lifeSign

***Status*™ RSV**

℞ ONLY | IVD

CLIA Waived

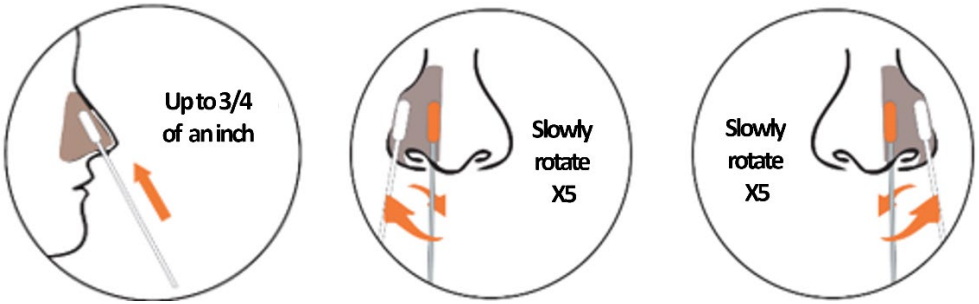
For *In Vitro* Diagnostic Use
For Prescription Use Only
For Use with Kit Provided Swabs

- CLIA waived for use with anterior nasal swabs.
- Laboratories with Certificate of Waiver must follow the manufacturer's instructions for performing the test.
- Certificate of Waiver is required to perform the test in a waived setting.

IMPORTANT:

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- This product has been cleared only for the detection of proteins from RSV, not for any other viruses or pathogens.
- The test is stable until the expiration date printed on the outside of the box. Do not use after the expiration date.
- The test kit should be stored at 2°C - 30°C in the original sealed pouch. Do not freeze and bring to room temperature at least 30 minutes prior to use.
- Once opened, the test device should be used within 90 minutes.
- Conduct all testing on a level surface and ambient conditions.
- Ensure that testing and result interpretation is conducted in a well-lit space with sufficient lighting.
- Refer to Specimen Collection: Nose and Throat at https://elsevier.health/en-US/preview/specimen-collection-nose-and-throat.
- For more information, refer to the Product Instructions for Use, test procedure, warnings, precautions, limitations, and the QC section.

Sample Collection Method



To collect the anterior nasal swab sample, tilt the patient's head back 70 degrees and insert the soft end of the swab into the patient's nostril no more than ¾ of an inch into the nose (no more than ½ inch if swabbing a child).
Slowly rotate the swab, gently pressing against the inside of the patient's nostril at least 5 times for a total of 15 seconds.
Get as much nasal discharge as possible on the soft end of the swab. Gently remove the swab.
Use the same end of the swab and repeat the same steps on the other nostril.

Note:
The freshly collected anterior nasal swab specimen is recommended to be processed no later than one hour after specimen collection when kept at room temperature (15°C - 30°C) or within 24 hours when stored at 2°C to 8°C.
Do not freeze swab specimens before testing.

Manufactured for: **LifeSign, LLC.**
Skillman, NJ, USA

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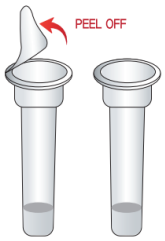
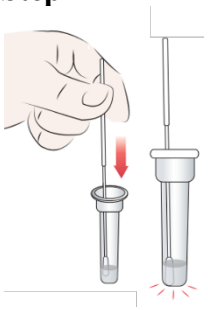
Sample Testing Procedure

Step 1



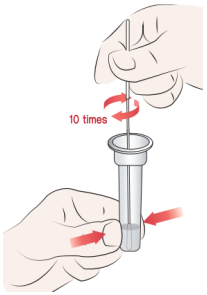
Peel off the aluminum foil from the top of the Reagent Tube containing 350 µL of extraction buffer.

Step 2



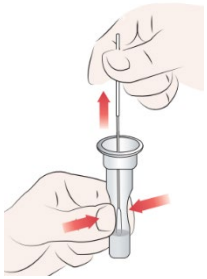
Insert the collected swab into the Reagent Tube until the swab head touches the bottom of the tube

Step 3



Hold the swab head at the bottom of the tube tightly by squeezing the tube. Then stir the swab at least **10 times**.

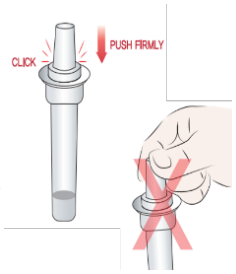
Step 4



Remove the swab while squeezing the sides of the tube to release the maximum amount of liquid from the swab head. Properly discard the swab.

Note: Specimens in extraction buffer can be processed up to 30 minutes after collection when kept at room temperature.

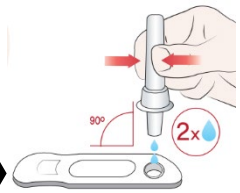
Step 5



Firmly push on the provided Dropper tip to close the Reagent tube.

Note: Do NOT touch or grab the hole of the dropper tip.

Step 6



Invert the processed Reagent Tube and hold it vertically above the sample well. Squeeze the tube gently and dispense **two (2) drops** of the sample into the sample well of the test device.

Note: Too few drops can result in invalid results, and too many drops could produce incorrect results.

Step 7

Read the results at 15 minutes visually.

Do not read the result earlier than 15 minutes or later than 20 minutes after the sample.

Note: False negative or false positive results can occur if read before or after 15-20 minutes.

Note: This test is read visually and has not been validated for use by those with impaired vision or color-impaired vision.

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Skillman, NJ, USA

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Results Interpretation

Positive

If the Control (C) line and the Test (T) line are visible, the test is positive.

Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive.

Negative

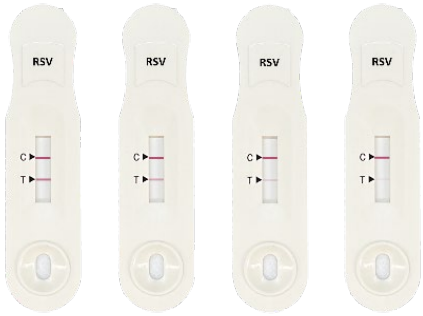
If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.
A negative test result indicates that the virus that causes RSV was not detected in the sample.

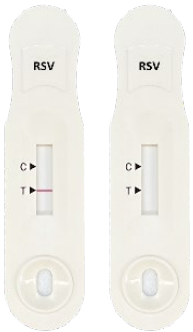
Note: Negative results are presumptive and may be confirmed with a molecular assay, if necessary, for patient management

Invalid

If a control (C) line is not visible, the test is not valid.
Re-test with a new swab and a new test cassette.

If the problem persists, please call +1-800-526-2125.





External Quality Control Test Step Instructions

External positive and negative control swabs are supplied with each kit. These controls provide additional quality control material to assess that the test kit reagents perform as expected. Process the provided control swabs in the same manner as clinical sample swab and follow the steps in the "Sample Testing Procedure" section. The positive and negative external control swabs must be run once for each new kit lot; each new shipment of the test kits; each new operator; or as required by internal quality control procedures and in accordance with local, state, and federal regulations or accreditation requirements.

Assistance:

For questions or technical support, please contact the Technical Service and Support at Tel: +1- 800-526-2125.

Manufactured For: LifeSign, LLC.
85 Orchard Rd., Skillman, NJ 08558, USA
Tel: 1-800-526-2125, www.lifesignmed.com

Cat. No. 33125
P/N EP-3450 LS-QRI (March 21, 2025)

Glossary

℞ ONLY Prescription use only	IVD For In Vitro use only	2°C-30°C Temperature limitation	LOT Batch code	Use by	Σ 25 Contains sufficient for 25 determinations
REF Catalog number	CONTROL + Positive control	CONTROL − Negative control	Do not re-use	Consult instructions for use	