LIAISON NES®

Diasorin

LIAISON NES® Group A Strep Control Swab Kit

Instructions for Use

REF NES2860

IVD Rx Only

For In Vitro Diagnostic Use.

CLIA Complexity: WAIVED*

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

For use with throat 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® Group A Strep Control Swab Kit is intended to be used as positive and negative controls with the LIAISON NES® Group A Strep 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® Group A Strep Control Swab Kit (NES2860) contains the following materials:

- (10) LIAISON NES® Group A Strep Positive Control swabs (NES2861)
- (10) LIAISON NES® Group A Strep Negative Control swabs (NES2862)
- (1) Printed copy of the LIAISON NES® Group A Strep Quick Reference Guide - Preparing For A Quality Control Test

MATERIALS REQUIRED BUT NOT PROVIDED

- LIAISON NES® Group A Strep Assay Kit (NES2850)
- Disposable, powder-free nitrile gloves
- Biohazard waste container
- LIAISON NES® instrument (NES1001)

KIT DESCRIPTION

The LIAISON NES® Group A Strep 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 (15-30°C). 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® Group A Strep Control Swab Kit	NES2860	10 positive control swabs 10 negative control swabs	1

COMPONENT DESCRIPTION

Kit Component	Contents
LIAISON NES® Group A Strep Positive Control Swab	The Group A Strep positive control swab contains *Streptococcus pyogenes* bacteria that have been inactivated using irradiation and chemical treatments. The solution is lyophilized into a ready-to-use swab.
LIAISON NES® Group A Strep Negative Control Swab	The Group A Strep Negative Control Swab is a ready-to use swab that does not contain any bacteria.

HANDLING AND STORAGE

1. Store LIAISON NES® Group A Strep Control Swab Kit at room temperature (15–30ºC).
2. Store the LIAISON NES® Group A Strep 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 2 hours (120 minutes). 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 (15–30°C).
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® Group A Strep Control Swab Kit Instructions for Use (IFU) (this document) before running a test.*

Gather materials:

- (2) LIAISON NES® Group A Strep Cartridges (NES2851)
- (2) NES sample vials with buffer and caps (NES1502)
- (1) LIAISON NES® Group A Strep Positive Control Swab (NES2861)
- (1) LIAISON NES® Group A Strep Negative Control Swab (NES2862)

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® Group A Strep Positive Control Swab (NES2861) 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 of the 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 of the 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® Group A Strep Negative Control Swab (NES2862) 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	• Positive control swab is positive, indicating the presence of *Streptococcus pyogenes* Group A *Streptococcus* DNA. • Negative control swab is negative, indicating the absence of *Streptococcus pyogenes* Group A *Streptococcus* DNA, and has a valid internal control (IC) result.
Fail	• Positive control swab is negative for the target. • Negative control swab is positive for the target • Internal control is not detected on negative control swab, indicating the inability to conclusively determine the presence or absence of *Streptococcus pyogenes* Group A *Streptococcus* DNA in the quality control swab • In case of a "Fail" result, the control needs to be retested. See "Fail Results" section. • For any concerns, contact our Technical Support Team at our toll-free number (800) 838-4548.

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 bacterial 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® Group A Strep 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		Telephone
	Consult instructions for use	IVD	In vitro diagnostic medical device
	Biological risks	REF	Catalog number
	Contains sufficient for <n> tests	LOT	Batch code
	Temperature limit	CONT	Kit contents
	Manufacturer	Rx Only	Prescription only
	Use by		Keep Dry
	Do not re-use		
	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.

Visit our website at www.diasorin.com/liaison-nes

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