Diasorin

LIAISON NES®

Operator Initial Use Checklist

Molecular Point-of-Care Testing | Implementation Guide

Note: *This checklist is a training aid, not a substitute for an SOP. Sites must maintain SOPs based on manufacturer instructions and site policies.*

Confirm you have completed, or would be able to complete, the following tasks. Refer to the Quick Reference Guides and Instructions for Use for complete step-by-step instructions.

1. Review Training Materials

Documents

- ☐ LIAISON NES® Assay Specific Quick Reference Guide – Prepare for a Patient Test and Running a Patient Sample
- ☐ LIAISON NES® Assay Specific Quick Reference Guide – Prepare for a Quality Control Test
- ☐ LIAISON NES® Instrument Quick Start Guide
- ☐ LIAISON NES® Troubleshooting Guide
- ☐ LIAISON NES® Assay Specific Test Kit Instructions for Use
- ☐ LIAISON NES® Assay Specific Control Swab Kit Instructions for Use
- ☐ LIAISON NES® User Manual
- ☐ LIAISON NES® Cloud User Manual

Videos

- ☐ LIAISON NES® Instrument Set-up Video
- ☐ LIAISON NES® Assay Specific Self Collection Demo
- ☐ Assay Specific Patient Testing + Sample Preparation
- ☐ Assay Specific Quality Control Testing
- ☐ LIAISON NES® System Replacement Workflow Video
- ☐ Diasorin Cloud Demo

Resources & Downloads: us.diasorin.com/liaison-nes/resources-download

2. Quality Control (QC) Testing

QC is required on first use, per lot, and per instrument. QC must be repeated at the interval set by your site administrator, up to a maximum of 60 days. Use assay kit components with Control Swabs (NES4460). Run Negative QC first, then Positive QC.

Note: Use only Control Swabs from the LIAISON NES® Control Swab Kit for QC. The patient test swab (LIAISON NES® Swab) is NOT used for QC..

For the complete procedure, refer to: LIAISON NES® Assay Specific Control Swab Kit Instructions for Use and LIAISON NES Assay Specific Quick Reference Guide - Preparing for a Quality Control Test

- ☐ Perform a Negative QC test following the quality control quick reference guide.
- ☐ Perform a Positive QC test following the quality control quick reference guide.
- ☐ Confirm both QC results show "PASS."
- ☐ Discard used cartridges, vials, and swabs in biohazardous waste.

Critical Points During QC:

CRITICAL: Squeeze the vial while rotating the swab.

CRITICAL: Keep cartridge LEVEL at all times. Do not tilt or shake.

CRITICAL: ALL liquid must be transfered into the cartridge.

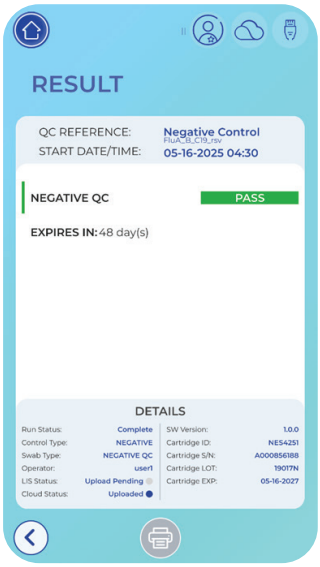
WARNING: Do not touch the cuvette (the flat protruding part on the back of the cartridge) while dispensing.

WARNING: If liquid spills or the vial is leaking or empty, discard and use a new vial.

WARNING: Run the test immediately after closing the sample port.

QC Result Interpretation

QC PASS



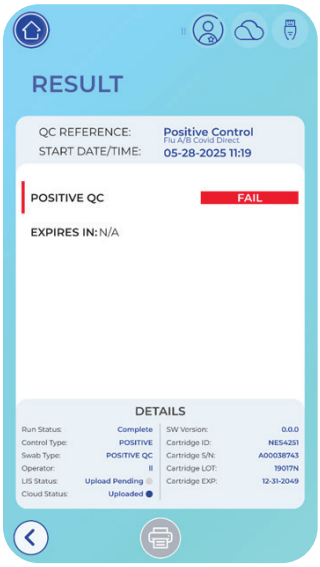
PASS

Proceed to the next control.

Repeat QC test for the other control swab.

CLOSE the door to view results.

QC FAIL



FAIL

In case of a FAIL, retest with a new cartridge.

Do not test patients until both Negative and Positive QC pass.

If persistent, see Troubleshooting Guide or call (800) 838-4548.

3. Patient Testing

For the complete procedure, refer to: LIAISON NES® Assay Kit Instructions for Use and LIAISON NES Assay Specific Quick Reference Guide - Prepare for a Patient Test and Running a Patient Sample

- ☐ Confirm QC passed before testing patients.
- ☐ Verify patient identity and specimen label per site policy.
- ☐ Collect a nasal swab specimen following the LIAISON NES® Quick Reference Guide – Specimen Collection procedure.
  Storage: Once collected, the sample can be stored inside the swab tube at room temperature and must be processed within 2 hours from collection.
  Transportation: The sample can be transported inside the swab tube at room temperature.
- ☐ Prepare the sample and load the cartridge following the quick reference guide.
- ☐ Run a patient test and confirm a valid result is displayed.
- ☐ If Invalid: Retest with a new cartridge and freshly collected specimen.
- ☐ Discard used cartridges, vials, and swabs in biohazard waste.

For all other issues refer to the troubleshooting guide (us.diasorin.com/sites/default/files/nes-resource/DSM-DRM-005278.pdf). If further assistance is required call Diasorin technical support.

Critical Points During Patient Testing:

CRITICAL: Swab BOTH nostrils with LIAISON NES® anterior nasal swab.

CRITICAL: Squeeze the vial while rotating the swab.

CRITICAL: Keep cartridge LEVEL at all times. Do not tilt or shake.

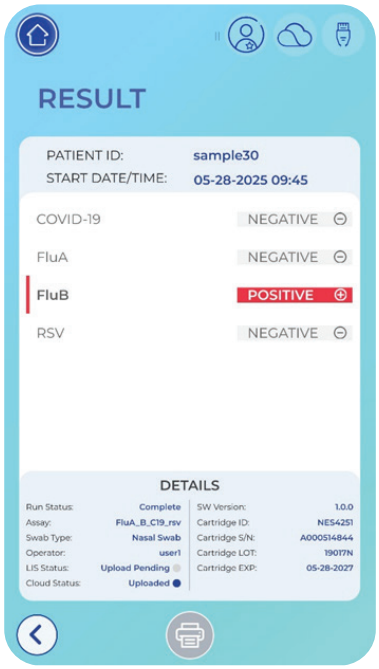
CRITICAL: ALL liquid must transfer into the cartridge.

WARNING: Do not touch the cuvette (the flat protruding part on the back of the cartridge) while dispensing.

WARNING: Run immediately after prep. Cartridge must be used within 2 hours of opening the foil pouch.

WARNING: If liquid spills or the vial is leaking or empty, discard and use a new vial.

4. Interpretation



Results display individually for each target:

COVID-19 | Flu A | Flu B | RSV

POSITIVE

Result indicates the presence of Flu A and/or Flu B and/or RSV and/or COVID-19 in the patient sample.

NEGATIVE

Result indicates the absence of Flu A and/or Flu B and/or RSV and/or COVID-19 in the patient sample.

INVALID

Collect a fresh sample and re-test with a new test cartridge from the same kit or a new kit.

If the problem persists, contact our Technical Support Team at our toll-free number (800) 838-4548.

Follow site-specific policies for result documentation and reporting.

5. Instrument Maintenance

- ☐ Log out of the instrument (If required by site policy).
- ☐ Wipe exterior with bleach-free disinfectant wipe. Follow with damp paper towel, then dry.
  Never use bleach on the touchscreen.
- ☐ Clean the work surface per site cleaning policy.
- ☐ Ensure reagents and control swabs are stored per storage requirements (15°C to 25°C).

Technical Support
US Toll-Free: +1-800-838-4548
Email for Technical Issues: ts.nes@diasorin.com
Email for Cloud Issues: ts.cloud@diasorin.com

For approved procedures, refer to the Assay Specific Instructions for Use and Quick Reference Guide documents available on the Resources & Downloads microsite.

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Operator Name Date

_____ _____

Trainer Signature Date

Diasorin
Cypress, CA
U.S.A.: (800) 838-4548
w: bit.ly/LIAISONNES

This document is intended for first-use training support. For approved testing procedures, refer to the IFU and QRG documents.

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