

Positive Control Kit

For Validating Quality of:

UltraSnap® (US2020), SnapShot (All SKUs), SuperSnap® (SUS3000/SUS3000X), SpotCheck Plus (GL100)

Part No: CK25 (25 vials)

Description/ Intended Use:

Positive Control Kit is intended to be used for validating efficacy and quality of UltraSnap, SnapShot, SuperSnap, and SpotCheck Plus test devices. The kit comes with 25 sealed glass vials containing approximately 5×10^{-13} moles of lyophilized adenosine triphosphate (ATP) and sugars to provide a predictable result if devices are used and stored correctly. Each vial provides a sample which produces a positive result when assayed with above Hygiena® products. It is recommended Positive Controls be used to test one device in each bag of test devices or whenever there is concern about product storage temperature. Incorporating Positive Control Kit into an overall Quality Control program will validate results of test devices. In addition to validating test device quality, Hygiena recommends calibration verification of EnSURE® Touch, EnSURE® or SystemSURE Plus™ luminometers with Calibration Control Kit (Part # PCD4000).

Directions:

1. Remove one Positive Control vial from kit box. Carefully remove crimped aluminum seal from top of vial. Without touching inner rim of vial, remove and discard rubber stopper.
2. Allow test device to equilibrate to room temperature (21 – 25 °C) before use. Holding swab tube firmly, twist and pull top of swab out of swab tube. Condensation may be visible on inside of swab tube; this is normal.
3. In a circular motion, swab bottom of Positive Control vial 10 times, taking care to reconstitute all freeze-dried material (white crystals) at bottom. In order to collect entire sample, apply constant pressure while swabbing and rotating swab inside vial.
4. After swabbing, replace swab back in swab tube and discard used vial.
5. 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.
6. Bathe swab bud in liquid by shaking for 5 – 10 seconds.
7. Once activated, ATP test devices must be read in luminometer within 30 seconds.
8. For SpotCheck Plus, devices that do not require a luminometer; activate device according to steps 5 and 6 above, then wait for color reaction that occurs in 60 seconds.

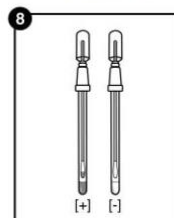
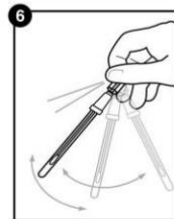
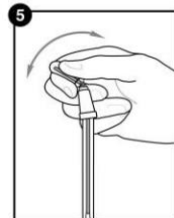
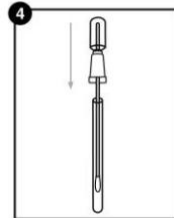
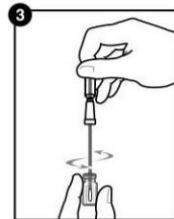
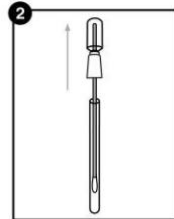
Positive Control Results for Hygiena ATP Devices:

Luminometer	Test Results (RLUs)	
	UltraSnap	SuperSnap
EnSURE and EnSURE Touch	200+	600+
SystemSURE Plus	100+	300+

Troubleshooting ATP Results for Hygiena Test Devices:

Low RLU Results

Lower than expected RLUs with an activated device may indicate insufficient sample collection, or devices are not performing as expected. If RLU result is below minimum RLU detailed above, a more thorough swabbing of vial may be necessary. Retest with another test device from same package



and new Positive Control vial, holding luminometer vertically while taking reading. Check luminometer calibration with Calibration Control Kit (Part #PCD4000). If luminometer is calibrated correctly and test device results are still low, contact Hygiena/distributor to order new test devices.

0 RLU Result

Reading of 0 RLU may be due to device not being activated properly. Activate device and reread in luminometer. Refer to product kit insert and/or instructional videos for activation instruction.

Positive Control Results for SnapShot ATP Devices:

Because Snapshot devices are used in luminometers not manufactured by Hygiena, determining an exact RLU output range by Positive Control can vary depending on luminometer calibration; therefore, a Positive Control can be used to show activity in Snapshot devices. Contact Hygiena/distributor for additional support.

Positive Control Results for SpotCheck Plus (GL100):

SpotCheck Plus will change color from clear to green in less than 60 seconds. If color change does not occur, ensure thorough sample collection was achieved. If color change still does not occur with proper sample collection and activation, contact Hygiena/distributor to order new test devices.

ATP Negative Control:

Negative Control result (background test) is just as important as the Positive Control result. Negative Control results are obtained by inserting new, unopened, activated swab device into luminometer and reading. Negative Control results should be from 0 to 2 RLU. Readings of 5 RLU or higher may indicate contamination of luminometer read chamber or luminometer is out of calibration. For best results with Negative Control, slowly insert swab device in luminometer to avoid static charge buildup and allow swab device to sit in chamber with lid closed for 2 minutes before initiating measurement.

Incorporating Controls into a Quality Control Program:

Positive Control Kit was designed to be incorporated into a Quality Control program that monitors and tracks performance of Hygiena equipment and/or devices. When using Positive Controls to test quality of Hygiena ATP systems, it is recommended that a program point (such as PROG 0) be assigned for Positive Control results. All results can be viewed directly from luminometer or downloaded to SureTrend™ data analysis software for tracking and trending results. Results should be evaluated on an ongoing, regular basis to ensure devices and luminometers are working according to specifications.

Calibration Control:

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

- Calibration Control Kit (Part # PCD4000)

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Storage & Shelf Life:

- Store at 2 – 8 °C (36 – 46 °F)
- Devices have a 24-month shelf life. Check expiration date on label.

Safety & Precautions:

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

- Positive Control Kit vials are for one-time use. Do not reuse.
- Use opened Control vial within 5 minutes of removing rubber stopper.
- Remove only Positive Controls vials needed for testing from refrigerated storage.
- Reconstitute all freeze-dried material in vial by swabbing thoroughly.
- Hold luminometer upright during testing to ensure accurate results.

For further safety instruction, refer to Safety Data Sheet (SDS).

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. Please contact Customer Service for a Returned Goods authorization number.

Contact Information:

If more information is required, please visit us at www.hygiena.com or contact us at:

Hygiena - Americas	Hygiena - International
Phone: 805.388.8007	Phone: +44 (0)1923 818821
Email: info@hygiena.com	Email: enquiries@hygiena.com