



Hygiena® EndoSwab

Endoscope Cleaning Verification Swab—For use with UltraSnap® or SuperSnap® ATP Tests

Product No. ENDOSWAB-1mm, ENDOSWAB-2mm, ENDOSWAB-3mm, ENDOSWAB-4mm (100 tests)

Introduction

Description and Intended Use

Hygiena® EndoSwab sampling devices are used to collect samples from hard-to-reach internal channels of reusable medical instruments like endoscopes to verify thorough cleaning. EndoSwab is designed to be used in conjunction with UltraSnap® or SuperSnap® ATP test devices and EnSURE® Touch or SystemSURE Plus® 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 (RLUs). 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 (Not Included)

- ATP test device (UltraSnap, Product No. US2020, or SuperSnap, Product No. SUS3000)
- Hygiena luminometer (EnSURE Touch, Product no. ETOUCH, or SystemSURE Plus, Product no. SS3H)
- Sterile scissors

Recommended (Not Included)

- ATP Positive Control Kit for ATP Test Devices (Product No. CK25)
- CalCheck LED Calibration Verification Device (Product No. CAL)
- SureTrend® Platform for data management and analysis (learn more at www.hygiena.com/analytics)

Test Procedure

Wear sterile gloves when collecting samples. Use aseptic technique.

1. Remove EndoSwab from packaging. Feed EndoSwab through the scope channel, leaving sufficient slack to grip the tail end of the wand.
2. Withdraw EndoSwab completely from the scope. Place the foam tip into an open ATP test device (i.e., UltraSnap or SuperSnap) tube. Using clean (autoclaved or wiped with alcohol) scissors, cut the sampling foam tip off the wand about 3 – 5 mm above the foam tip so that the foam tip drops into the ATP test device tube.

Tip: For ease of use, place the ATP test device tube upright in a test tube holder.

Note: Ensure that the foam tip is at the bottom of the ATP test device tube.

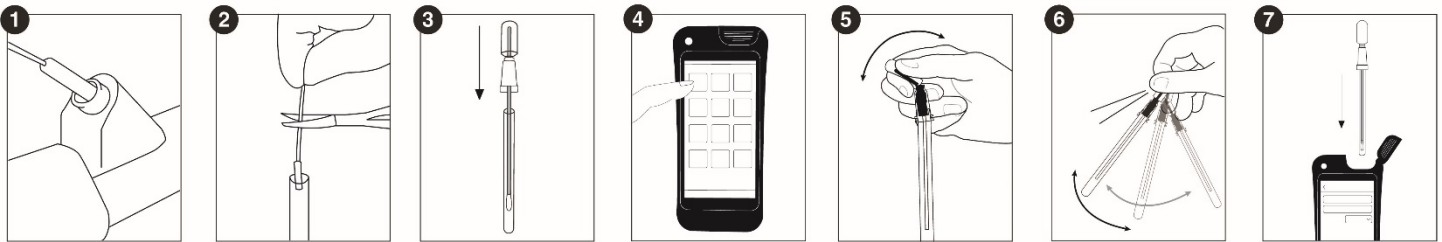
3. Replace the ATP test device swab back in the swab tube.



- If using the EnSURE Touch luminometer, navigate to 'Quick Test,' select 'UltraSnap' and complete the information on the screen.

Note: If using SystemSURE Plus, continue to the next step.

- Activate the device by holding the swab tube firmly and using your thumb and forefinger to bend the bulb forward and backward to break the Snap-Valve. Squeeze the bulb twice to expel all the liquid down the swab shaft.
- Shake for 10 seconds to bathe the EndoSwab foam tip in the liquid. Once activated, the sample must be read in the luminometer within 30 seconds.
- Holding the luminometer upright, insert the entire ATP test device into the Hygiena luminometer. Refer to the instrument manual for operating instructions. In brief:
 - If using the EnSURE Touch luminometer, close the lid and press "Run Test" to initiate the measurement. Results will be displayed in 10 seconds.
 - If using the SystemSURE Plus[®] luminometer, close the lid and press "OK" to initiate the measurement. Results will be displayed in 15 seconds.



Additional Information

Interpretation of Results

Hygiena luminometers are preset with Pass and Fail RLU limits (Table 1) that are based on industry standards and published study recommendations.

Table 1. Recommended RLU Limits for EndoSwab with UltraSnap Devices.

Luminometer	RLU Measurement	Result	Action
EnSURE Touch	0 – 20	Pass	No action required
	21 – 59	Caution	Follow SOP for retesting and recleaning procedures
	≥60	Fail	Reclean and retest
SystemSURE Plus	0 – 45	Pass	No action required
	≥46	Fail	Reclean and retest

Calibration and Controls

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

- ATP Positive Control Kit for ATP Test Devices
- CalCheck LED Calibration Verification Device



Storage and Shelf Life

- Store at 20 to 25 °C (68 to 77 °F).
- Do not use past the expiration date on the label.

Disposal

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

Safety and Precautions

- Components of EndoSwab devices do not pose any risk when used in accordance with standard laboratory practices and procedures within this insert.
- EndoSwab devices are for one-time use. Do not reuse.
- For further safety instructions, refer to the Safety Data Sheet (SDS).

Hygiena Liability

Hygiena will not be liable to the user or others for any loss or damage, whether direct or indirect, incidental or consequential from use of these devices. If this product is proven to be defective, Hygiena's sole obligation will be to replace the product or at its discretion, refund the purchase price. Promptly notify Hygiena within 5 days of discovery of any suspected defect and return the product to Hygiena; please contact Customer Service for a Returned Goods Authorization Number.

Contact Information

For more information, visit www.hygiena.com/contact. For technical support, visit www.hygiena.com/support.