QUIDEL

QuickVue® RSV TEST

QUICK REFERENCE INSTRUCTIONS

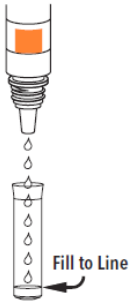
Refer to the Package Insert for complete instructions. Read the complete test procedure, including recommended Quality Control procedures, before performing the test.

Test Procedure

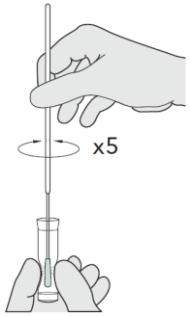
All clinical specimens must be at room temperature before beginning the assay.
Performing the assay outside the time and temperature ranges provided may produce invalid results.
Assays not performed within the established time and temperature ranges must be repeated.
Expiration date: Check expiration on each individual test package or outer box before using. *Do not use any test past the expiration date on the label.*

Nasopharyngeal Swab Test Procedure

1 Add Extraction Reagent to the test tube up to the **fill line**.

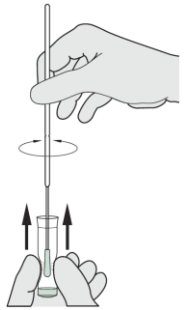


2 Add patient swab to the tube. **Squeeze** the bottom of the tube so the swab head is compressed. **Rotate the swab 5 times**.



Keep swab in the tube for 1-2 minutes.

3 Express **all** liquid from the swab head by **squeezing** the tube as the swab is removed. Discard swab.

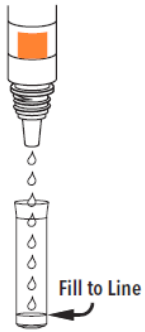


4 Place the Test Strip into the tube with the arrows pointing down. Do not handle or remove the Test Strep for 15 minutes.

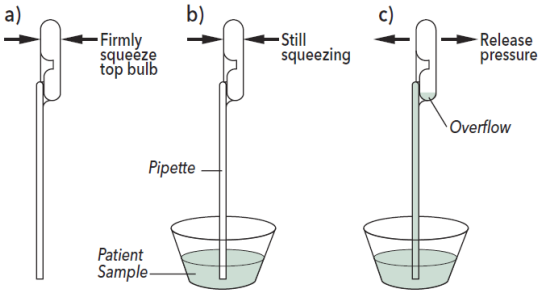
5 **Remove the Test Strip**, and read the result according to the Interpretation of Results section (see back page).

Nasopharyngeal Aspirate or Nasal/Nasopharyngeal Wash Test Procedure

1 Add Extraction Reagent to the test tube up to the **fill line**.

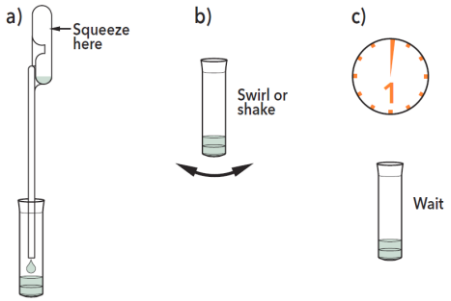


2 **To fill the pipette with the sample*:**
a) FIRMLY squeeze the top bulb.
b) Still squeezing, place the pipette tip into the liquid sample.
c) With the pipette tip still in the liquid sample, release pressure on bulb to fill the pipette (extra liquid in the overflow bulb is OK).



**Note: The pipette is designed to collect and dispense the correct amount of liquid sample.*

3 **To add the sample to the test tube:**
a) Firmly squeeze the top bulb to add the sample in the pipette to the test tube with reagent. The correct amount will be added, even though the overflow bulb will not empty. Discard the pipette.
b) Swirl or shake the tube to mix.
c) Wait 1-2 minutes to allow mixture to react.



4 Place the Test Strip into the tube with the arrows pointing down. Do not handle or remove the Test Strep for 15 minutes.

5 **Remove the Test Strip**, and read the result according to the Interpretation of Results section (see back page).

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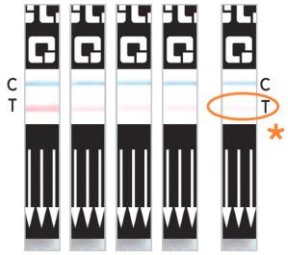
INTERPRETATION OF RESULTS

POSITIVE Result:

At 15 minutes, the appearance of **ANY shade of a pink-to-red Test Line AND** a blue procedural Control Line indicates a positive result for the presence of RSV viral antigen.

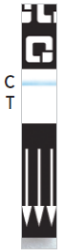


C= Control Line
T= Test Line

** Look closely! This is a positive result. Even if you see a very faint, pink Test Line and a blue Control Line, you must report the result as POSITIVE.*

NEGATIVE Result:

At 15 minutes, the appearance of **ONLY** the blue procedural Control Line indicates the sample is negative for RSV viral antigen.

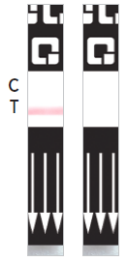


INVALID Result:

If at 15 minutes, the blue procedural Control Line does not appear, even if any shade of a pink-to-red Test Line appears, **the result is invalid**.

If at 15 minutes the background color does not clear and it interferes with the reading of the test, the result is also invalid.

If the test is invalid, a new test should be performed.



INTENDED USE

The QuickVue RSV test is a dipstick immunoassay, which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, or nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (18 years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use.
- Performance characteristics have not been established for use with adult or immunocompromised patients.
- Use appropriate precautions in the collection, handling, storage, and disposal of patient samples and used kit contents. Use of Nitrile or Latex gloves is recommended when handling patient samples.
- Dispose of containers and used contents in accordance with Federal, State and Local requirements.
- To obtain accurate results, you must use the proper volume of Extraction Reagent.
- To avoid erroneous results, you must rotate the swab a minimum of five (5) times as indicated in the test Procedure.
- Proper specimen collection, storage, and transport are critical to the performance of this test.
- Seek specific training or guidance if you are not experienced with specimen collection and handling procedures.
- M4-3 and Amies transport media are not compatible with this device. To obtain optimal results, use the transport media recommended in the Package Insert.
- For proper test performance, use the nasopharyngeal swabs supplied in the kit.
- Individuals with color-impaired vision may not be able to adequately interpret test results.

Note: *Review the Package Insert for a complete list of Warnings and Precautions.*

SPECIMEN COLLECTION AND HANDLING

Specimen Collection

Nasopharyngeal Swab Method:
To collect a nasopharyngeal swab sample, carefully insert the swab into the nostril and using gentle rotation, push the swab into the posterior nasopharynx. Gently rotate the swab three times, then remove it from the nasopharynx.

Nasopharyngeal Aspirate Method:
Instill a few drops of sterile saline into the nostril to be suctioned. Insert the flexible plastic tubing along the nostril floor, parallel to the palate. After entering the nasopharynx, aspirate the secretions while removing the tubing. The procedure should be repeated for the other nostril if inadequate secretions were obtained from the first nostril.

Nasopharyngeal Aspirate Method:
Follow your Institution's Protocol for obtaining wash specimens. **Use the minimal amount of saline that your procedure allows**, as excess volume will dilute the amount of antigen in the specimen. The following are examples of procedures used by clinicians:

The child should sit in the parent's lap facing forward, with the child's head against the parent's chest. Fill the syringe or aspiration bulb with the minimal volume of saline required per the subject's size and age. Instill the saline into one nostril while the head is tilted back. Aspirate the wash specimen back into the syringe or bulb. The aspirated wash sample will likely be at least 1 cc in volume.

Alternatively, following instillation of the saline, tilt the child's head forward and let the saline drain out into a clean collection cup.

Specimen Transport and Storage

Specimens should be tested as soon as possible after collection. If the transport of the specimens is required, the following transport media are recommended when specimens are stored at 2°C to 30°C for up to 8 hours prior to testing: Hank's Balanced Salt Solution, M4-RT or M5 Media, Stuart's, Universal Transport Media, Bartels Viratrans or saline. For longer storage at 2°C to 8°C for up to 48 hours, only Bartels and M4-RT are recommended. Alternatively, samples may be stored at 2°C to 30°C, in a clean, dry, closed container for up to 8 hours prior to testing.

EXTERNAL QUALITY CONTROL

External controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run once for each new operator, once for each shipment of kits – provided that each different lot received in the shipment is tested – and as deemed additionally necessary by your internal quality control procedures.

The Nasopharyngeal Swab Test Procedure described in this Package Insert should be used when testing the external controls.

If the controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens. Note that the External Positive Control Swab provided in the kit is a moderately high positive sample which may not represent the performance of a low positive RSV specimen in the QuickVue RSV test.

CLIA WAIVER CONSIDERATIONS

A certificate of CLIA waiver is required to perform the QuickVue RSV test in a waived setting. Waived laboratories must follow the manufacturer's instructions in the Quick Reference Instructions and Package Insert for performing this test.

Study the Package Insert thoroughly before using Quick Reference Instructions. This is not a complete Package Insert.

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