QUIDEL | QuickVue®

RSV Test

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the QuickVue RSV Test?
The suggested CPT code is 87807QW.* For the current Medicare National Limit amount** click here.

What is the CLIA complexity of the test?
The test is CLIA waived.

How often should external controls be run on the kit?
Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new 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, and in accordance with Local, State, and Federal regulations or accreditation requirements.

Who may be tested with the kit?
The test is designed for symptomatic pediatric patients 18 years of age and younger.

What are the approved sample types for the kit?
Nasopharyngeal swabs, nasopharyngeal aspirate and nasal/nasopharyngeal wash specimens may be used.

What is the shelf life of the kit? How should it be stored?
The shelf life is 24 months from the date of manufacture. The kit should be stored at room temperature 15°C to 30°C.

How long can specimens be stored?
Samples should be tested as soon as possible after collection. 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.

How should specimens be transported when using the QuickVue RSV test?
If 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, Remel® M4RT® or M5® Media, Modified Liquid Stuart's, Bartels® Viratrans, COPAN® Universal Transport Medium®, BD® Universal Viral Transport Media, or saline. For longer storage at 2°C to 8°C for up to 48 hours, only Bartels Viratrans and M4RT are recommended. (Note: M4 and Amies transport media are not compatible with this device.)

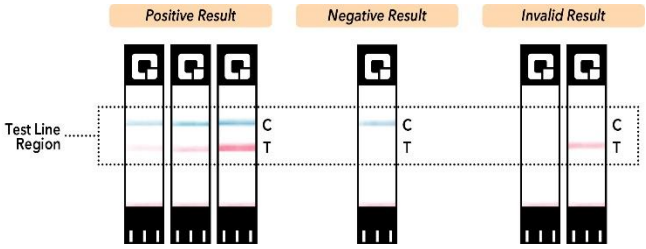
Can I use a different type of swab to collect the sample?
For proper test performance, use ONLY the swabs supplied in the kit. Additional swabs made by Copan Diagnostics (Quidel Cat. #20226) are also available. These swabs are also available in dry transport tubes and can be ordered from Quidel or various distributors, using Copan Item #551C.

Can RSV be contracted from contact with the controls?
No. The Positive Control Swab is coated with non-infectious RSV antigen, and the Negative Control Swab is coated with formalin-inactivated, non-infectious Streptococcus C antigen.

How accurate is the QuickVue RSV Test?
Nasopharyngeal aspirate sensitivity is 99% and specificity is 92%. Nasopharyngeal swab sensitivity is 92% and specificity is 92%. Nasal/nasopharyngeal wash sensitivity is 83% and specificity is 90%. These data were obtained in comparison to culture.

Refer to the Package Insert on our website at **quidel.com** for additional performance claims.

I see a pink line, but it's not in the same spot as in the User Instructions. Is this a positive result?
Only a pink line about a half of a centimeter below the blue control line in the Test Line Region should be considered a positive result. Pink lines in any other area of the test strip should not be called a positive result. Even a very faint blue control line indicates a valid result.



If I see pink shading on the strip bordering the black label(s), is this a positive result?
Only a pink line about half of a centimeter below the blue control line should be considered a positive result. A pink line bordering the black label with the arrows, a vertical pink line, or a faint grey line next to the blue control line is not considered a positive test line and should not be called a positive result.

What if the cap of my extraction reagent bottle is a different color or another component of my kit looks different than before?
Due to supply chain challenges, occasionally small cosmetic changes are made to components within the kits. These are cosmetic changes only and do not affect the performance of the test. An example of this would be an extraction reagent bottle with a white cap instead of the typical orange.

***** This information is being provided as a reference, for informational purposes only, with no expressed or implied warranty and does not purport to provide legal or certified coding advice. Nothing in this document is intended to serve as reimbursement advice, a guarantee of coverage, or a guarantee of payment. ***Under Federal and State law, it is the individual provider's responsibility to determine appropriate coding, charges and claims for a particular service.*** Policies regarding appropriate coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corporation strongly recommends that providers contact their own regional payers to determine appropriate coding and charge or payment levels prior to submitting claims.

**For state by state fee schedule go to www.cms.gov. "QW" modifier is added to report use of CLIA-Waived test system(s) for Medicare/Medicaid claims.

FQ20193003EN00 (11/22)