



Procedure Verification Approval and Review Sheet

PREPARED BY:

DATE:

SUPERVISOR REVIEW:

DATE:

CLIA LABORATORY DIRECTOR
OR DESIGNEE APPROVAL:

IMPLEMENTATION DATE:

SUPERSEDES PROCEDURE
VERSION/DATED:

DATE PROCEDURE RETIRED:

Periodic Review Log

Record each scheduled review of this procedure. The CLIA laboratory director (or designee) signs and dates each time the procedure is reviewed, per your laboratory’s review schedule.

CLIA Laboratory Director or Designee	Date Reviewed

This form is provided as an optional template to support recordkeeping. It should not replace your laboratory’s established training, competency assessment, or applicable regulatory requirements.

LIAISON NES® FLU A/B, RSV & COVID-19 Verification Form

ACCOUNT NAME:

ADDRESS:

TELEPHONE:

LIAISON NES® FLU A/B, RSV & COVID-19
LOT / EXP (LIST EACH LOT USED):

DATE(S) TESTED:**SUPERVISOR SIGNATURE:**

Record the results from the reference samples below. For each sample, document the Sample Number, the LIAISON NES[®] FLU A/B, RSV & COVID-19 result, the tester's initials, and any applicable comments. Once the LIAISON NES[®] result has been recorded as positive or negative for each target, document the expected result. Reference samples are processed using the LIAISON NES[®] FLU A/B, RSV & COVID-19 Control Swab Kit (NES4460), which includes positive control swabs (NES4461) and negative control swabs (NES4462).

LIAISON NES® External Quality Control Log (Supplemental Form)

The LIAISON NES® system uses quality control (QC) tests to ensure the accuracy of test results. Each site should establish its own frequency of QC testing based on applicable local laws, regulations, and standard good laboratory practice. QC testing should be performed in the following instances:

- Before using a new cartridge lot
- For every new assay added to the instrument menu
- For each new lot of assays on an instrument
- Every 60 days for each lot on each instrument

It is also recommended that QC testing be performed in the following instances:

- After adding a new user to the system
- Every 30 days for each lot on each instrument

Quality Control Expiration Settings

For administrator use only:

- QC Lot Lockout: Toggle to enable or disable requiring quality control (QC) testing for each lot of consumables. Disabled by default. When enabled, QC testing is required for each new lot of consumables before it can be used in patient testing.
- QC Expiry Period: Adjust the quality control expiration settings as needed between 1-365 days.

Date	Instrument SN	Kit LOT / EXP	Positive Control LOT / EXP	Negative Control LOT / EXP	Positive Control Result	Negative Control Result	Tester's Initials	Comments

Name: _____ Date: _____

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Patient Test Record

LIAISON NES® INSTRUMENT SERIAL #: _____

For each test, record the Date, Patient Name, Patient ID Number, Patient Test Result (Positive, Negative, or Invalid), and the Tester's initials. If a result is Invalid, collect a fresh sample and re-test with a new cartridge according to the Instructions for Use.

LIAISON NES Cleaning Log

The LIAISON NES instrument exterior surfaces, as well as surfaces visible when the lid is open, should be cleaned regularly and immediately following any potential patient sample contamination. The surrounding bench area should also be cleaned. Refer to the LIAISON NES User Manual for approved cleaning agents and complete maintenance instructions.

- Power off the instrument before cleaning.
- Clean all exterior surfaces with a bleach-free disinfectant wipe containing at least 0.184% n-alkyl dimethyl benzyl ammonium chloride and 0.184% n-alkyl dimethyl ethyl benzyl ammonium chloride (e.g., Clorox® Disinfecting Wipes or equivalent), then wipe with a water-dampened paper towel and dry.
- **Never use bleach on the touchscreen,** and never clean internal parts or the cartridge bay with detergents or solvents. Wear appropriate PPE and treat all used materials as biohazardous.

MONTH: _____ YEAR: _____ SERIAL NUMBER: _____

MONTHLY REVIEW DATE: _____ INITIALS: _____

Day	Performed By (Initials)	Comments / Corrective Action	Day	Performed By (Initials)	Comments / Corrective Action
1			17		
2			18		
3			19		
4			20		
5			21		
6			22		
7			23		
8			24		
9			25		
10			26		
11			27		
12			28		
13			29		
14			30		
15			31		
16					

This form is provided as an optional template to support recordkeeping. It should not replace your laboratory's established Quality Assessment policies, procedures, or applicable regulatory requirements. Each site is responsible for its own quality assessment program per applicable local, state, and federal regulations and good laboratory practice.

Quality Assessment Review Form and Checklist

These forms are used for periodic review of the patient testing process (e.g., at least annually, or per your laboratory's defined schedule). The completed forms should be filed with the quality assessment records.

Quality Assessment Activity	Comments	Date	Initials
Patient test management: evaluate criteria for specimen submission, handling, and rejection; test results requisitions and reporting, accuracy and reliability of reports.			
Quality control: assess control data, errors in reporting results, and corrective actions taken with appropriate documentation records.			
Proficiency testing: review the effectiveness of corrective actions taken for unsatisfactory performance or failures.			
Comparison of test results: review at least semi-annually comparative results for multiple methods, instruments, or site correlations when more than one procedure exists.			
Relationship of patient test information to test results: evaluate patient test reports for accuracy of patient information, test results, and normal ranges. Identify and evaluate results inconsistent with patient's age, sex, diagnosis, and other test parameters.			
Personnel: evaluate the effectiveness of policies and procedures for assuring employees' competence of testing and reporting test results.			
Communications: evaluate documented problems and corrective actions that occur between the laboratory and the authorized individual who orders or receives the test result.			
Complaint investigation: evaluate documented complaints and corrective actions.			
Quality assessment reviews with staff: document discussion with staff regarding identified problems and corrective actions during the QA review.			

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Corrective Action Form

Use this form to document problems or errors identified during testing and the corrective actions taken. For instrument errors, follow the on-screen troubleshooting instructions and the LIAISON NES User Manual. If the issue persists, contact Diasorin Technical Support at (800) 838-4548.

TECHNOLOGIST: _____ DATE: _____

SUPERVISOR: _____ DATE: _____

LABORATORY DIRECTOR: _____ DATE: _____

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Room Temperature Log

EQUIPMENT: _____

NAME OF FACILITY: _____

TO BE RECORDED AT THE BEGINNING OF EACH WORKDAY.

TEMPERATURE RANGE: _____

Note: Use the correct range for the equipment being logged. For assay kit/reagent storage, use the range printed on the kit label (do not refrigerate or freeze). For the LIAISON NES instrument, the operating temperature is 15–30 °C (59–86 °F).

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LIAISON NES® Training/Competency Record

This is to verify that personnel responsible for running the LIAISON NES FLU A/B, RSV & COVID-19 assay at _____ have received thorough in-service training on the test and its associated procedures. This has included:

- Review of the package insert and Quick Reference Guides (QRGs)
- Demonstration of the product assay
- Successful performance of the LIAISON NES assay and interpretation of results

Names of the personnel who have been trained with the LIAISON NES and are responsible for reporting patient results:

Print Name	Signature	Date

Signature of Laboratory Director(s) responsible for personnel and testing:
SIGNATURE: _____ DATE: _____
TRAINER: _____ DATE: _____

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