

EndoSwab

Endoscope cleaning verification swab

For use with UltraSnap or SuperSnap ATP Tests



Description/ Intended Use:

EndoSwab is used to collect samples from hard to reach internal channels of reusable medical instruments like endoscopes to verify thorough cleaning. EndoSwab sampling device is designed to be used in conjunction with UltraSnap or SuperSnap ATP test devices and SystemSURE Plus or EnSURE luminometers. This system measures adenosine triphosphate (ATP), the universal energy molecule found in all animal, plant, bacterial, yeast and mold cells. Blood and other biohazard waste contain large amounts of ATP. When ATP is brought into contact with the unique liquid-stable Luciferase/ Luciferin reagent in the ATP test device, light is emitted in direct proportion to the amount of ATP present. Hygiena luminometers measure the amount of light generated in Relative Light Units (RLU). The result provides information on the level of ATP left behind after cleaning to ensure cleaning procedures are effective. After cleaning, all sources of ATP should be significantly reduced.

Required Materials:

- ATP Test Device (UltraSnap, Part No: US2020 or SuperSnap, Part No: SUS3000)
- Hygiena Luminometer (SystemSURE Plus, Part No: SS3H or EnSURE Part No: ENSURE)
- Sterile scissors

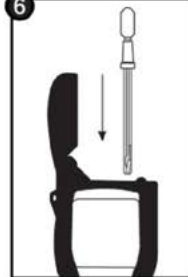
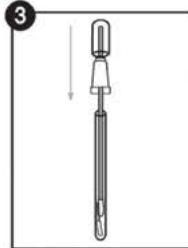
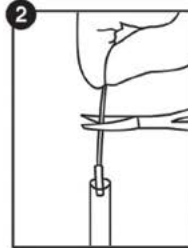
Directions:

1. Wear sterile gloves when collecting sample; use aseptic technique. Remove EndoSwab from packaging. Feed EndoSwab through scope channel. Leave sufficient slack to grip tail end of wand.
2. Withdraw EndoSwab completely out of scope. Place foam tip into open UltraSnap or SuperSnap tube. Using clean (autoclaved or wiped with alcohol) scissors, cut sampling foam tip off wand (about 3 – 5 mm above foam tip), so foam tip drops into test device tube. Ensure foam tip is at bottom of tube.
Tip: ATP test device tube may be placed upright in a test tube holder for ease of use.
3. Replace ATP test device swab in swab tube.
4. To activate device, hold swab tube firmly and use thumb and forefinger to break Snap-Valve by bending bulb forward and backward. Squeeze bulb twice, expelling all liquid down swab shaft.
5. Bathe EndoSwab foam tip in liquid by shaking for 10 seconds. Once activated, sample must be read in luminometer within 30 seconds.
6. Holding luminometer upright, insert entire ATP test device into Hygiena luminometer. Close lid and press “OK” to initiate measurement. Refer to instrument manual for operating instructions. Results will be displayed in 15 seconds. Refer to Interpretation of Results below.

Interpretation of Results:

Table 1: RLU Limits for EndoSwab with UltraSnap and SystemSURE Plus

RLU Measurement	Result	Action
0 - 45	Pass	No action required.
46+	Fail	Re-clean and re-test.



Calibration Control:

It is advisable to run positive and negative controls according to Good Laboratory Practices. Hygiena offers the following controls:

- (Part # PCD4000) Calibration Control Kit for Hygiena Luminometers
- (Part # CK25) ATP Positive Control Kit for ATP Test Devices

Storage & Shelf Life:

- Store at 20 – 25 °C (68 – 78 °F)
- EndoSwabs have a shelf life of 5 years. Check expiration date on label.

Disposal:

Used devices are not a biohazard and may be discarded in the trash.

Safety & Precautions:

Components of EndoSwab do not pose any risk when used in accordance with standard laboratory practice and procedures of this insert.

- EndoSwab test devices are for one-time use. Do not reuse. For further safety instruction, refer to Safety Data Sheet (SDS).

Hygiena Liability:

Hygiena will not be liable to user or others for any loss or damage whether direct or indirect, incidental or consequential from use of this device. If this product is proven to be defective, Hygiena's sole obligation will be to replace product or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return product to Hygiena.