

LIAISON NES[®]

Diasorin



LIAISON NES[®] FLU A/B, RSV & COVID-19 Control Swab Kit

Instructions for Use



REF NES4460

IVD

Rx Only

For In Vitro Diagnostic Use.

CLIA Complexity: WAIVED*

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

For use with 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 modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

INTENDED USE

The LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit is intended to be used as positive and negative controls with LIAISON NES® FLU A/B, RSV & COVID-19 assay for use on the LIAISON NES® instrument. These controls are not intended for use with other assays or systems.

MATERIALS PROVIDED

The LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit (NES4460) contains the following materials:

- (10) LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control swabs (NES4461)
- (10) LIAISON NES® FLU A/B, RSV & COVID-19 Negative Control swabs (NES4462)
- (1) Printed copy of the Quality Control Test Quick Reference Guide

MATERIALS REQUIRED BUT NOT PROVIDED

- LIAISON NES® FLU A/B, RSV & COVID-19 Kit (NES4450)
- Disposable, powder-free nitrile gloves
- Biohazard waste container
- LIAISON NES® instrument (NES1001)

KIT DESCRIPTION

The LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit contains 10 individually wrapped positive control swabs and 10 individually wrapped negative control swabs. Each control swab can be used only once. Upon receipt of the kit, store at room temperature (Store all components at the temperature range indicated on the label). Each control swab must be used immediately after opening the sleeved pouch.

Component Name	REF	Number of swabs/Kit	Number Needed to Perform One Test
LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit	NES4460	10 positive control swabs 10 negative control swabs	1

COMPONENT DESCRIPTION

Kit Component	Contents
LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control Swab	The FLU A/B, RSV & COVID-19 Positive Control Swab contains influenza A, influenza B, respiratory syncytial virus A (RSV-A), and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) viral particles that have been inactivated using irradiation and chemical treatments. The solution is lyophilized into a ready-to-use swab.
LIAISON NES® FLU A/B, RSV & COVID-19 Negative Control Swab	The FLU A/B, RSV & COVID-19 Negative Control Swab is a ready-to-use swab that does not contain any viral particles.

HANDLING AND STORAGE

1. Store LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit at room temperature (15–30°C).
2. Store the LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit away from sunlight.
3. Do not refrigerate or freeze the control swabs.
4. Do not use the control swabs beyond their expiration dates.
5. After opening the test cartridge from the pouch, use it within 1 hour (60 minutes).
6. Perform the test immediately after preparing the cartridge.

WARNINGS AND PRECAUTIONS

1. Do not open the cartridge pouch until ready to use.
2. The negative and the positive control swabs are intended for single use only.
3. Consult the LIAISON NES® User Manual for additional warnings, precautions, and procedures related to the operation of the LIAISON NES® instrument.
4. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling kit reagents and equipment. Wash hands thoroughly after completion of the test.
5. Do not eat, drink, smoke, handle contact lenses or apply makeup in areas where kit reagents and/or human specimens are used.
6. Dispose of used and/or unused kit reagents and human specimens according to local, state, and federal regulations.
7. Contamination of human specimens or reagents can produce erroneous results. Handle samples and reagents according to standard laboratory practices.
8. Test should be performed at room temperature (Store all components at the temperature range indicated on the label).
9. Avoid touching, scratching, or tampering with the underside foil on the cartridge. Avoid scratching or tampering with the cartridge wells and reagents located on the bottom of the cartridge. Only open the cap to input the specimen. Do not attempt to break open the cartridge.
10. Before inserting a prepared cartridge (with sample loaded) into the instrument, ensure the cartridge cap is fully closed.

11. Upon inhalation or skin contact with the reagents, first aid measures should be taken. Refer to the Safety Data Sheet (SDS) for the product for additional information regarding emergency response and exposure measures.
12. Use the sample vial provided in the kit to dispense specimen into the cartridge sample port.
13. Do not use kit or contents if kit packaging or contents appear broken or damaged. Contact Diasorin Technical Support.
14. This product must be handled in accordance with Biosafety Level 1 practices as described in the United States Department of Health and Human Services Centers for Disease Control and Prevention (CDC) and National Institutes of Health (NIH), Biosafety in Microbiological and Biomedical Laboratories, or other equivalent guidelines. Although this product has been inactivated, there is no known test or inactivation method that can assure that this product will not transmit infection.^{1,2}
15. If packaging or contents appear to be broken or damaged, do not use and contact Diasorin Technical Support. Contact information is located on the last page of this document.”

INSTRUCTIONS FOR USE



Read this entire LIAISON NES® FLU A/B, RSV & COVID-19 Control Swab Kit Instructions for Use (IFU) (this document) before running a test.

Gather materials:

- (2) LIAISON NES® FLU A/B, RSV & COVID-19 cartridges (NES4451)
- (2) NES sample vials with buffer and caps (NES1502)
- (1) LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control Swab (NES4461)
- (1) LIAISON NES® FLU A/B, RSV & COVID-19 Negative Control Swab (NES4462)

To perform a Quality Control test, run BOTH the positive and negative control swabs provided in the kit.

Prepare the working area:

- Disinfect the surface where the procedure will be performed. Remove and lay out the material gathered.
- Wash hands with soap and water. If soap and water are unavailable, use hand sanitizer to disinfect hands.

Test Procedure *(Refer to the quick reference guide provided with the kit for a pictorial depiction of the test procedure.)*

1. Take a LIAISON NES® cartridge from a single test box and open the sample port.
2. Take a NES pre-filled sample vial from a single test box and remove the foil seal to open it.



If any liquid spills or if a vial is leaking – DO NOT USE. Use a new sample vial.

3. Take a LIAISON NES® FLU A/B, RSV & COVID-19 Positive Control Swab (NES4461) from the control swab kit and tear open. Save the packaging with the QR code to scan later.
4. Place the QC swab into the sample vial and rotate the swab ten (10) times while squeezing the swab head.

5. After rotation, break swab shaft at red mark by snapping along the rim of the sample vial. *(Refer to the quick reference provided with the kit for a pictorial depiction.)*
6. Twist the blue cap onto the sample vial with the swab head inside.
 -  *Dispose swab handle into biohazardous waste.*
7. Unscrew the clear nozzle cap of the sample vial.
 -  *Place the cartridge on a hard flat surface and keep level.*
8. Insert tip of the sample vial into the LIAISON NES® Cartridge sample port.
9. Firmly squeeze the sample vial to dispense ALL the liquid.
 -  *Failure to transfer ALL the liquid into the cartridge can cause invalid results.*
10. Carefully remove the sample vial and close the cartridge securely.
 -  *Dispose sample vial and clear nozzle cap into biohazard waste.*
 -  *Keep cartridge upright- do not tilt or shake. Perform the test immediately.*
11. Log into the LIAISON NES® instrument.
12. Press “Run QC” Test from the home screen.
13. Scan the QR code from the emptied control swab packaging using the ‘Barcode Scanning Window’ on the LIAISON NES® instrument. The door will open automatically.
14. Ensure the cartridge is labeled with the corresponding control type provided in the control swab kit
15. Insert the labeled LIAISON NES® test cartridge into the LIAISON NES® instrument with specimen port facing outwards. *(Refer to the quick reference guide provided with this kit for a pictorial depiction.)*
16. Fully close the LIAISON NES® instrument door.
17. Run the test following on-screen instructions.
18. The door will automatically open when the test run is completed. Remove and dispose the cartridge.
19. Close the door to view the test results.

After the completion of the run, the same instructions should be repeated using the LIAISON NES® FLU A/B, RSV & COVID-19 Negative Control Swab (NES4461) to complete the quality control procedure.

RESULTS

Upon completion of a quality control run, results will display automatically.

The software displays a result (“Pass” or “Fail”) for the control.

Results	Interpretation
Pass	<ul style="list-style-type: none"> Positive control swab is positive, indicating the presence of flu A, flu B, RSV, and SARS-CoV-2 RNA Negative control swab is negative, indicating the absence of flu A, flu B, RSV, and SARS-CoV-2 RNA, and has a valid IC result
Fail	<ul style="list-style-type: none"> Positive control swab is not positive for all four (4) targets Negative control swab is not negative for all four (4) targets A “Fail” result could also indicate the inability to conclusively determine the presence or absence of flu A and/or flu B and/or RSV and/or SARS-CoV-2 RNA in the quality control swab. In case of a “Fail” result, the control needs to be retested. See “Fail Results” section.

The results are automatically uploaded to the Diasorin cloud (if connected), LIS (if connected), or can be saved as a PDF on the USB key. Refer to the LIAISON NES® user manual for additional details.

Results can be wirelessly printed to any printer connected within the network. Consult the LIAISON NES® user manual to set up a printer.

FAIL RESULTS

In case of a “Fail” result, use a fresh control swab and re-test with a new NES cartridge. If the problem is unresolved, please contact [Diasorin Technical Support – contact information located on the last page of this document](#).

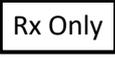
LIMITATIONS

1. For in vitro diagnostic use only.
2. For prescription use only.
3. The detection of viral nucleic acid is dependent upon proper swab handling, storage, and preparation. Failure to observe proper procedures in any one of these steps can lead to incorrect results.
4. This product was prepared using suitable inactivation methods. However, there is no known test or inactivation method that can assure that this product will not transmit infection. Universal laboratory precautions are recommended, and material should be treated as though it was potentially infectious.
5. These controls have been evaluated using the LIAISON NES® FLU A/B, RSV & COVID-19 assay and are not intended for use with other methodologies or systems.

REFERENCES

1. US Department of Health and Human Services PHS/CDC/NIH. Biosafety in microbiology and biomedical laboratories, Washington DC: US Government Printing Office, 2007.
2. CLSI: MM3-A2 Molecular diagnostic methods for infectious disease; approved guideline, 2nd ed. Wayne, PA: Clinical Laboratory Standards Institute, 2006.

GLOSSARY*

	Caution, consult accompanying documents		Telephone
	Consult instructions for use		In vitro diagnostic medical device
	Biological risk		Catalog number
	Contains sufficient for <n> tests		Revision
	Temperature limitation		Batch code
	Manufacturer		Kit contents
	Use by		Prescription only
	Do not reuse		
	Keep away from sunlight		

*ISO 15223-1

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If you experience any technical issues or concerns, please contact our Technical Support Team at our toll-free number (800) 838-4548.

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