

SAMPLING GUIDE*

Recommended Procedure for Sampling Olympus® Model Flexible Bronchoscopes

This document provides the recommended procedure for obtaining acceptable samples from an Olympus® model flexible bronchoscope after manual cleaning and testing for residual clinical soil.

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



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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| – Bronchoscope that has been manually cleaned | – 3M™ Clean-Trace™ ATP Water Test H2O | – Rack or holder to stabilize the collection containers |
| – Olympus® Single Use Suction Valve MAJ-209 | – 3M™ Clean-Trace™ ATP Water Test Accessory Kit WTK | – 60 cc syringe: sterile, disposable |
| – Olympus® Single Use Biopsy Valve MAJ-210 | – 3M™ Clean-Trace™ Luminometer | – Sterile water, at least 80 mL in a container large enough to accommodate a 60 cc syringe |
| – Clean, lint-free towel | – Sterile sample collection containers (ie. 50 ml conical tubes or specimen cups) | – Personal Protective Equipment (PPE): clean gloves, gown and goggles or face shield |
| – 3M™ Clean-Trace™ ATP Surface Test UXC | | |

* 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 bronchoscopes 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.

Olympus® Single Use Biopsy Valve MAJ-210



Figure 1

Olympus® Single Use Suction Valve MAJ-209



Figure 2



Figure 3

Sample Exterior Surface

Using one 3M™ Clean-Trace™ ATP Surface Test UXC and starting at the distal end of the bending section of the insertion tube, swab all sides for a length of 10 cm.

1. Follow the instructions for use for proper operation of the 3M™ Clean-Trace™ ATP Surface Test UXC and 3M™ Clean-Trace™ Luminometer.
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 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 Bronchoscope for Sampling of Suction/Biopsy Channel

Preparation for sampling of the bronchoscope interior channels requires the installation of the Olympus® Single Use Suction Valve. Install the valve according to Figure 1. The biopsy port should also be capped with either a Olympus® Single Use Suction Valve or an appropriate cover. Appropriate PPE should be worn while preparing and sampling the bronchoscope.

Sampling Bronchoscope Channel

A connector is required so that a syringe may be used to sample the interior channels of the bronchoscope. 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.

1. Attach the suction/biopsy connector to the end of the barb hose located on the single use suction valve (Figure 2).
2. Fill a 60 cc syringe with air.
3. Attach the syringe to the connector and slowly push the air through the lumen. This process removes any cleaning agent remaining in the lumen.
4. Remove the 60 cc syringe from the connector and draw-up 40 cc of sterile water from the water container. Draw-up an additional 20 cc of air into the syringe.
5. Attach the syringe to the connector. Make sure the instrument port is capped to avoid sample leakage.
6. Depress and hold the Biopsy Valve (Figure 3).

Sampling Bronchoscope Channel (continued)

7. With the distal end of the endoscope inside the 50 mL conical collection tube, 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 bronchoscope does not go below the 40 mL mark (Figure 3).
8. 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.
9. 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.
10. 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.
11. 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.
12. 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.

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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