Influenza A+B Test

Frequently Asked Questions

What is the difference between this test and the QuickVue Influenza Test?
Both tests detect influenza A and B, while the A+B test differentiates between Types A and B, with separate test lines.

What is the CMS suggested CPT code and National Limit amount for the QuickVue Influenza A+B kits?
The suggested CPT codes are:*

- Influenza A: 87804QW
- Influenza B: 87804QW, 59

The Medicare National Limit amount** is $16.55.

What is the CLIA complexity of this test?
This test is CLIA waived.

What is Quidel's quality control recommendation for these tests?
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.

If the Controls do not perform as expected, repeat the test or contact Quidel Technical Support before testing patient specimens.

External Positive and Negative Control Swabs are supplied in the kit and should be tested using the Swab Procedure.

What is the shelf life and how should the kit be stored?
The kit shelf life is 24 months from date of manufacture. The kit should be stored at room temperature.

How should the specimens be transported when using the QuickVue Influenza A+B Test?
Samples should be tested as soon as possible after collection. If transport of the sample is required, the following transport media are recommended and have been tested and found not to interfere with the performance of the test when specimens are stored at 2°C to 25°C for up to 8 hours prior to testing: Hank's Balanced Salt Solution, BD VTM, Copan UTM, M5 Media, Bartel's Flextrans Media or saline. For longer storage at 2°C to 25°C for up to 24 hours or 2°C to 8°C for up to 48 hours, only Copan Universal Transport Media or BD Universal Viral Transport Media are recommended. It is advised that a total volume of 1 mL of media be used for transport. When performing the QuickVue test, use 300 µL of the sample suspended in the media per the Nasal Wash/Nasal Aspirate test procedure. Alternatively, samples may be stored refrigerated or at room temperature (2°C to 25°C) in a clean, dry, closed

container for up to 8 hours prior to testing. Nasal wash specimens may also be stored frozen (–70°C or colder) for up to 1 month.

Can I use a different type of swab to collect the sample?
For proper test performance, use ONLY the swabs provided in the kit to collect nasal swab specimens. To order additional nasal swabs use Quidel Cat. #20103 or 20171 (swabs in transport tubes). For the QuickVue Influenza A+B Test, we recommend the Copan Nylon Flocked swab (Quidel Cat. #20226) for nasopharyngeal samples. These Copan NP swabs are also available in dry transport tubes and can be ordered from Quidel or various distributors using Copan Item #551C.

Can influenza be contracted from contact with the controls?
No. All control swabs are coated with non-infectious material.

Can these tests be used year after year when different influenza strains emerge?
Yes. The QuickVue Influenza A+B Test detects the highly conserved antigens in the viral nucleoproteins. These antigens currently appear to be unaffected by the variations in new strains.

Does the QuickVue Influenza A+B Test detect H5N1 or other strains of "avian" influenza viruses?
The QuickVue Influenza A+B Test has been shown to detect cultured avian influenza; as with other rapid tests for influenza, the ability of the QuickVue Influenza A+B Test to detect influenza Type A in patients infected with H5N1 has not been established.

Will the QuickVue Influenza A+B Test specify that a patient has avian influenza?
No.

Where can I find up-to-date news and information on avian influenza?
The World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC) post information on their websites:
http://www.who.int/csr/disease/avian_influenza/avian_faqs/en/index.html
http://www.cdc.gov/flu/avian

Does the QuickVue Influenza A+B Test detect the 2009 H1N1 Influenza A virus?
Although the QuickVue Influenza A+B Test has been shown to detect the 2009 H1N1 virus cultured from a positive human respiratory specimen, the performance characteristics of this device with clinical specimens that are positive for the 2009 H1N1 influenza virus have not been established.

Will the QuickVue Influenza A+B Test specify that a patient has the 2009 H1N1 Influenza A virus?
No. The QuickVue Influenza A+B Test can distinguish between Influenza A and B viruses, but it cannot differentiate influenza subtypes.

Where can I find up-to-date news and information on the 2009 H1N1 Influenza A virus?
The Centers for Disease Control and Prevention (CDC) post information on their website:
http://www.cdc.gov/h1n1flu/update.htm

How accurate is the QuickVue Influenza A+B Test?
In a recent clinical study, sensitivity with nasal swab samples was 94% for Type A and 70% for Type B. Specificity was 90% for Type A and 97% for Type B. Additional clinical performance characteristics are listed as follows:

Sensitivity	A-94%, B-70% – Nasal swab A-83%, B-62% – Nasopharyngeal swab A-77%, B-82% – Fresh Nasal aspirate/nasal wash A-86% – Frozen Nasal wash
Specificity	A-90%, B-97% – Nasal swab A-89%, B-98% – Nasopharyngeal swab A-99%, B-99% – Fresh Nasal aspirate/nasal wash A-95% – Frozen Nasal wash
Positive Predictive Value	A-62%, B-82% – Nasal swab A-67%, B-80% – Nasopharyngeal swab A-91%, B-90% – Fresh Nasal aspirate/nasal wash A-93% – Frozen Nasal wash
Negative Predictive Value	A-99%, B-94% – Nasal swab A-95%, B-95% – Nasopharyngeal swab A-96%, B-97% – Fresh Nasal aspirate/nasal wash A-90% – Frozen Nasal wash
Overall Accuracy:	A-91%, B-93% – Nasal swab A-88%, B-94% – Nasopharyngeal swab A-95%, B-96% – Fresh Nasal aspirate/nasal wash A-91% – Frozen Nasal wash

The performance of any rapid flu test is dependent on sample collection and handling and the adherence to the Package Insert.

Will the QuickVue test show a positive test result after someone has had a nasally administered vaccine?
Individuals who received nasally administered influenza vaccine may have a positive influenza A and/or influenza B test result. According to the FDA in May 2007, an individual may have positive test results for up to 3 days after vaccination.[1] The CDC has recently stated that a person who has received LAIV (Live Attenuated Intranasal Vaccine) can test positive on a rapid influenza test for up to 7 days after vaccination.[2] Also, in the MedImmune Package Insert for the FluMist Live Influenza Intranasal Vaccine, at least one vaccine strain was recovered from 80% of the patients who had received one dose of FluMist from 1-21 days post vaccination (mean duration of 7.6 days ± 3.4 days).[3]

Can an individual contract influenza more than once each season?
Yes. Reinfection of an individual by viruses of the same type may occur within a relatively short period of time when the paired strains differ by changes in their hemagglutinins. An example of such a paired strain is the Panama and Fujian variants in 2003.[4]

[1] Guidance for Industry and FDA Staff : In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path. May 1, 2007 (Page 10)
[2] http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm
[3] MedImmune: FluMist® Influenza Vaccine Live, Intranasal, Intranasal Spray, 2009-2010 Formula. Section 14.5: Transmission Study, June 2009
[4] Smith, CB, Cox, NJ, Subbarao, K, et. al; Molecular Epidemiology of Influenza A(H3N2) virus reinfections, Journal of Infectious Disease, Apr. 1, 2002; 185(7):980-5.

What is the liquid inside the small plastic vials?

Each small plastic vial contains 340 µL of salt solution. In the event that one is lost or misplaced, use a sterile pipette to dispense 300 µL of sterile saline into the extraction tube, which contains the white powder. Continue with the procedure as stated in the Package Insert.

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

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

**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. Depending on individual payer coding policies, it is possible that certain payers will require one of the following coding scenarios:

- Influenza A, Influenza B: 87804QW reported with 2 units of service
- Influenza A: 87804QW, Influenza B: 87804QW59

FQ20183001EN00 (01/18)