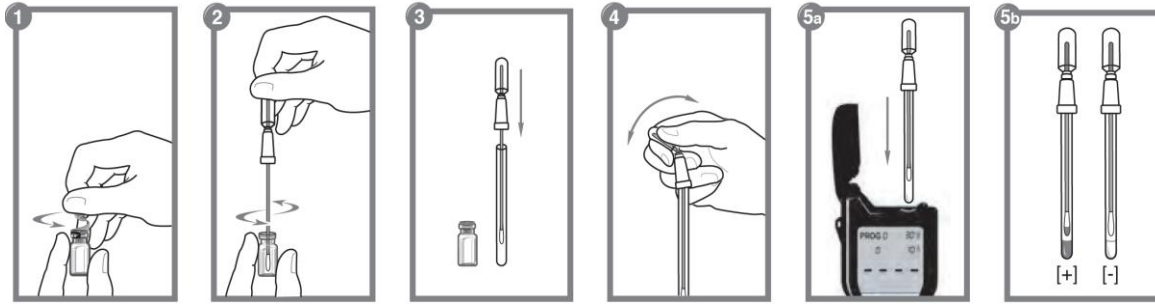


Positive Control Kit | Part Number: CK25 | Quantity: 25 Control Vials
Positive Controls for Validating Quality of:
Ultrasnap™ (US2020), Snapshot™ (All SKUs), SuperSnap™ (SUS3000), SpotCheck™ (L0100), SpotCheck Plus™ (GL100)
Description/ Intended Use:

CK25 is intended to be used for validating the efficacy and quality of Ultrasnap, Snapshot, SuperSnap, SpotCheck and SpotCheck Plus. CK25 comes with 25 sealed glass vials containing approximately 5×10^{-13} moles of lyophilized adenosine tri phosphate (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 that Positive Controls be used to test one device in each bag of 25 devices or whenever there is concern about the product storage temperature. Incorporating the Positive Control Kit into the overall Quality Control program will validate results of luminometer and devices.

Shelf life and Storage: 24 months at refrigerated temperatures. Positive Control vials must be refrigerated at 2° - 8°C (36° – 46°F).

Directions for Use:


1. Remove 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. Following normal procedural steps for device being tested. Gently shake down excess wetting agent in swab shaft tube by shaking device for 2 or 3 seconds or tapping it on the palm of your hand 5 times. Remove swab from swab tube by pulling the top part of device while holding swab tube still. Swab tip must be moist. Do not touch swab, swab shaft, or inside tube body. With 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.
3. Reinsert swab into swab tube.
4. Activate device. Tip device horizontally to immerse swab bud in reagent and shake lightly for 2 seconds. Then hold swab vertically and shake side to side for 10 seconds.
- 5a. Immediately insert swab device into luminometer and take reading.
- 5b. For Hygiena devices that do not require an luminometer; activate device and wait for color reaction that occurs in less than 60 seconds

Interpreting Positive Control Results:

Luminometers	Test Results (RLUs)		
	Snapshot	Ultrasnap	SuperSnap
EnSURE	200 – 600 RLUs	200 – 600 RLUs	1000 – 3000 RLUs
SystemSURE Plus	100 – 300 RLUs	100 – 300 RLUs	500 – 1500 RLUs

The Positive Control should yield these results. If results are:

- Lower than expected RLUs with an activated device may indicate a problem with luminometer. If less than one minute has elapsed since low result, reinsert swab device in luminometer and reread, making sure that luminometer is in vertical position while reading. If more than one minute has elapsed since low result, repeat test with new vial and new swab, holding luminometer vertically while taking reading. Check luminometer calibration with Calibration Control Kit (Part #PCD4000).
- Between 50 to 100 RLUs, a more thorough swabbing of vial may be necessary. Retest with new device and new Positive Control vial.
- Reading of 0 RLUs, may be due to device not being activated properly. Activate device and reread in luminometer.
- Greater than 300 RLUs, may indicate device is contaminated or contamination occurred in testing procedure by either touching inside of vial or device. Retest another device with new Positive Control vial and if reading is again higher than 300 RLUs check SystemSURE Plus luminometer with Calibration Control Kit PCD400. If SystemSURE Plus is calibrated correctly, call Hygiena or distributor to request new devices.

If results fall out of range with further testing, contact Hygiena or distributor from whom luminometer or devices were purchased.

Interpreting Positive Control Results for SpotCheck (L0100) & SpotCheck Plus (GL100):

SpotCheck and SpotCheck Plus will change color from clear to green in less than 60 seconds.

Interpreting Positive Control Results for Snapshot:

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.

Incorporating the Positive Control Kit 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 UltraSnap and SystemSURE Plus luminometer, it is recommended that program point 0 (PROG 0) be assigned for Positive Control results. 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 RLUs. Readings of 5 RLUs or higher may indicate contamination of luminometer read chamber or that 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. Read result. All results can be viewed directly from luminometer or downloaded to computer. The customizable SureTrend™ data analysis software is also available to assist in trending and tracking results. Results should be evaluated to ensure devices and luminometers are working according to specifications.

Warnings and Precautions:

- Do not use Positive Controls past expiration date.
- 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.
- Do not touch swab, internal surfaces of swab tube or the inside of Positive Control vial.
- Do not allow liquids into luminometer.
- For devices that have a color change, bathe swab bud in reagent for 10 seconds by shaking device.
- When reading swab device in SystemSURE Plus & EnSURE luminometers, luminometer must be kept upright. See luminometer manual for further directions.

For more information, visit: www.hygiena.com or email questions to: enquiries@hygiena.com