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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, WM-8-46-12, S-16480, S-1648CT
Intended Use	The Duodenoscope Sampling Kit provides items to collect a sample from a duodenoscope and ship to Nelson Labs® for further testing for the presence of microorganisms. If present, the organisms will be quantified, and two (2) organisms will be identified. Additional organism identification can be conducted for a fee. 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	• Sample Collection Container (Clicktainer™) • Scissors • WarmMark® • Shipping box (shipping label included) • Two (2) Ice packs • Two (2) 30 mL syringes • One (1)-5 mL syringe • Ice Blanket • Clicktainer™ Labels • Instrument channel extraction tool (240cm long) • Distal tip extraction tool • Alcohol wipe • Two one (1)-mL pipettes • Swab • DE Broth • 95 kPa transport bag • Absorbent pad • One (1)-Packing tape.

Shipping & Storage	
Shipping Conditions & Requirements	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	• 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 manufacture.

Instructions for Using Product	
Description of Use(s)	Collect a sample from **Duodenoscopes** and send out to Nelson Labs® for further testing for presence of microorganisms. If present, the organisms will be quantified and up to two (2) organisms will be identified.
Preparation for Use	1. Upon receiving the kit, remove the ice packs and ice blanket that are around the DE Broth. 2. Store the WarmMark® in a freezer or a refrigerator. 3. Freeze the **ice packs and ice blanket laid flat (without any folds) in a freezer** for 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 of the scope. 6. Supplies to be provided by the facility include:

- One (1)-Disinfecting wipe
- One (1)-Sterile pad/drape (large enough to have an endoscope to be placed flat on it for testing).
- Forty-five (45) mL of sterile water.
- Appropriate personal protective equipment (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.
- 10x Magnifier
- Sterile elevator wire channel washing/flushing/cleaning tube adapter.

7. Prepare test area:
   - Allow enough counter/surface space for the flexible endoscope being tested to lie flat on the sterile pad/drapes.
   - Wipe down the counter with the disinfecting wipe per the instructions for use (IFU).
   - Place a sterile pad/drape on counter/surface.
   - Don PPE.

8. Sampling Preparation:
   - (Using a 10x magnifier), perform a visual inspection of the flexible endoscope's distal end for debris or other concerns. 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)

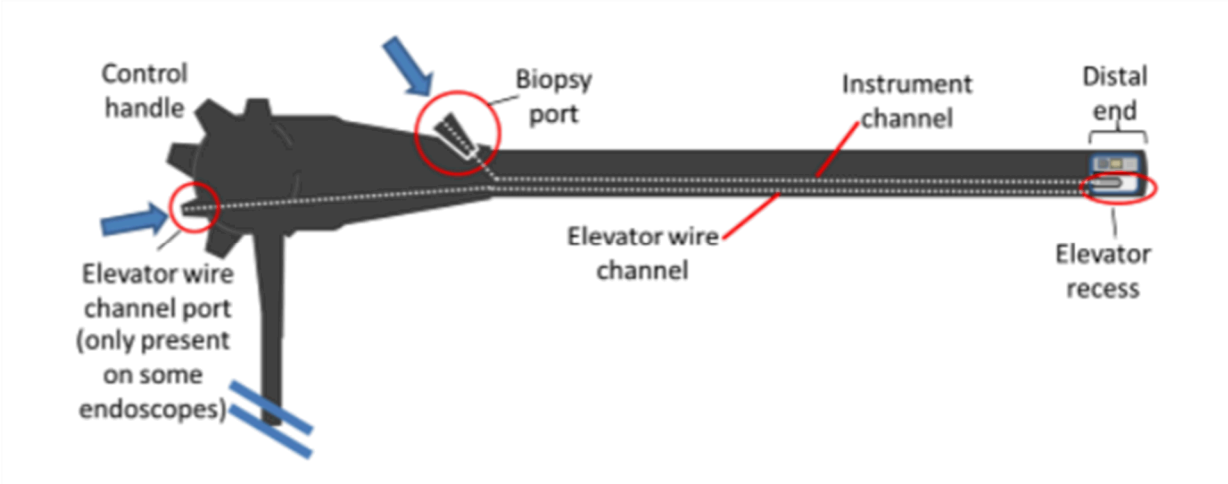
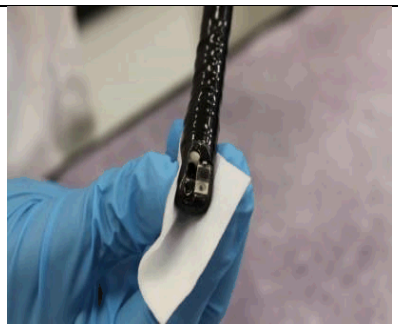
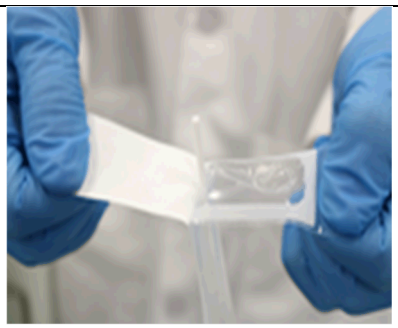


Figure 2 Duodenoscope Diagram

Photos of Steps for Use of Product: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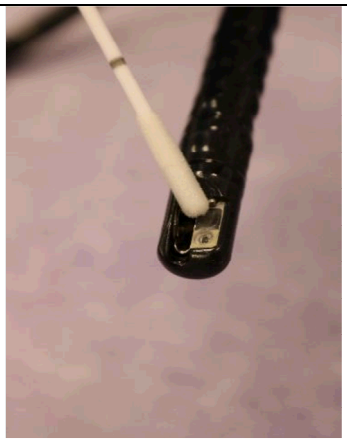	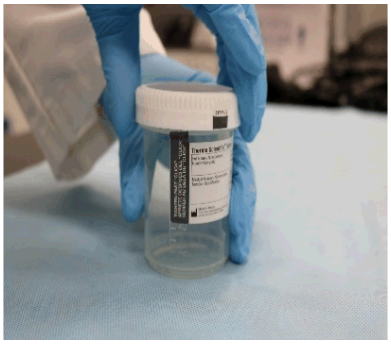	
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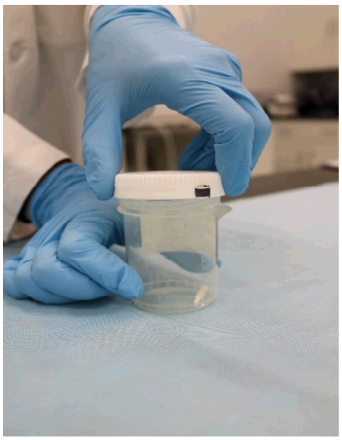	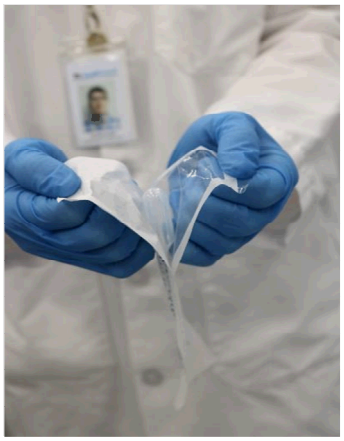	
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	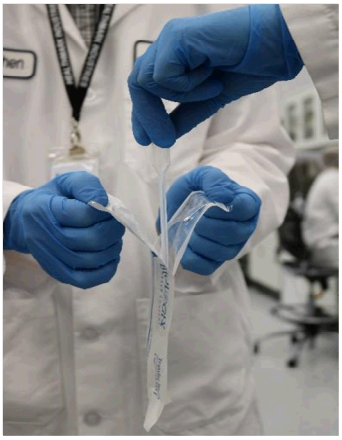		
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	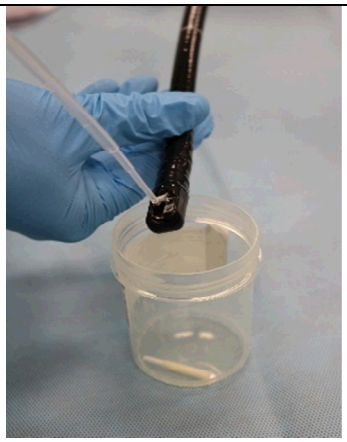	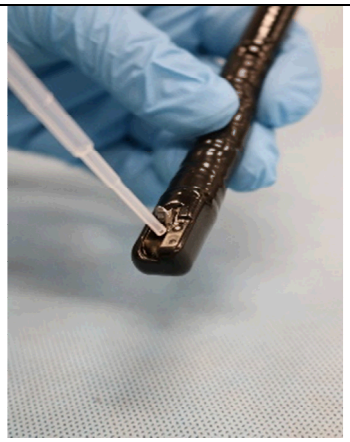	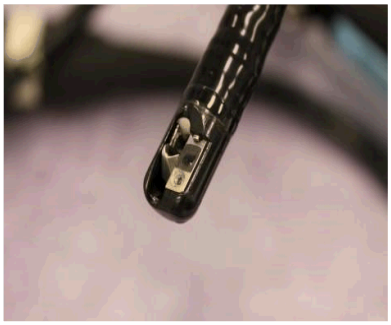
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		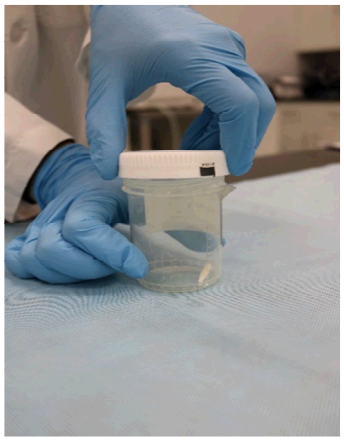	
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		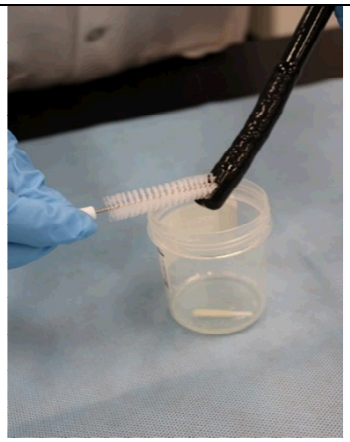	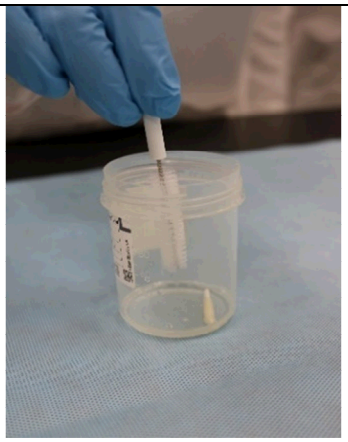
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	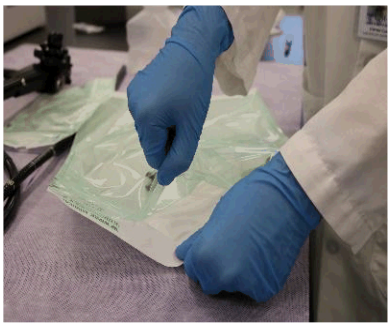	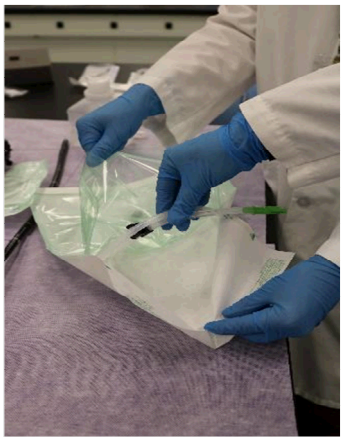	
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		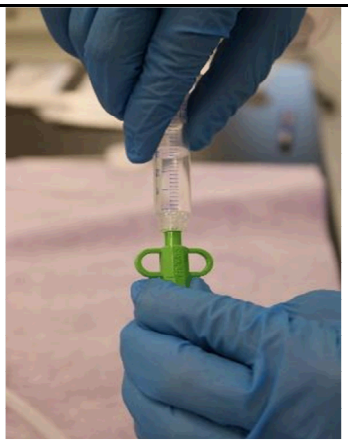
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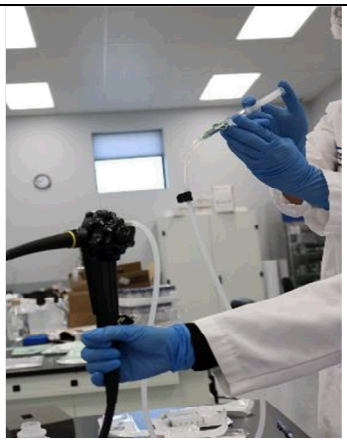	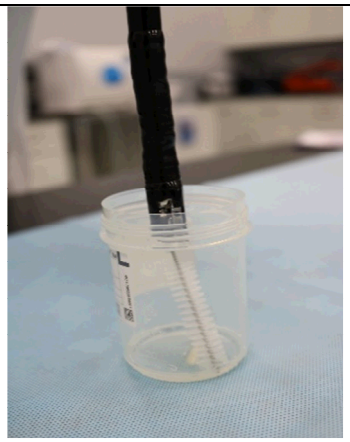	
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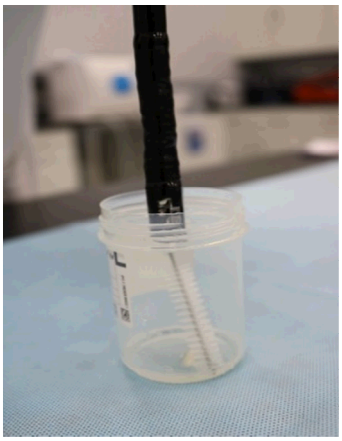		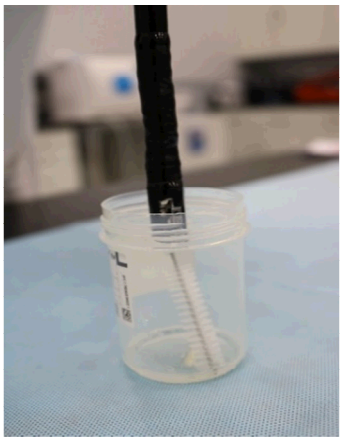
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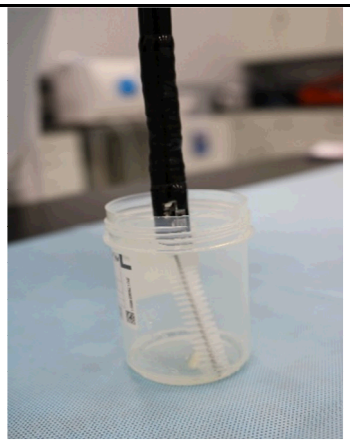

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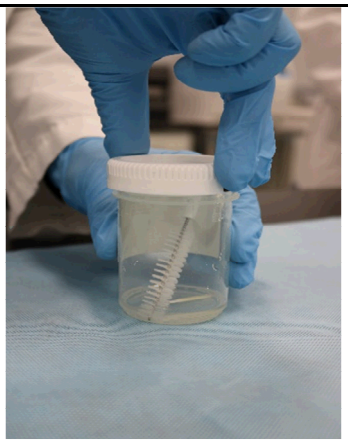

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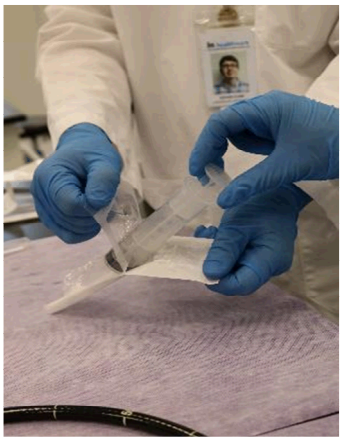

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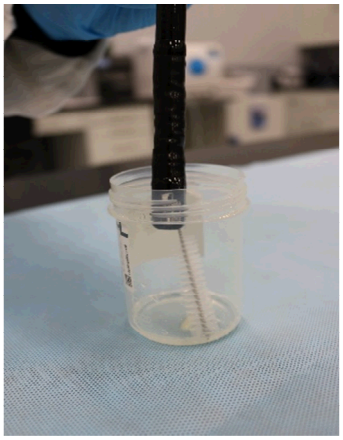

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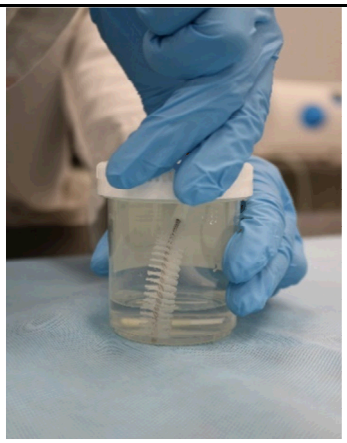
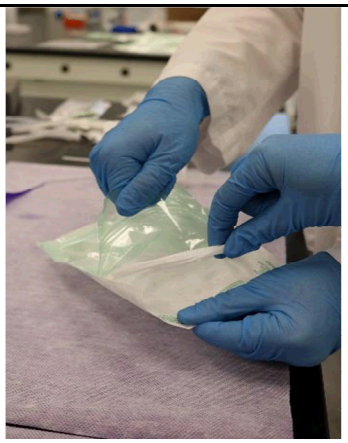
<tr><td>  </td><td>  </td><td>  </td></tr>
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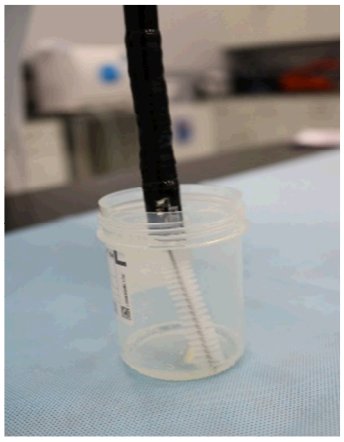
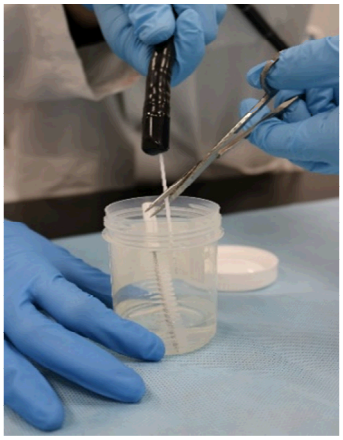
<tr><td>.  </td><td>  </td><td>  </td></tr>
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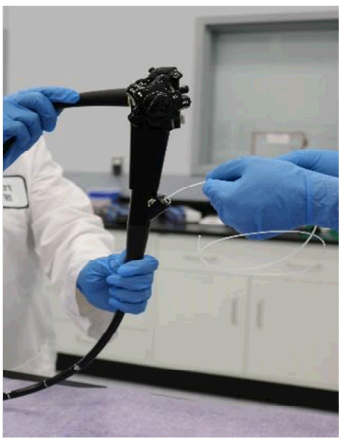
<tr><td>  </td><td>  </td><td>  </td></tr>
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<tr><td>Steps for Use of Product</td><td><u>Distal Cap Seam Sampling</u>
The pictures above refer to the steps for sample collection.

1. Facilitator: Open an alcohol wipe package.

2. Sampler: Remove alcohol wipe from package.

3. Sampler: Wipe exterior of distal end with alcohol wipe.</td></tr>
</table>

a. Ensure that the elevator recess and the seams near the elevator recess are not exposed to alcohol during wiping. **(Fig. 86).**

b. Wipe away from the elevator recess taking care to avoid the elevator lever, recess, and the seams between the distal cap and distal end.

c. Allow the alcohol to dry.

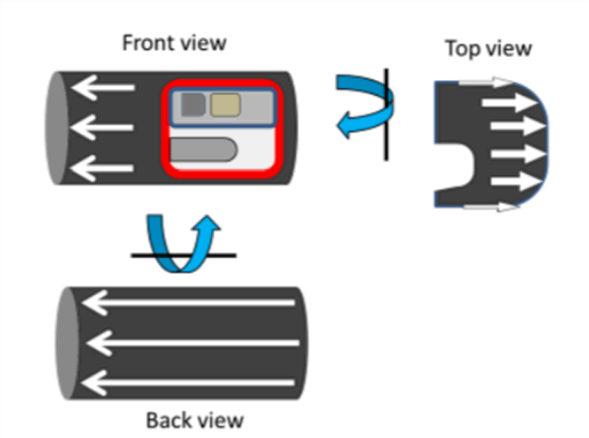

Figure 86: Close-up of duodenoscope distal end, and **location and direction of alcohol wiping (white arrows)** of the exterior of the distal end, and **location of seams to swab for sampling (in red)**. The seams between the distal cap and the distal end may be of variable design with different models of duodenoscopes and may not extend completely around the elevator recess.

4. Facilitator: Lower the elevator lever.

5. Facilitator: Open the swab package.

6. Facilitator: Open the sterile swab package.

7. 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).

8. Sampler: Remove the swab from the package.

9. Sampler: Moisten the swab in sterile water. This may be done by dipping the swab tip in the water.

10. Sampler: Swab along the seam between the distal cap and the distal end **(refer to Photo 13 above)**. The distal cap is frequently a plastic material, whereas the distal end is frequently made of metal.

11. Facilitator: Open the sample collection container and hold the container.

12. Sampler: **Break off the tip of the swab** into the sample collection container. (NOTE: The provided swab has a breakpoint for breaking off the tip.)

13. 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):

14. Facilitator: Open the package for the pipette.

15. Facilitator: Open the sterile water container (loosely place the cap back on the sterile water container after the sampler has withdrawn sterile water).

16. Sampler: Remove the pipette from the package and fill with one (1)-mL of fresh sterile water.

17. Facilitator: Lower the elevator lever.

18. Sampler: While holding the distal end so that it is parallel to or lying flat on the sterile drape or pad, apply one (1)-mL of sterile water into the elevator recess with the sterile pipette into the sample collection container.

19. Sampler: Use the same pipette to apply a second one (1)-mL of sterile water to the elevator recess, capturing fluid in the sample collection container. (NOTE: (loosely place the cap back on the sterile water container after the sampler has withdrawn sterile water.)

20. Facilitator: Raise the elevator lever.

21. Facilitator: Open the sample collection container.

22. Sampler: repeat the previous two steps by applying the sterile water into the recess twice, allowing the extraction fluid to drain into the sample collection container.

23. Sampler: Use the sterile pipette to capture remaining fluid as it exits around the distal end.

24. Facilitator: Close the container after the Sampler has added the sample.

25. Facilitator: Lower the elevator lever.

26. Facilitator: Open the package for the distal tip extraction tool.

27. Facilitator: Open the sterile water container

28. Sampler: Remove the distal tip extraction tool from the packaging and moisten in fresh, sterile water. This may be done by dipping the brush head in the sterile water. (NOTE: Facilitator loosely places the cap back on the sterile water container after the sampler has moistened the brush in sterile water).

29. Sampler: Brushe the proximal area of elevator recess while Facilitator raises and lowers the elevator.

30. Sampler: Repeat Step# 29 twice.

31. Sampler: Brush the distal area of elevator recess.

32. Sampler: Repeat Step# 31 twice.

33. Sampler: Brush the distal areas of the external surface.

34. Sampler: Repeat Step# 32 twice.

35. Sampler: Place the brush head into the sampling container. (NOTE: The brush may bend when placed into the sample collection container.)

36. Sampler With a new pipette, repeat the above sampling steps (17-24) to flush again after brushing.

For Pentax Duodenoscopes

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

37. Facilitator: Open the package for the pipette.

38. Facilitator: Open the sterile water container.

39. Sampler: Remove the pipette from the package and fill with one (1)-mL of fresh sterile water.

40. Facilitator: Loosely place the cap back on the sterile water container after the Sampler has withdrawn sterile water). Lower the elevator lever.

41. While Sampler hold 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.

42. Sampler: Applies one (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.

43. Sampler: Applies a second one (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.

44. Facilitator: Raise the elevator lever.

45. Sampler: Repeat the previous two steps (44 and 45) by applying one (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.

46. Facilitator: Open the package for the distal tip extraction tool.

47. Sampler: Remove the distal tip extraction tool from the packaging.

48. Sampler: Moisten the elevator sampling brush in fresh, sterile water.

49. Sampler: Brush the elevator recess, while Facilitator raises and lowers the elevator.

50. Sampler: Put the brush in the sampling container.

51. With a new pipette, repeat the steps above sampling steps (steps 33-41).

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

52. Facilitator: Open the packaging for the elevator wire channel washing/flushing/cleaning tube adapter.

53. Sampler: Remove the elevator wire channel washing/flushing/cleaning tube adapter and attaches it to the elevator wire channel port.

54. Facilitator: Open the packaging for the five (5) mL syringe.

55. Sampler: Remove the five (5) mL syringe from the packaging and draw up three (3) mL of sterile water into the syringe.

56. Sampler: Attach the syringe to the elevator wire channel washing/flushing/cleaning tube adapter.

57. Facilitator: Position the duodenoscope so that it is nearly vertical.

58. Facilitator: Hold 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.

59. Sampler: Ensure the sample collection container is at the distal end to allow for collection of the liquid.

60. Facilitator: Slowly flushes three (3) mL of sterile water into the elevator wire channel and the Sampler captures the fluid at the distal end.

61. While the Facilitator continues to hold the duodenoscope, Sampler places the sample collection container on the drape.

62. Sampler: Remove the syringe from the elevator wire channel adapter, fills the syringe with air, and re-attaches the syringe to the elevator wire channel adapter.

63. Sampler: Take the sample collection container and positions it under the distal end of the duodenoscope

64. Facilitator: Flush five (5) mL of air into the elevator wire channel to evacuate the channel of fluid water.

65. Sampler: Continue to ensure the sample collection container is at the distal end to allow collection of the fluid.

66. After the air has been flushed into the channel, the Sampler may cap the sample collection container and make sure the cap clicks. The Sampler will open the container again to finish the process. Place sample collection container on the sterile drape.

67. Facilitator: Remove 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

68. Sampler: Attache a single use biopsy valve (Olympus MAJ-1555) to the instrument channel port.

69. Facilitator: Open the packages for two (2) 30 mL syringes.

70. Sampler: Remove each syringe from the packaging.

71. Facilitator: Open the sterile water bottle, while Sampler fills each syringe with 20 mL of sterile water.

72. Sampler: Place the syringes on the sterile drape.

73. Facilitator: Lower the elevator lever.

74. Facilitator: Elevates the control handle of the duodenoscope so that the duodenoscope is nearly vertical and, plug the suction cylinder with a finger(s) at the same.

75. Sampler: Opens the sample collection container.

76. Sampler: Hand a syringe to the facilitator and holds the distal end over the sample collection container.

77. Facilitator: Flush the instrument channel with 20 mL of sterile water, which Sampler captures in the sample collection container.

78. Facilitator: Fill the syringe with air and flushes air into the instrument channel. Any residual fluid is captured in the sample collection container.

79. After the air has been flushed into the channel, the Sampler may cap the sample collection container and place it on the sterile drape..

80. Facilitator: Place the duodenoscope on the sterile drape.

81. Facilitator: Open the sterile instrument channel extraction tool package and scissors package.

82. Sampler: Remove instrument channel extraction tool from the packaging.

83. Facilitator: Hold the duodenoscope vertically, while Sampler inserts the instrument channel extraction tool into the biopsy port.

84. Once the brush has been inserted about three (3) inches, the Sampler transfers the brush handle to the Facilitator.

85. Sampler: Open sample collection container and holds it at the distal end to capture any fluid that exits the channel with the brush—making sure not to touch the distal end.

86. Facilitator: Continue to push the brush through the instrument channel until it exits the distal tip.

87. After the brush head exits the distal tip of the duodenoscope, the Sampler will use scissors to cut the entire head of the bristled portion and place it into the sample collection container.

88. The remainder of the brush should be pulled out of the duodenoscope from the biopsy port. Do not attempt the brush handle out through the distal tip of the duodenoscope.

89. Discard the brush handle appropriately.

90. Repeat the above sampling steps (steps 71-78) for an additional fluid flush to be added to the collection container.

Addition of neutralizer solution and transport preparation:

91. Add the provided DE Broth to the sample:
    a. Do not allow the duodenoscope to contact the neutralizer solution in the sample collection container.
    b. Accidental immersion of any part of the duodenoscope distal end into the neutralizer solution will necessitate complete reprocessing.
    c. DE Broth is added to facilitate outgrowth of microbes potentially damaged by the reprocessing process.

92. Tightly close the lid of sample collection container by turning the cap until you hear the cap click.

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. Ensure the label is properly filled out and adhere it to the sample collection container. **(Fig. 1)**.

Figure 1

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

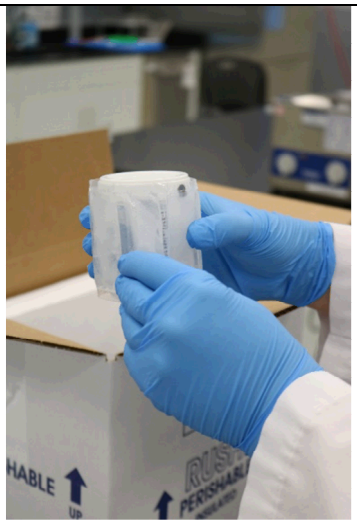

Figure 2

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

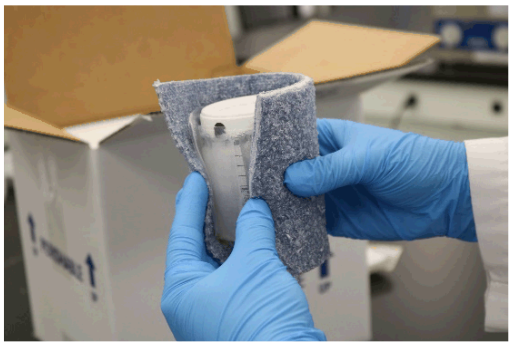

Figure 3

4. Place the wrapped sample 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 (**Fig. 4**) in the provided cubed foam insert. **(Fig. 7)**.
    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**).

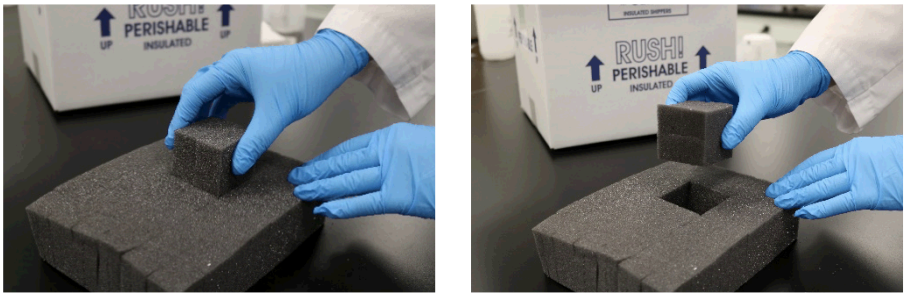

Figure 6

    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 complaint 95 kPa (zipper) bag. **(Fig. 9).**

Figure 9

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

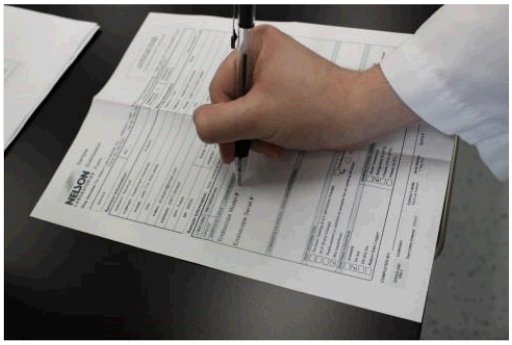

Figure 10

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

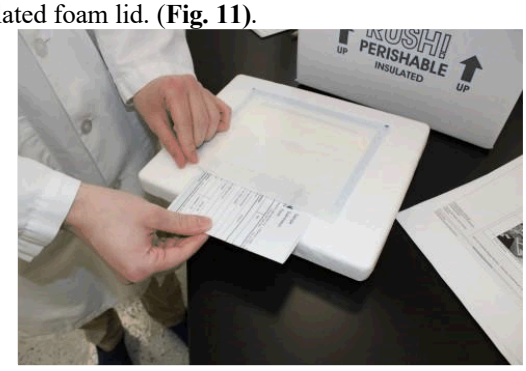

Figure 11

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

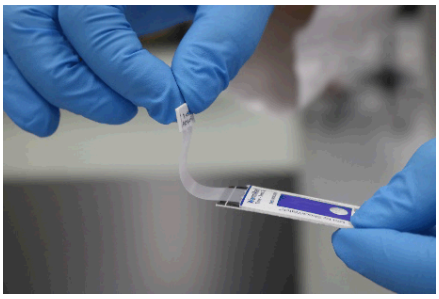

Figure 12a

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 from the WarmMark®. **(Fig. 13)**.
    b. Place the WarmMark® on the lid of the culture kit cooler. **(Fig. 13a)**.

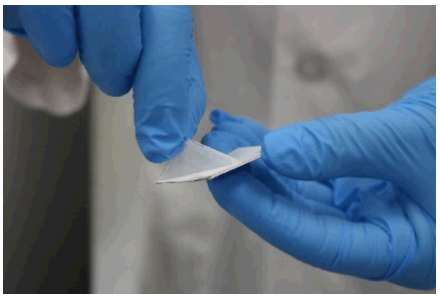

Figure 13

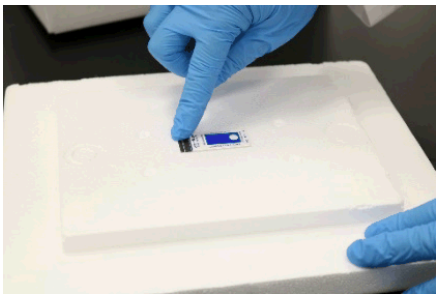

Figure 13a

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

	 **Figure 14** 14. Take the package immediately 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 an Additional Species, there is an additional fee. 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