



CLIA Complexity: WAIVED*

*This statement only applies to customers within the United States:

For use with anterior nasal swab specimens.

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA Waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA Waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA.

Failure to follow the instructions or modifications to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Materials Needed from Control Swab Kit and Single Test Box

Cartridge



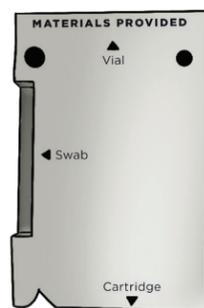
Sample vial



QC swab (Positive or Negative)



Single test box



LIAISON NES® Instrument



A. Touch Screen **B.** Cartridge Bay **C.** Barcode Scanner Window

Before performing this test, refer to the LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit Instructions for Use for the complete QC Test Procedure and the LIAISON NES® User Manual for additional information.

NOTE: Run **BOTH** a positive and negative QC.

All LIAISON NES® Kit disposable components are designed for single use only and must not be reused.

Do Not remove or tamper with the foil on the underside of the cartridge.

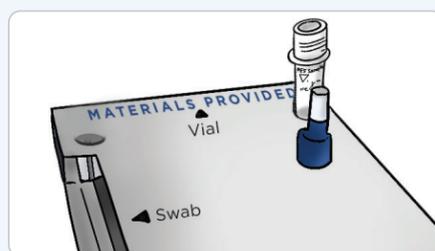
Do Not use any components after the printed expiration date.

To perform a QC test, follow the directions below.

1 PREPARE TO PERFORM THE QC TEST

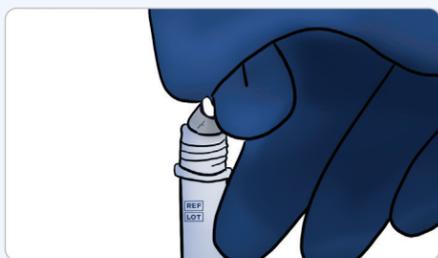


Wear new nitrile or latex gloves and appropriate personal protective equipment (PPE). Sanitize the work surface.

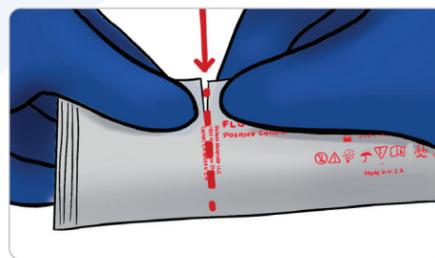


Materials set-up in single test box.

2 PREPARATION OF QC SWAB

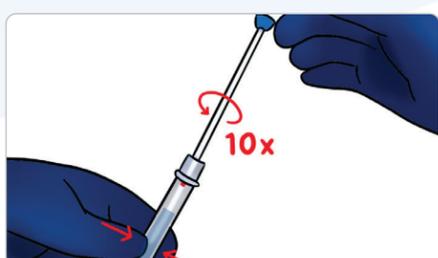


Remove the foil seal from the sample vial.

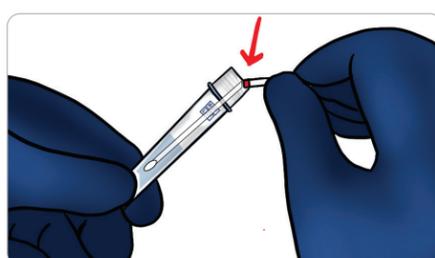


Tear open the control swab package.

SAVE PACKAGING WITH QR CODE.



Place the QC swab into the sample vial. Rotate the swab **10 times while squeezing** the swab head.



Break the swab shaft at the red mark by snapping along the rim of the sample vial.

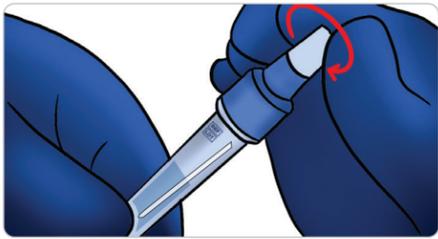
Dispose of the swab handle into the biohazardous waste.



Twist blue cap onto the sample vial with the swab head inside.

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3 CARTRIDGE PREPARATION



Unscrew the clear nozzle cap.



WARNING!
Place cartridge on hard flat surface and keep level.



Insert the tip of the sample vial into the cartridge sample port. Firmly squeeze the sample vial to dispense **ALL** the liquid into the cartridge.



Carefully remove the sample vial and close the cartridge lid securely.
Dispose of the sample vial and clear nozzle cap into the biohazardous waste.

Failure to transfer ALL the liquid into the cartridge can cause invalid results.

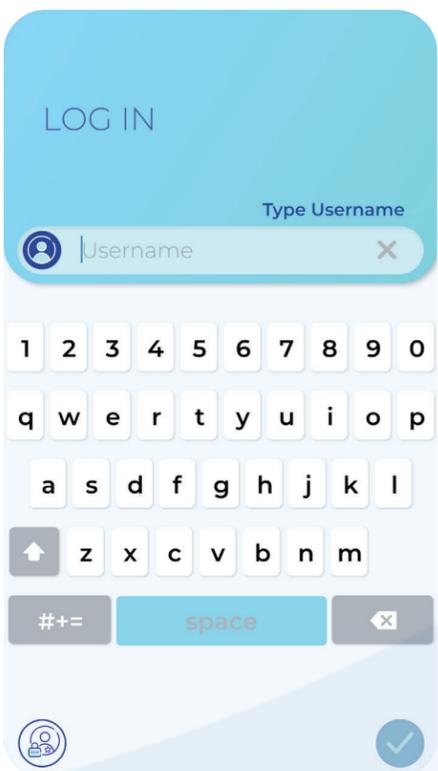


DO NOT TILT OR SHAKE

WARNING!

Keep cartridge upright - do not tilt or shake. Perform the test immediately.

4 START QC TEST

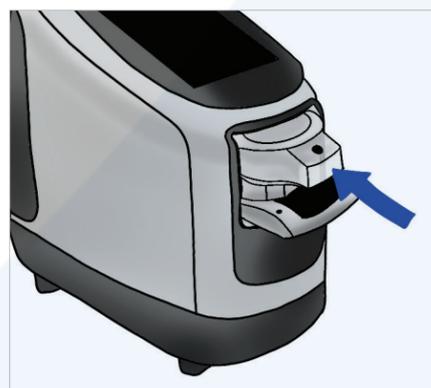


Login to the LIAISON NES® instrument.



Press "Run QC" Test from the home screen.

Scan the QR Code from the emptied control packaging. The instrument door will automatically open.

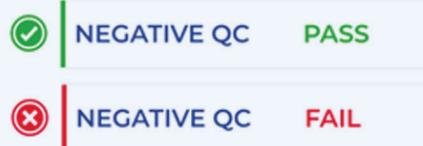


Ensure cartridge is labeled with control type and loaded.
Run the test following on-screen instructions.

5 COMPLETING THE TEST



Door automatically opens, remove and dispose of the cartridge.



Repeat QC test for the other control swab.

CLOSE the door to view results.
In case of a **FAIL**, retest.

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Refer to the LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit Instructions for Use and LIAISON NES® User Manual for complete instructions.

Rx Only. For In Vitro Diagnostic Use. Products are region specific and may not be approved in some countries/regions.

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