

Clarity RSV Antigen Test

QUICK REFERENCE INSTRUCTIONS

For *in vitro* diagnostic use.
For prescription use only.

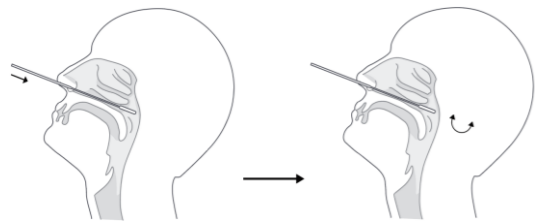
Carefully read the Instructions for Use (IFU) before performing the test. Failure to follow the instructions may result in inaccurate test results.

Collect the specimen using either the Nasopharyngeal Swab OR Nasal Aspirate sample collection procedure, prior to starting the Test Procedure. More detailed instructions can be found in the SPECIMEN COLLECTION section of the IFU.

NASOPHARYNGEAL SWAB SAMPLE COLLECTION

1 Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Using gentle rotation, push the swab until resistance is met at the level of the turbinate (less than one inch into the nostril). Rotate the swab a few times against the nasal wall.

2 Nasopharyngeal specimens should be placed in a maximum of 3 mL normal saline or transport medium prior to processing.



The following transport media have been tested and found to be compatible with the Clarity RSV Antigen Test:

- Saline, Sterile Normal
- Phosphate Buffered Saline
- PBS plus 0.5% gelatin
- PBS plus 0.5% Bovine Serum Albumin (BSA)
- Viral Culturette™ (ideal for testing a negative result)
- Veal Infusion Broth (VIB)
- VIB plus 0.5% BSA
- Earle's Minimal Essential Medium (EMEM)
- EMEM with Lactalbumin Hydrolysate
- Tripticase™ Soy Broth plus 0.5% gelatin
- M5 media
- Microgen™/ Swab Combo in M4 media* by MicroTest (ideal for testing a negative result)

NASAL ASPIRATE SAMPLE COLLECTION

1 FOR OLDER CHILDREN AND ADULTS

Fill aspiration bulb or bulb syringe with 2.0 - 2.5 mL of sterile normal saline. Insert the tip of the bulb into the nostril until the nostril seals around the bulb and instill the saline into one nostril while the head is tilted back. Release the pressure on the bulb to aspirate the specimen back into the bulb. Transfer the specimen to a clean dry specimen container.

2 Repeat for the other nostril and collect the fluid into the same specimen container.

FOR YOUNGER CHILDREN

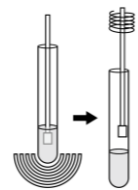
The child should sit on the parent's lap facing forward, with the child's back against the parent's chest. The parent should wrap one arm around the child in a manner that will restrain the child's body and arms.

Fill aspiration bulb or bulb syringe with 1.5 - 2.0 mL of sterile normal saline (depending on the size of the child).

⚠ To collect nasal aspirate samples please refer to the IFU.

TEST PROCEDURE

3 Vortex or agitate the swab and transport medium or saline solution for 15-20 seconds to dislodge specimen from the swab. Roll the swab head against the inside of the transport tube or specimen container as you remove it.

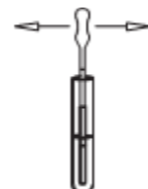


OR

Gently agitate with swirling motion or vortex aspirate sample to suspend cellular material in sample.



4 Draw 160 µL (second notch) of the sample up into a disposable pipette.



TEST PROCEDURE

5 Add the entire contents of the Pipette to the extraction tube.



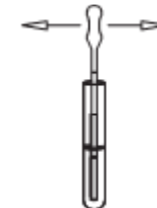
6 Add four (4) free falling drops of R1 to the extraction tube while holding the bottle vertically over the tube.



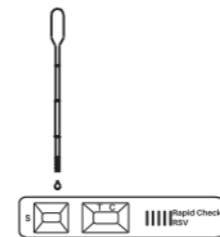
7 Gently swirl the extraction tube to mix the sample and R1.



8 Draw 160 µL (second notch) of the sample up into a disposable pipette.



9 Squeeze the entire contents of the pipette dropper into the sample well of the test device.



10 Read the test result between fifteen (15) and twenty-five (25) minutes after applying the extracted sample to the test device.

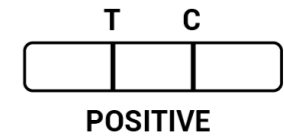


15 - 25 minutes

⚠ Do not interpret results after 25 minutes.

POSITIVE TEST RESULT

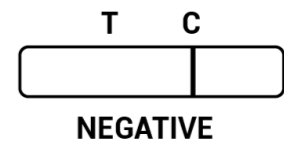
BOTH 'C' and 'T' are visible



For a positive specimen, the appearance of TWO pink to red lines, one at the procedural control line (C) and one at the test line (T) indicates the presence of respiratory syncytial virus antigen. Any pink to red test line, even if it is only slightly pink, is considered a positive test.

NEGATIVE TEST RESULT

ONLY 'C' Line is visible



For a negative specimen, the appearance of ONLY ONE pink to red line at the procedural control line (C) and no pink to red line at the Test Line (T) indicates that the sample is negative for RSV viral antigen.

INVALID TEST RESULT

Missing 'C' line



If after 15 minutes, the pink to red procedural control line (C) does not appear, even if any shade of pink to red test line (T) appears, the result is considered invalid. If the test is considered invalid because a control line fails to appear, the test should be repeated with a new test device.



For Symbol Index, refer to Instructions for Use.

Clarity Diagnostics, LLC
1080 Holland Drive, Suite 1
Boca Raton, FL 33487
Phone: 877-485-7877
www.ClarityDiagnostics.com