



## Frequently Asked Questions

### **What is the difference between the two tests?**

Both tests detect Influenza A and B, while the A+B test differentiates between Types A and B.

### **What is the CMS suggested CPT code and National Limit Amount for the QuickVue® Influenza and Influenza A+B kits?**

The Medicare National Limit Amount\* is \$17.18. The suggested\*\*\* CPT codes are:

- QuickVue Influenza kit:  
87804QW\*\*
- QuickVue Influenza A+B kit:  
Influenza A: 87804QW\*\*  
Influenza B: 87804QW\*\*, 59

### **What is the CLIA complexity of the tests?**

Both tests are waived under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88).

### **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 kits 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: Hank's Balanced Salt Solution, BD/Copan UTM, M5 Media, Multitrans Medium by Starplex Scientific, Bartel's Flextrans Media or saline. It is advised that a total volume of 1 mL of media be used for transport. When performing the QuickVue assay, use 300 µL of the sample suspended in the media per the Nasal Wash/Nasal Aspirate test procedure. Alternatively, samples may be stored refrigerated (2-8°C) or at room temperature (15-30°C) in a clean, dry, closed container for up to eight hours prior to testing. Nasal wash specimens may also be stored frozen (-70°C or colder) for up to one month.

**How should the specimens be transported when using the QuickVue Influenza test (A/B)?**

Samples should be tested as soon as possible after collection. Do not use any kind of transport media to store or transport samples. Samples may be stored refrigerated (2-8°C) or at room temperature (15-30°C) in a clean, dry, closed container for up to 8 hours prior to testing.

**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. For the QuickVue Influenza A+B test, we recommend the Copan nasopharyngeal swab (part #501CS01.US), for nasopharyngeal samples. These nasopharyngeal swabs are available through Fisher Scientific, Cardinal Health, Hardy Diagnostics, Diagnostic Hybrids Inc., and Infolab.

**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 test and the QuickVue Influenza A+B test detect 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.

**Does the QuickVue Influenza test (A/B) detect H5N1 or other strains of "avian" influenza viruses?**

The QuickVue Influenza test (A/B) has not been evaluated with avian influenza viruses.

**Will the QuickVue Influenza A+B test specify that a patient has avian influenza?**

No.

### 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 flu A and/or flu B test result. According to the FDA in May 2007, an individual may have positive test results for up to three days after vaccination.<sup>1</sup> 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 seven days after vaccination.<sup>2</sup> 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  $\pm$  3.4 days).<sup>3</sup>

<sup>1</sup> Guidance for Industry and FDA Staff : In Vitro Diagnostic Devices to Detect Influenza A Viruses: Labeling and Regulatory Path. May 1, 2007 (Page 10)

<sup>2</sup> [http://www.cdc.gov/h1n1flu/vaccination/clinicians\\_qa.htm](http://www.cdc.gov/h1n1flu/vaccination/clinicians_qa.htm)

<sup>3</sup> MedImmune: FluMist® Influenza Vaccine Live, Intranasal, Intranasal Spray, 2009-2010 Formula. Section 14.5: Transmission Study, June 2009

### **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.<sup>4</sup>

### **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.

### **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.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.

### **Does the QuickVue Influenza test (A/B) detect the 2009 H1N1 Influenza A virus?**

The QuickVue Influenza test (A/B) has not been evaluated with the 2009 H1N1 Influenza A virus

### **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>

Refer to our website at [www.quidel.com](http://www.quidel.com) for additional performance claims.

\*For state by state fee schedule go to [www.cms.gov](http://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: 87804QW\*\*

**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.

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<sup>4</sup> 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.