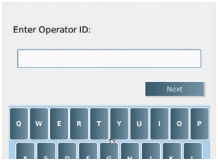
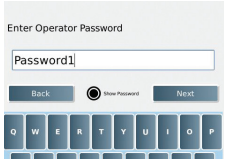
the endosafe® nexgen-pts™

INHIBITION/ENHANCEMENT (I/E) CARTRIDGE ASSAY GUIDE

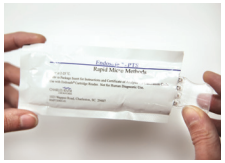


01 At the **Enter Operator ID** prompt, enter your username and click **Next**. A valid Operator ID must be entered if User Management is turned ON.



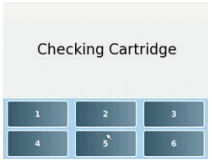
02 If User Management is turned on, at the **Enter Operator Password** prompt, enter your password and click **Next**.

03 As the reader warms in preparation for use, the **Initializing** message appears. When the unit has reached 37.0 °C, the screen will display the **Insert Cartridge** message. The reader will display a **Log Out** button if User Management is turned ON.



04 Allow refrigerated cartridges to reach room temperature before using. Remove cartridge from pouch; avoid touching the sample wells.

05 Insert the cartridge firmly into the slot at the front of the reader with sample wells facing up.



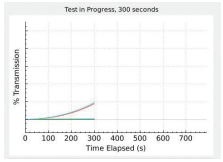
06 The reader will then verify cartridge integrity; used or damaged cartridges will signal an alert.

07 Prior to testing, be sure you have access to the **Certificate of Analysis** (COA), which can be found within your Endosafe®-PTS™ cartridge package. This information includes the cartridge lot number and calibration code.

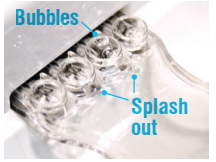
08 A series of prompts will appear for you to enter the information necessary to run the assay. Enter values for each field, clicking the forward arrow until all fields are complete. Include **Cartridge Lot #, Cartridge CAL Code, Sample ID, Sample Lot,** and **Dilution**. **Sample ID, Lot Number,** and **Dilution Factor** will be entered for up to four (4) dilutions.

09 Once the necessary values are entered, the reader will display a prompt to **Add Sample to Cartridge**.

10 With a calibrated pipettor, dispense exactly 25 μL of the first sample dilution into well 1 and repeat for subsequent dilutions into wells 2 through 4, holding the pipettor so that the tip is at an angle and not completely at the bottom of the sample reservoir. Click the **Done – Start Test** icon on the home screen to initiate testing.



11 Tests results will appear on screen when the assay is complete. You can send this data to a network printer, Zebra printer, download to Charles River Cortex™, or save to a USB.



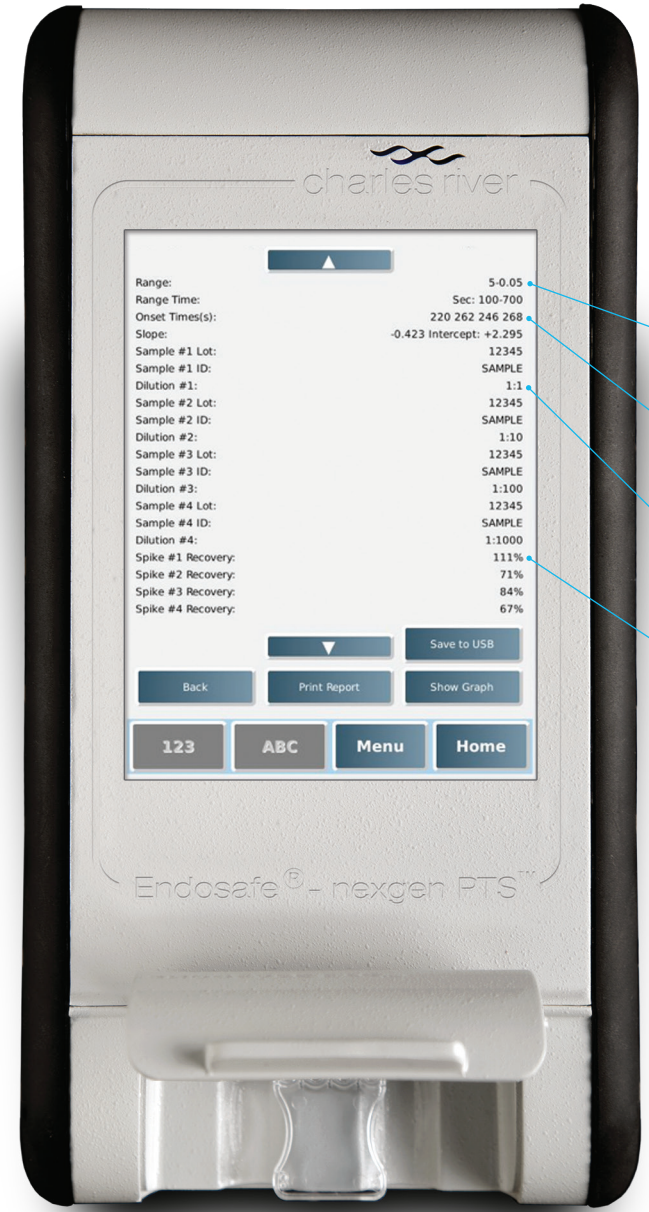
*IMPROPER TECHNIQUE

12 Holding the pipette straight up and down at the bottom of the sample well can force some sample into the channel early and disrupt the reagent mixing stations. Avoid any technique that is prone to splash out or bubbles.

13 Splash out will render the volume inaccurate, which can lead to invalid test results. Bubbles can cause false onset times due to the disturbance of light transmittance and can interfere with reconstitution of reagents within the cartridge.

Results: The Inhibition/Enhancement Cartridges are designed to provide an approximation of the least interfering dilution prior to performing a product validation. The I/E Cartridges provide the spike recovery of up to four (4) different dilutions or four (4) different samples. These cartridges are unlicensed and cannot be used for release testing of a product. When the assay is complete, the results are displayed on the reader and can be sent to a network printer , Zebra printer, download to Charles River Cortex™, or save to a USB. The Sample ID, Sample Lot Number, Dilution, and Spike Recovery for each sample well is displayed. Valid Spike Recovery should be between 50%-200%. Note: the product validation must be performed using the chosen dilution on FDA licensed cartridges.

Spike recovery: The spike is an aliquot of test sample together with a known amount of endotoxin. The spike serves as the check for interference (inhibition and enhancement). Inhibition and enhancement are conditions that adversely alter the recovery of endotoxin in a test sample. Inhibition is a condition where an LAL test sample decreases LAL reactivity, resulting in endotoxin recovery being less than expected. Enhancement is a condition where an LAL test sample reacts more rapidly than expected, resulting in endotoxin recovery being greater than expected. For a valid assay, the spike recovery value must be between 50% and 200%, thus indicating no significant interference from the test sample.



Cartridge sensitivity range
Lambda = lowest value (0.05 EU/mL)

Reaction time of 4 channels
All 4 channels are spiked channels

Dilution factor/Concentration
1:1=neat, 1:10, 1:100, 0.1 mg/mL, 0.01 mg/mL, etc.

Spike recovery
Represents % of spike that was recovered in all 4 channels. Must be between 50% and 200% for a valid test result

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