SPECTRUM
MEDICAL DIAGNOSTICS

RSV Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- The RSV Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is intended for professional in vitro diagnostic use only.
- Follow the specimen collection and preparation instructions carefully, and make sure all materials are at room temperature before testing.

Intended Use

- The intended use of the RSV Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is to qualitatively detect the presence of Respiratory Syncytial Virus (RSV) antigen in nasopharyngeal swab or nasal aspirate specimens.
- It is specifically designed for professional in vitro diagnostic use.
- The test is meant to aid in the rapid differential diagnosis of RSV viral infections, particularly in cases of respiratory illness.

Warnings & Precautions

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
4. The used test should be discarded according to local regulations.
5. Read and follow all instructions carefully before performing the test.
6. The test results should be interpreted in conjunction with other clinical information available to the physician.
7. The RSV Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is a qualitative test and cannot determine the quantitative value or rate of increase in RSV concentration.
8. False negatives may result from improper sample collection or storage.
9. Excess blood or mucus on the swab specimen may interfere with test performance and yield a false positive result.
10. Over-the-counter and prescription nasal sprays at high concentrations can interfere with test results, leading to either invalid or incorrect results.
11. Proper control standards should be tested to confirm the test procedure and verify the test's performance.
12. The test kit should be stored as packaged at room temperature or refrigerated, and it should not be frozen. It should not be used beyond the expiration date.

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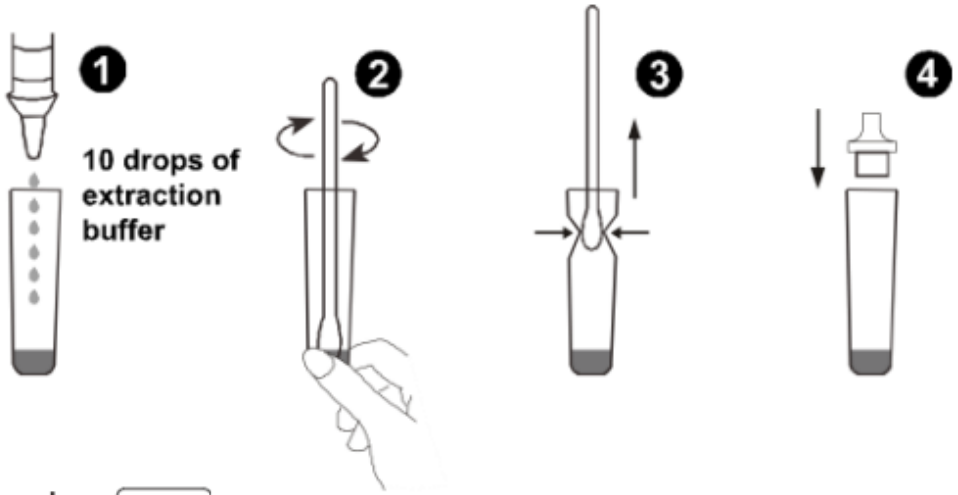
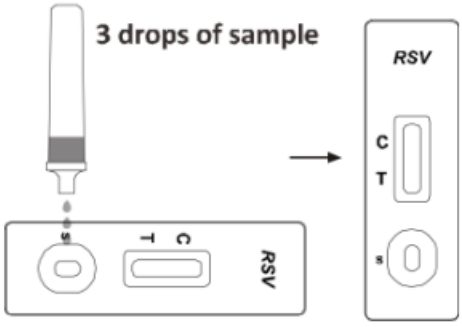
Test Procedure

1. Open the sealed foil pouch and remove the test cassette promptly for optimal results.
2. Set up the workstation and place the Extraction Tube within it. Hold the extraction reagent bottle upside down and gently squeeze it to allow the solution to drop freely into the extraction tube without touching its edges. Add 10 drops of solution (Approx. 500µl) to the Extraction Tube. **Refer to illustration 1.**
3. Carefully place the swab specimen into the Extraction Tube. Rotate the swab for about 10 seconds while pressing its head against the inside of the tube to release the antigen. **Refer to illustration 2.**
4. Remove the swab from the Extraction Tube while gently squeezing its head against the inside of the tube to remove excess liquid. Dispose of the swab following proper biohazard waste disposal guidelines. **Refer to illustration 3.**
5. Attach the dropper tip to the extraction tube and position the test cassette on a clean, level surface. **Refer to illustration 4.**
6. Add 3 drops of the solution (approx. 120µl) to the sample well (S) on the test cassette, and start the timer.
7. Wait for **15 minutes**, then read and interpret the result. Do not continue interpreting the result after 20 minutes.





QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is the internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that a positive control and a negative control be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

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Positive Result:

- When **two distinct coloured lines appear**, with one in the control region (C) and another in the test region (T), it indicates a positive result.
- A positive result in the test region suggests that Respiratory Syncytial Virus (RSV) antigen was detected in the sample.

Negative Result:

- If only **one coloured line appears** in the control region (C) and there is no apparent coloured line in the test line region (T), it indicates a negative result.
- This suggests that RSV antigen was not detected in the sample.

Invalid Result:

- An invalid result is indicated **when the control line fails to appear.**
- This can be due to insufficient specimen volume or incorrect procedural techniques.
- It is advised to review the procedure, repeat the test with a new kit, and ensure proper specimen volume.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com

LIMITATIONS

1. The RSV Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate) is designed for professional in vitro diagnostic use only and is suitable for detecting Respiratory Syncytial Virus (RSV) in nasopharyngeal swab or nasal aspirate specimens. This qualitative test cannot determine the quantitative value or rate of increase in RSV concentration.
2. Like any diagnostic test, it is crucial to interpret all results in conjunction with other clinical information available to the physician.
3. The Respiratory Syncytial Virus Antigen Rapid Test Cassette serves as an acute-phase screening test for qualitative detection. Samples collected may contain antigen levels below the sensitivity threshold of the reagents, so a negative test result does not rule out the possibility of an RSV infection.
4. Excessive blood or mucus on the swab specimen can potentially interfere with the test's performance and result in a false positive outcome.
5. The accuracy of the test relies on the quality of the swab sample. Improper sample collection or storage can lead to false negatives.
6. The use of over-the-counter and prescription nasal sprays at high concentrations can disrupt the test results, potentially causing either invalid or inaccurate outcomes.

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RSV Rapid Test Training Quiz

What is the intended use of the RSV Rapid Test Cassette (Nasopharyngeal Swab/Nasal Aspirate)?
a) Detection of RSV antibodies
b) Qualitative detection of RSV antigen
c) Quantitative measurement of RSV viral load
d) Differential diagnosis of respiratory illnesses

True or False: The RSV Rapid Test Cassette can determine the quantitative value or rate of increase in RSV concentration.
a) True
b) False

Which region(s) should show coloured lines to indicate a positive result?
a) Control region (C)
b) Test region (T)
c) Both Control region (C) and Test region (T)
d) Neither Control region (C) nor Test region (T)

What does it mean if only the control line appears in the test result?
a) Positive result for RSV antigen
b) Negative result for RSV antigen
c) Invalid result due to control line failure
d) The test needs to be repeated with a new kit

What precautions should be taken when handling specimens?
a) Treat all specimens as potentially hazardous and handle them accordingly
b) Use standard precautions for infectious agents
c) Follow local regulations for proper disposal of used tests
d) All of the above

What should be done if the control line fails to appear in the test result?
a) Assume a positive result for RSV antigen
b) Interpret the test as negative for RSV antigen
c) Repeat the test with a new kit and proper procedural techniques
d) Contact the local distributor for further instructions