False Positive and Negative results on the EnSURE Touch

On occasions an unexpectedly high (positive) or low (negative) result may be obtained. There are a number of reasons that false results can occur and the guide below will help identify some of the main reasons.

False Positives

Light Leakage

Light leakage occurs when light from external sources enter the instrument read chamber through the case or lid. This can happen if the case or lid is damaged, the chamber plug was not set correctly, or contaminants from a test device enter the read chamber.

- Inspect the case and lid for damage. If the case is damaged or the lid is not flush with the top of the chamber then a repair may be required.
- Check chamber plug is securely on the base of the instrument. The plug is a threaded cap. If the plug is lose, screw the plug in with the provided tool or an appropriately sized hex key. See our <u>cleaning instructions</u> for more information on removing or replacing the chamber plug.
- Inspect the chamber. If contaminants are present, clean the chamber using <u>these instructions</u>. Remember to promptly discard test devices after recording a result.

Operator Error

- Touching the stem of the sample collection device can introduce contaminants to the test.
- Review the product instructions and confirm instrument operators are following proper test procedures.

Sanitizer Interference

Residual sanitizer on surfaces can potentially interact with the chemistry of the

test device and cause a higher or lower reading.

- Perform the test after cleaning but before applying a sanitizer to eliminate the effects of your sanitizer.
- If you are unable test before applying a sanitizer, allow the for the sanitizer to fully evaporate from the surface before testing.
- Review this <u>technical document</u> for a list of known interactions and a process for testing the effect of your sanitizer.

Hardware Issue

The light sensor can be damaged if the EnSURE Touch is not handled correctly. Solution or liquid spills that enter the instrument can damage the hardware and cause inaccurate readings.

 Perform a calibration check through the Calibration app using a <u>Calcheck</u>. If the calibration check passes, then the equipment is working as intended. If the calibration check fails, then a repair may be required.

False Negatives

Operator Error

- Test devices that are not stored at appropriate temperatures will likely give a false negative. Review the product instructions for your test device for storage requirements. Tests that were not stored at the correct temperature should be discarded.
- Expired tests will have reduced efficacy and a weaker reaction, resulting in a lower reading. Tests that are past the expiration date on the label should be discarded.
- Generally, the test reaction occurs within a small window. Measuring a test device well after the reaction has occurred will result in a lower reading. Review the product instructions for your test and confirm you are activating and testing your device within the appropriate timeframe.
- Overloading the test device can cause a quenching effect. Other materials
 present in the sample may consume the reagents without producing the
 desired reaction. Surface tests are intended for visibly clean surfaces. A

dilution may be required when testing products.

 Significantly delaying testing after sample collection can potentially cause lower results. Most tests contain a wetting solution to aid in sample collection. Prolonged exposure to the wetting solution can damage the sample. Test ATP samples within 30 minutes of sample collection.

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Contact Hygiena Technical Support for further assistance.

- Phone: 1-888-HYGIENA (1-888-494-4362, option 2)
- Email: techsupport@hygiena.com
- <u>Submit a Support Ticket</u>
- <u>Schedule a Microsoft Teams meeting with support</u>