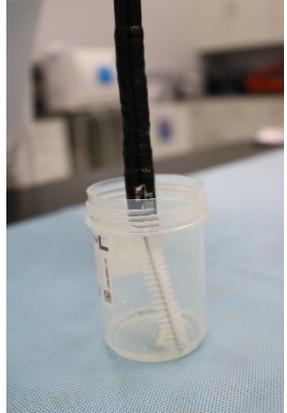


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71A



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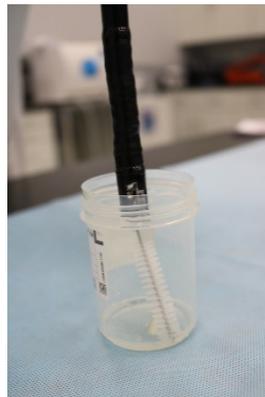
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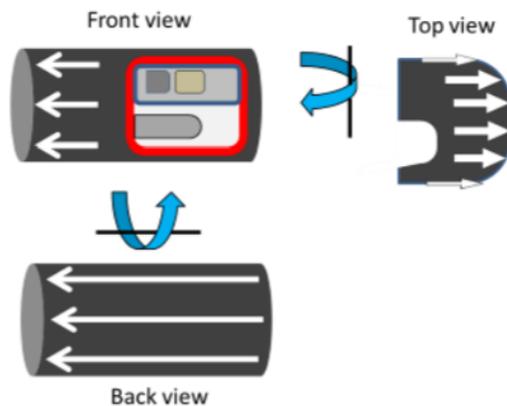


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Steps for Use of Product

Distal Cap Seam Sampling

1. Facilitator: Open an alcohol wipe package.
2. Sampler: Remove alcohol wipe from package.
3. Sampler: Wipe exterior of distal end with alcohol wipe.
4. Ensure that the elevator recess and the seams near the elevator recess are not exposed to the alcohol during wiping (refer to Figure below).
5. Sampler: Wipe away from the elevator recess taking care to avoid the elevator lever, recess, and the seams between the distal cap and distal end.
6. Allow the alcohol to dry.
7. Figure below: Close-up of duodenoscope distal end, and **location and direction of alcohol wiping (white arrows)** of the exterior of the distal end, and **location of seams to swab for sampling (in red)**. The seams between the distal cap and the distal end may be of variable design with different models of duodenoscopes and may not extend completely around the elevator recess.



8. _____
9. Facilitator: Open the swab package.

10. Facilitator: Open the sterile water container (loosely place the cap back on the sterile water container after the sampler has moistened the swab in sterile water).
11. Sampler: Remove the swab from the package.
12. Sampler: Moisten the swab in sterile water. This may be done by dipping the swab tip in the water.
13. Sampler: Swab along the seam between the distal cap and the distal end (refer to Figure 13 above). The distal cap is frequently a plastic material, whereas the distal end is frequently made of metal.
14. Facilitator: Open the sample collection container and hold the container.
15. Sampler breaks off the tip of the swab into the sample collection container. The provided swab has a breakpoint for breaking off the tip.
16. Facilitator: Close the sample collection container.

Elevator Recess Sampling

For Olympus and Fujifilm Duodenoscopes

Elevator recess sampling method for a duodenoscope with a fixed distal cap with no hole (Olympus and Fujifilm):

17. Facilitator: Open the package for the pipette.
18. Facilitator: Open the sterile water container (loosely place the cap back on the sterile water container after the sampler has withdrawn sterile water).
19. Sampler: Remove the pipette from the package and fill with 1 mL of fresh sterile water.
20. Facilitator: Lower the elevator lever.
21. Sampler: While holding the distal end so that it is parallel to or lying flat on the sterile drape or pad, apply 1 mL of sterile water into the elevator recess with the sterile pipette.
22. Sampler: Use the same pipette to draw that fluid up and down into pipette five times.
23. Sampler suctions the fluid into the pipette while facilitator raises the elevator lever.
24. Sampler repeats the previous two steps by applying the fluid into the recess five times.
25. Facilitator: Open the sample collection container (close the container after the sampler has added the sample).
26. Sampler: Use the same pipette to remove fluid from the elevator recess and transfer the fluid to the sample collection container.
27. Facilitator: Open the package for the distal tip extraction tool.
28. Facilitator: Open the sterile water container (loosely place the cap back on the sterile water container after the sampler has moistened the brush in sterile water).
29. Sampler: Remove the distal tip extraction tool from the packaging and moisten in fresh, sterile water. This may be done dipping the brush head in the water.
30. Sampler brushes the elevator recess while facilitator raises and lowers the elevator.
31. Sampler puts the brush in the sampling container.
32. With a new pipette, repeat the above sampling steps (steps 17-26)

For Pentax Duodenoscopes

Elevator recess sampling for a duodenoscope with a hole in the distal cap or with a removable distal cap (PENTAX):

33. Facilitator: Open the package for the pipette.
34. Facilitator: Open the sterile water container (loosely place the cap back on the sterile water container after the sampler has withdrawn sterile water).
35. Sampler: Remove the pipette from the package and fill with 1 mL of fresh sterile water.
36. Facilitator: Lower the elevator lever.
37. While sampler holds the distal end so that it is parallel to the draped counter surface, facilitator places the open sample collection container underneath the distal end of the duodenoscope.
38. Sampler applies 1 mL of sterile water into the elevator recess with the pipette and allows that volume to drain into the sample collection container by gravity.
39. Sampler applies a second 1 mL volume of sterile water to the elevator recess, capturing the volume as it exits the elevator recess or drains through the hole in the back of the cavity and into the sample collection container.
40. Facilitator raises the elevator lever.
41. Sampler repeats the previous two steps by applying 1 mL of sterile water to the elevator recess twice, allowing the extraction fluid to drain from the cavity by gravity and into the sample collection container.
42. Facilitator opens the package for the distal tip extraction tool.
43. Sampler removes the distal tip extraction tool from the packaging.
44. Sampler moistens the elevator sampling brush in fresh, sterile water.
45. Sampler brushes the elevator recess while facilitator raises and lowers the elevator.
46. Sampler puts the brush in the sampling container.
47. With a new pipette, repeat steps the above sampling steps (steps 33-41)

Elevator Wire Channel Sampling (only for duodenoscopes with an open elevator wire channel)

48. Facilitator: Open the packaging for the elevator wire channel washing/flushing/cleaning tube adapter.
49. Sampler removes the elevator wire channel washing/flushing/cleaning tube adapter and attaches it to the elevator wire channel port.
50. Facilitator: Open the packaging for the 5 mL syringe.
51. Sampler: Remove the 5 mL syringe from the packaging and draw up 3 mL of sterile water into the syringe.
52. Sampler: Attach the syringe to the elevator wire channel washing/flushing/cleaning tube adapter.
53. Facilitator positions the duodenoscope so that it is nearly vertical.
54. Facilitator holds the control handle of the duodenoscope and the syringe (attached to the elevator wire channel adapter) while sampler holds the distal end. Having the facilitator stand on a step stool while holding the control handle may assist in keeping the duodenoscope vertical.

55. Sampler ensures that the sample collection container is at the distal end to allow for collection of the liquid.
56. Facilitator slowly flushes 3 mL of sterile water into the elevator wire channel and the sampler captures the fluid at the distal end.
57. While the facilitator continues to hold the duodenoscope, the sampler places the sample collection container on the drape.
58. Sampler then removes the syringe from the elevator wire channel adapter, fills the syringe with air, and re-attaches the syringe to the elevator wire channel adapter.
59. Sampler takes the sample collection container and positions it under the distal end of the duodenoscope.
60. Facilitator flushes 5 mL of air into the elevator wire channel to evacuate the channel of fluid water.
61. Sampler continues to ensure that the sample collection container is at the distal end to allow collection of the fluid.
62. After the air has been flushed into the channel, the sampler may cap the sample collection container and make sure the cap clicks, the brush may bend in the container. Place sample collection container on the sterile drape.
63. Facilitator removes the elevator wire channel washing/flushing/cleaning tube/adapter from the elevator wire channel port and places the duodenoscope on the sterile drape.

Instrument Channel Sampling

64. Facilitator opens the packages for two 30 mL syringes.
65. Sampler removes each syringe from the packaging.
66. Facilitator opens the sterile water bottle while sampler fills each syringe with 20 mL of water.
67. Sampler places the syringes on the sterile drape.
68. Facilitator elevates the control handle of the duodenoscope so that the duodenoscope is nearly vertical.
69. Sampler opens the sample collection container.
70. Sampler hands a syringe to the facilitator and holds the distal end over the sample collection container.
71. Facilitator flushes the instrument channel with 20 mL of sterile water, which sampler captures in the sample collection container.
72. Facilitator fills the syringe with air and flushes air into the instrument channel. Any residual fluid is captured in the sample collection container.
73. After the air has been flushed into the channel, the sampler may cap the sample collection container and place it on the sterile drape.
74. Facilitator places the duodenoscope on the sterile drape.
75. Facilitator opens scissors package.
76. Sampler removes Instrument channel extraction tool from the packaging.
77. Facilitator holds the duodenoscope vertically while sampler inserts the instrument channel extraction tool into the biopsy port.
78. Once the brush has been inserted about 3 inches, the sampler transfers the brush handle to the facilitator.

79. Sampler holds the collection container at the distal end to capture any fluid that exits the channel with the brush, making sure not to touch the distal end.
80. Facilitator continues to push the brush through the instrument channel.
81. After the brush head exits the distal tip, the sampler uses 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.
82. The remainder of the brush should be pulled out of the duodenoscope from the biopsy port.
83. Repeat the above sampling steps (steps 69-73) for an additional fluid flush to be added to the collection container.

Addition of neutralizer solution and transport preparation:

84. Add the provided DNP neutralizing agent to the sample.
 - Do not allow the duodenoscope to contact the neutralizer solution in the sample container.
 - Accidental immersion of any part of the duodenoscope 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.
85. Tightly close lid of sample container by turning the cap until you hear the cap clicks.

Sampling of additional channels

Healthcare facilities may also choose to sample additional channels in duodenoscopes, 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**

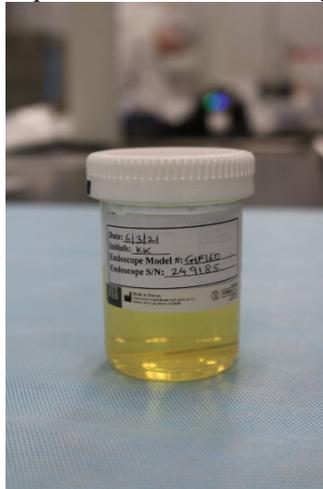


Fig. 1

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 one 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**

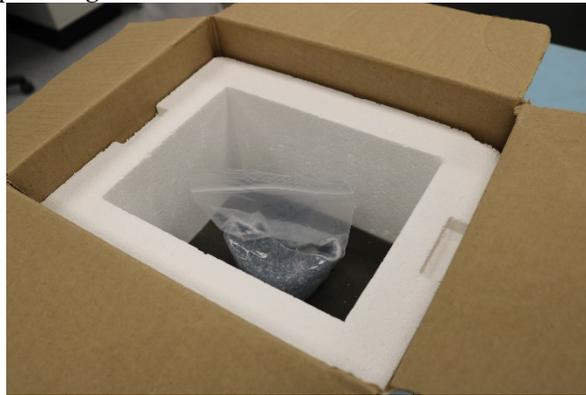


Fig 6

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**

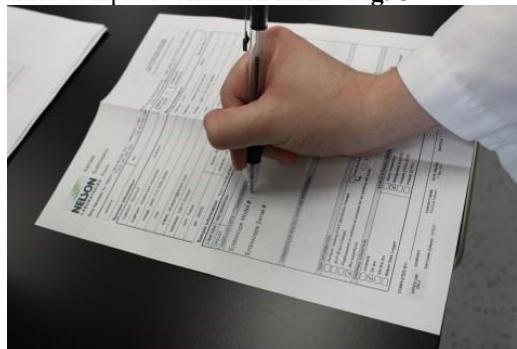


Fig. 8

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

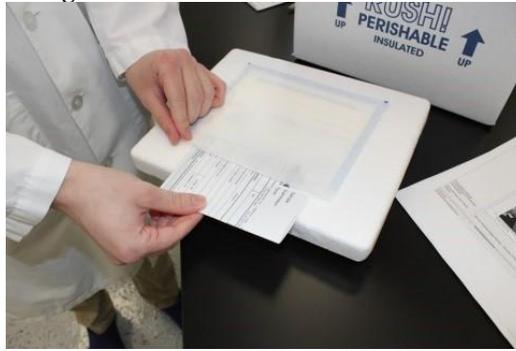


Fig. 9

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



Fig. 10

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



Fig. 11

13. Close the lid of the shipping box with the included packing 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).

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	DNP neutralizing agent store at room temperature at a range of 59°F-77°F.
Additional Information	The kit includes species identification for two species. To ID an additional species, there is an additional charge of \$200 per species. The facility will be contacted for authorization to conduct further speciation.

Related Healthmark Products	ChannelCheck™, FlexiCheck™
Other Product Support Documents	FDA's Duodenoscope Surveillance Sampling and Culturing Protocols, 2018
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

2021-07-08 Ralph J Basile