



Recommended Procedure for Testing Endoscopes with an Elevator Mechanism

This document provides the recommended procedure for obtaining acceptable samples from a duodenoscope or other endoscopes with an elevator guidewire channel (after manual cleaning) and testing for residual ATP. This procedure may be used for all models of duodenoscopes or other endoscopes with an elevator guidewire channel. The Olympus® model TJF 130 Series Duodenoscope with an unsealed elevator guidewire channel is featured for purposes of illustration.

Recommended Test Points for Neogen® Clean-Trace® ATP Monitoring System for Endoscopes with an Elevator Mechanism



Neogen® Clean-Trace® ATP Surface Test UXC



Neogen® Clean-Trace® ATP Water Test H2O

Materials Required

- Endoscope with elevator mechanism that has been manually cleaned
- Suction and biopsy valves/covers for the suction biopsy channel and instrument port (specific to the endoscope model being tested)
- Elevator guidewire cleaning tube (no longer than 12 inches)**
- Appropriate, clean Personal Protective Equipment (PPE), including gloves, gown, and goggles or face shield
- Neogen® Clean-Trace® Luminometer
- Clean-Trace ATP Surface Test UXC (2)
- Clean-Trace ATP Water Test H2O
 - One (1) Clean-Trace Water Test H2O is required if the elevator guidewire channel is sealed
 - Two (2) Clean-Trace Water Tests are required if the elevator guidewire channel is open
- Clean-Trace Water Test Accessory Kit WTK, which contains a syringe connector and valve plug
- Sterile sample collection containers and holder
 - 100 mL sterile specimen cup (facility to provide)
 - 5 mL sterile conical collection tube and test tube holder (facility to provide)**
 - Neogen Sample Stand holder (available from Neogen)
- 60 mL sterile syringe
- 10 mL sterile syringe**
- Sterile water (100 mL)

*It is Neogen's recommendation that high-risk endoscopes be monitored after every use. FDA safety communications on endoscopes with elevator mechanisms (duodenoscopes, EUS) and bronchoscopes support our choices for high-risk endoscopes.^{1,2} Neogen 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.

**Only needed if the elevator guidewire channel is unsealed.



Figure 1

Test 1: Surface Test for the Outer Distal End

1. Remove one Clean-Trace ATP Surface Test UXC from the plastic sleeve. Starting at the distal end of the bending section of the insertion tube, swab all sides of the outer surface for a length of 10 cm (Figure 1). Do not swab the elevator mechanism itself at this time.
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 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, proceed to the next step if the RLU value is below 200 or the facility threshold. If the RLU value does not meet those requirements, the endoscope should be recleaned and retested.

Test 2: Surface Test for the Elevator Mechanism and Recessed Housing



Figure 2



Figure 3



Figure 4



Figure 5

1. Turn the control knob so the elevator mechanism is in the down position (Figure 2).
2. Using a fresh Clean-Trace ATP Surface Test UXC, carefully swab the exposed parts of the elevator mechanism and the recessed housing. Swab the visible crevices as thoroughly as possible (Figure 3).
3. Turn the control knob so the elevator mechanism is now in the full Up position (Figure 4).
4. Using the same Clean-Trace Surface Test UXC, carefully swab the exposed parts of the elevator mechanism and the recessed housing (Figure 5).
5. 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.
6. To measure the ATP level, open the sample chamber on the 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.
7. For verification of manual cleaning, proceed to the next step if the RLU value is below 200 or the facility threshold. If the RLU value does not meet those requirements, the endoscope should be recleaned and retested.



Figure 1



Figure 2



Figure 3

Test 3a: Water Test for the Suction Biopsy Channel — Recommended Procedure

Prepare Endoscope to Test the Suction/Biopsy (S/B) Channel

Preparation for testing of the flexible endoscope interior channels requires installation of a connector. This allows a syringe to be attached to flush sterile water through the channel and obtain a sample.

1. Place the syringe connector on the barb hose fitting for the S/B channel, located on the light-guide end of the flexible endoscope. The syringe connector is provided as part of the Neogen® Clean-Trace® WTK Water Test Kit. All kit components are **single-use only** (Figure 1).
2. To prevent leaks during the testing process, insert the suction valve into the suction port, then attach the biopsy value over the instrument channel port (Figure 2).

Test the Suction Biopsy (S/B) Channel

NOTE: Treat all liquid samples as biohazardous. Use aseptic technique during sampling to maintain sample integrity.

1. Fill a 60 cc syringe with air and attach the syringe to the connector. Depress the suction valve (with red dot) located on the control head (Figures 1 and 2).
2. Slowly depress the syringe plunger to push the air through the lumen to remove any cleaning agent.
3. Set up a sample collection container and make sure it is stable (Figure 3).
4. Secure the distal end of the flexible endoscope into the sample collection container. To avoid contamination of the sample, make sure that the distal end of the flexible endoscope does not go below the 40 mL mark.
5. 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.
6. Attach the syringe to the S/B connector on the light-guide end of the suction biopsy port. Depress the suction valve (with red dot) located on the control head.
7. Keeping the suction valve depressed, slowly depress the syringe plunger to push the water through the channel, allowing the rinsate to flow into the collection container.
8. Release the suction valve and detach the syringe from the S/B connector. Draw air into the syringe up to the 60 cc mark and re-attach the syringe to the S/B connector.



Figure 4



Figure 5



Figure 6



Figure 7



Figure 8

9. Depress the suction valve. Keeping the suction valve depressed, slowly depress the syringe plunger to push all the air through the S/B channel of the endoscope. This will allow any remaining rinsate to flow into the collection container (Figure 4).
10. If not testing the rinsate immediately, securely cap the sample collection container to maintain sample integrity (Figure 5).
11. When you are ready to measure the ATP level, open the sample collection container.
12. Remove the Clean-Trace ATP Water Test H₂O from the plastic sleeve and slowly immerse in the water sample, just up to the collar (Figure 6).
13. 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 (Figure 7).
14. To measure the ATP level, open the sample chamber on the 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 (Figure 8).
15. For verification of manual cleaning, proceed to the next step if the RLU value is below 200 or the facility threshold. If the RLU value does not meet those requirements, the endoscope should be recleaned and retested.
16. Remove and/or discard all single-use items.



Figure 1



Figure 2



Figure 3

Test 3b: Water Test for the Suction/Biopsy (S/B) Channel — Alternate Procedure

This method inserts a silicone plug in the suction port, freeing a hand to hold the distal end of the endoscope over the sample collection cup. Some find this method easier because there is no need to stabilize the sample collection cup.

NOTE: This alternate procedure for testing flexible endoscopes should **ONLY** be used on Olympus® brand flexible endoscopes. The silicone plugs in the Clean-Trace Water Test Accessory Kit WTK do not fit all flexible endoscope models and may cause damage if used improperly.

Prepare to Test the Suction/Biopsy (S/B) Channel

Preparation for testing of the flexible endoscope interior channels requires installation of a connector and a small plug.

1. Place the syringe connector on the barb hose fitting for the S/B channel, located on the light-guide end of the universal cord of the endoscope (Figure 1). The syringe connector is provided as part of the Clean-Trace WTK Water Test Kit. All kit components are **single-use only**.
2. Plug the suction port with the silicone plug provided in the Clean-Trace Water Test Accessory Kit WTK. All kit components are **single-use only**. The plug fits into the suction port at the control head of the endoscope and prevents leakage of rinsate during sampling.
3. Attach the biopsy valve over the instrument channel port (Figure 2).

Test the Suction Biopsy (S/B) Channel (Figure 3)

NOTE: Treat all liquid samples as biohazardous. Use aseptic technique during sampling to maintain sample integrity.

1. Set up a sample collection container.
2. Fill a 60 cc syringe with air and attach the syringe to the connector.
3. Slowly depress the syringe plunger to push the air through the lumen to remove any cleaning agent. The fluid removed during this flush should not be collected in the sample container.
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 4



Figure 5



Figure 6



Figure 7



Figure 8

5. Attach the syringe to the S/B connector on the light-guide end of the suction biopsy port.
6. With the distal end of the flexible endoscope inside the 50 mL collection container, slowly depress the syringe plunger to push the water through the channel, allowing the rinsate to flow into the collection container. 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 4).
7. Detach the syringe from the S/B connector. Draw air into the syringe up to the 60 cc mark and re-attach the syringe to the S/B connector.
8. Slowly depress the syringe plunger to push all the air through the S/B channel of the endoscope. This will allow any remaining rinsate to flow into the collection container.
9. If not testing the rinsate immediately, securely cap the sample collection container to maintain sample integrity (Figure 5).
10. When you are ready to measure the ATP level, open the sample collection container.
11. Remove the Clean-Trace ATP Water Test H₂O from the plastic sleeve and slowly immerse in the water sample, just up to the collar (Figure 6).
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 (Figure 7).
13. To measure the ATP level, open the sample chamber on the 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 (Figure 8).
14. For verification of manual cleaning, proceed to the next step if the RLU value is below 200 or the facility threshold. If the RLU value does not meet those requirements, the endoscope should be recleaned and retested.
15. Remove and/or discard all single-use items.



Figure 1



Figure 2



Figure 3



Figure 4



Figure 5

Test 4: Water Test for the Elevator Guidewire Channel

This test is only necessary if the duodenoscope being tested has an open (unsealed) elevator guidewire channel.

Prepare to Test the Elevator Guidewire Channel

1. Set up the 5 mL collection container in the test tube holder.
2. Attach the elevator guidewire channel cleaning tube to the elevator guidewire port. This tube is available from the endoscope manufacturer. The cleaning tube should be no longer than 12" (Figure 1).
3. Fill a 10 cc syringe with air and attach the syringe to the cleaning tube. Slowly depress the syringe plunger to push the air through the lumen to remove any cleaning agent. The fluid removed during this flush should not be collected in the sample container.
4. Detach the syringe from the cleaning tube and draw up 5 cc of sterile water; then pull up an additional 5 cc of air. Attach the syringe to the cleaning tube. Hold the distal end of the duodenoscope over the sample collection container. Slowly and firmly depress the syringe plunger, expelling the rinsate into the sample collection tube (Figure 2).
5. If not testing the rinsate immediately, securely cap the sample collection container to maintain sample integrity (Figure 2).
6. When you are ready to measure the ATP level, open the sample collection container.
7. Remove the Clean-Trace ATP Water Test H₂O from the plastic sleeve and slowly immerse in the water sample, just up to the collar (Figure 3).
8. 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 (Figure 4).
9. To measure the ATP level, open the sample chamber on the 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 (Figure 5).
10. For verification of manual cleaning, proceed to the next step if the RLU value is below 200 or the facility threshold. If the RLU value does not meet those requirements, the endoscope should be recleaned and retested.
11. Remove and/or discard all single-use items.

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.



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