

SAMPLING GUIDE*

Recommended Procedure for Sampling Gastrointestinal Flexible Endoscopes

This document provides the recommended procedure for obtaining acceptable samples from a flexible endoscope without an elevator mechanism (after manual cleaning) and testing for residual ATP. Although this procedure applies to all flexible endoscopes without an elevator mechanism, an Olympus® flexible GI endoscope is highlighted for purposes of illustration. Photos for sampling Pentax® and Fujinon® flexible endoscopes without an elevator mechanism are located on page 6.

Recommended Test Points for 3M™ Clean-Trace™ ATP Monitoring System for Flexible Endoscopes



Test Point: Distal End

3M™ Clean-Trace™ ATP
Surface Test UXC



Test Point: Suction/Biopsy Channel

3M™ Clean-Trace™ ATP
Water Test H2O

Materials Required

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- | | | |
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| <ul style="list-style-type: none">– Flexible Endoscope that has been manually cleaned– Clean, lint free towel– 3M™ Clean-Trace™ ATP Surface Test UXC– 3M™ Clean-Trace™ ATP Water Test H2O | <ul style="list-style-type: none">– 3M™ Clean-Trace™ Water Test Accessory Kit– 3M™ Clean-Trace™ Luminometer– Sterile sample collection container (50 mL conical tubes or specimen cups, for example)– Rack or holder to stabilize the collection containers | <ul style="list-style-type: none">– 60 cc syringe: sterile, disposable– Sterile water, at least 80 mL in a container large enough to accommodate a 60 cc syringe– Personal Protective Equipment (PPE): clean gloves, gown and goggles or face shield |
|--|--|--|
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* It is 3M's recommendation that high-risk endoscopes be monitored after every use. FDA safety communications on endoscopes with elevator mechanisms (duodenoscopes, EUS) and endoscopes support our choices for high-risk endoscopes.^{1,2}

3M is providing this sampling guide as a resource. You are responsible for determining whether the recommendations contained herein are appropriate for your setting and whether they will enable you to comply with any governmental or facility requirements, and your facility's policies and protocols.



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Sample Exterior Surface

1. Using one 3M™ Clean-Trace™ ATP Surface Test UXC and starting at the distal end of the bending section of insertion tube, swab all sides for a length of 10 cm (Figure 1).
2. Activate the test by returning it to the plastic sleeve and pushing down firmly on the blue cap until fully depressed. Grip the top of the test and shake rapidly side-to-side for at least five seconds.
3. To measure the ATP level, open the sample chamber on the 3M™ Clean-Trace™ Luminometer, insert the test and then close the cap. Follow the screen prompts to take a measurement. Always refer to the instructions for use for proper use of the Clean-Trace ATP Surface Test UXC and Clean-Trace Luminometer.
4. For verification of manual cleaning, if the RLU value is below 200 or below the facility designated threshold, proceed to the next step. If the RLU value is above 200 or above the facility designated threshold, the endoscope should be re-cleaned and re-tested.

Preparation of Flexible Endoscope for Sampling of Suction/Biopsy Channel

Preparation for sampling of the flexible endoscope interior channels requires the installation of a connector (Figure 2). A connector is required so that a syringe may be used to sample the interior channels of the flexible endoscope. Connectors can be obtained from 3M as part of the 3M™ Clean-Trace™ ATP Water Test Accessory Kit. The connectors are for single use only. Appropriate PPE should be worn while preparing and sampling the flexible endoscope.

Placement of Connector

The connector fits on the suction/biopsy channel located on the light guide end of the universal cord of the flexible endoscope (Figure 3).

To prevent leaking during the sampling process:

- Ensure that the suction biopsy valve is secured in the suction biopsy port (Figure 5).
- Ensure the instrument port is covered with the instrument port cap (Figure 5).

The endoscope is now ready for sample collection.

Sample Suction/Biopsy Channel

Treat all liquid samples as biohazardous. Use aseptic technique so that sample integrity is maintained.

1. Fill a 60 cc syringe with air and attach the syringe to the connector (Figure 4).
2. Depress the Suction Valve located on the Control Head (valve with red dot). Slowly push the air through the lumen. This process removes any cleaning agent in the lumen (Figure 5).
3. Secure the distal end of the flexible endoscope into the 50 mL conical sample collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 mL mark (Figure 6).
4. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container. Pull up an additional 20 cc of air.

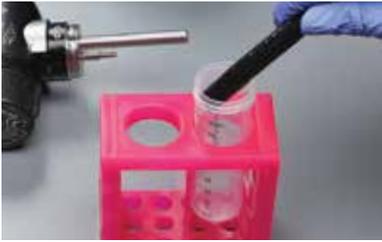


Figure 6



Figure 7

5. Attach the syringe to the suction/biopsy connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage (Figure 5).
6. Depress the Suction Valve located on the Control Head (valve with red dot) (Figure 5).
7. Keeping the Suction Valve depressed, push the water through the endoscope by depressing the syringe plunger. The rinsate should flow into the collection tube (Figure 6).
8. Release the Suction Valve and detach the syringe from the suction/biopsy connector.
9. Draw air into the syringe up to the 60 cc mark.
10. Attach the syringe to the suction/biopsy connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage (Figure 5).
11. Depress the Suction Valve.
12. Keeping the Suction Valve depressed, use the syringe plunger to push all the air into the endoscope. This process will displace the 40 mL rinsate into the 50 mL conical collection tube (Figure 7).
13. If not testing the rinsate immediately, securely cap the sample collection container to maintain sample integrity. When you are ready to measure the ATP level, open the sample collection container.
14. Remove the 3M™ Clean-Trace™ ATP Water Test H₂O from the plastic sleeve and slowly immerse in the water sample, just up to the collar.
15. Slowly remove the test and activate by returning it to the plastic sleeve and pushing down firmly on the red cap until fully depressed. Grip the top of the test and shake rapidly side to side for at least five seconds.
16. To measure the ATP level, open the sample chamber on the 3M™ Clean-Trace™ Luminometer, insert the test then close the cap. Follow the screen prompts to take a measurement. Always refer to the instructions for use for proper use of the Clean-Trace ATP Water Test H₂O and Clean-Trace Luminometer.
17. For verification of manual cleaning, if the RLU value is below 200 or below the facility designated threshold, proceed to the next step. If the RLU value is above 200 or above the facility designated threshold, the endoscope should be re-cleaned and re-tested.

Alternate Procedure for Collection of Samples from Flexible Endoscopes

The flexible endoscope can be sampled in an alternative manner that involves plugging the suction port on the Control Head.

NOTE: The Alternate Procedure for Collection of Samples from Flexible Endoscopes should **ONLY** be used on Olympus® brand flexible endoscopes. The silicone plugs in the 3M™ Clean-Trace™ ATP Water Test Accessory Kit do not fit all flexible endoscope models and may cause damage if used.



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Sample Flexible Endoscope Exterior Surface

1. Using one 3M™ Clean-Trace™ ATP Surface Test UXC and starting at the distal end of the bending section of insertion tube, swab all sides for a length of 10 cm (Figure 1).
2. Activate the test by returning it to the plastic sleeve and pushing down firmly on the blue cap until fully depressed. Grip the top of the test and shake rapidly side-to-side for at least five seconds.
3. To measure the ATP level, open the sample chamber on the 3M™ Clean-Trace™ Luminometer, insert the test then close the cap. Follow the screen prompts to take a measurement. Always refer to the instructions for use for proper use of the Clean-Trace ATP Surface Test UXC and Clean-Trace Luminometer.
4. For verification of manual cleaning, if the RLU value is below 200 or below the facility designated threshold, proceed to the next step. If the RLU value is above 200 or above the facility designated threshold, the endoscope should be re-cleaned and re-tested.

Preparation of Flexible Endoscope for Sampling of Suction/Biopsy Channel

Preparation for sampling of the flexible endoscope interior channels requires the installation of a connector and a small plug. Appropriate PPE should be worn while preparing and sampling the flexible endoscope.

A connector is required so that a syringe may be used to sample the interior channels of the flexible endoscope (Figure 2 and Figure 3). Connectors can be obtained from 3M as part of the 3M™ Clean-Trace™ ATP Water Test Accessory Kit. The connectors are **for single-use only**.

Water Test Accessory Kit Plug

This plug fits into the suction port at the control head of the endoscope and prevents leakage of rinsate during sampling. The plug should be clean and is **for single-use only** (Figure 4).

Placement of Plug on the Control Head

The plug fits into the Suction port located on the control head. This placement prevents leakage of the rinsate during sampling (Figure 5). A green plug was used for Figure 5 so that placement of the plug could be seen more clearly. The plug in the accessory kit is clear, not green.

To prevent leaking during the sampling process:

- Ensure the instrument port is covered with the instrument port cap (Figure 5).

The endoscope is now ready for sample collection.



Figure 6



Figure 7

Sample Suction/Biopsy Channel

Treat all liquid samples as biohazardous. Use aseptic technique so that sample integrity is maintained.

1. Fill a 60 cc syringe with air.
2. Attach the syringe to the connector and slowly push the air through the lumen. This process removes any cleaning agent remaining in the lumen (Figure 6).
3. Remove the 60 cc syringe from the connector and draw up 40 cc of sterile water from the water container.
4. Attach the syringe to the suction/biopsy connector on the light guide end on the universal cord. Make sure the instrument port is capped to avoid sample leakage (Figure 6).
5. Use a 60 cc syringe to draw up 40 cc of sterile water from the water container.
6. Attach the syringe to the suction/biopsy connector on the light guide end on the universal cord.
7. With the distal end of the endoscope inside the sample collection container, depress the syringe plunger to push the water through the endoscope and into the collection tube. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 mL mark (Figure 7).
8. Detach the syringe from the suction/biopsy connector and draw air into the syringe up to the 60 cc mark.
9. Re-attach the 60 cc syringe to the suction/biopsy connector and push all the air into the endoscope. This process will displace the 40 mL of rinsate into the 50 mL conical collection tube (Figure 6).
10. If not testing the rinsate immediately, securely cap the sample collection container to maintain sample integrity. When you are ready to measure the ATP level, open the sample collection container.
11. Remove the 3M™ Clean-Trace™ ATP Water Test H2O from the plastic sleeve and slowly immerse in the water sample, just up to the collar.
12. Slowly remove the test and activate by returning it to the plastic sleeve and pushing down firmly on the red cap until fully depressed. Grip the top of the test and shake rapidly side to side for at least five seconds.
13. To measure the ATP level, open the sample chamber on the 3M™ Clean-Trace™ Luminometer, insert the test then close the cap. Follow the screen prompts to take a measurement. Always refer to the instructions for use for proper use of the Clean-Trace ATP Water Test H2O and Clean-Trace Luminometer.
14. For verification of manual cleaning, if the RLU value is below 200 or below the facility designated threshold, proceed to the next step. If the RLU value is above 200 or above the facility designated threshold, the endoscope should be re-cleaned and re-tested.

Example of Sampling Set up for Pentax® and Fujinon® Flexible Endoscopes

Collecting samples from flexible endoscopes manufactured by Pentax® or Fujinon® are carried out in the exact same manner as described on first page. The photos below show the correct placement of connectors and syringes.

NOTE: The Alternate Procedure for Collection of Samples from Flexible Endoscopes (found on page 4), should ONLY be used on Olympus brand flexible endoscopes. The silicone plugs in the 3M™ Clean-Trace™ ATP Water Test Accessory Kit do not fit all flexible endoscope models and may cause damage if used.

Pentax®



Placement of connector and syringe on Pentax® flexible endoscope



Sampling a Pentax® flexible endoscope

Fujinon®



Placement of connector and syringe on Fujinon® flexible endoscope



Sampling a Fujinon® flexible endoscope

References

1. U.S. Food and Drug Administration. Reprocessed Flexible Bronchoscopes: FDA Safety Communication - Risk of Infection. <https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm462949.htm>. Updated September 17, 2015.
2. U.S. Food and Drug Administration. Design of Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes May Impede Effective Cleaning: FDA Safety Communication. <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm434871.htm>. Updated March 4, 2014.



Infection Prevention Division
3M Health Care
2510 Conway Avenue
St. Paul, MN 55144-1000 USA
800-228-3957
www.3M.com/cleantrace

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