



Sofia®

Influenza A+B FIA

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit for the Sofia Influenza A+B FIA?

The suggested CPT codes are:*

- Influenza A: 87804
- Influenza B: 87804-59
- Add a QW Modifier to each CPT code when billing for nasal swab or nasopharyngeal swab specimens for Medicare/Medicaid Claims

The Medicare National Limit amount** is \$16.55.

Since my test is being run utilizing an analyzer, reader or system, is there an additional code which I can use in submitting for Influenza A+B reimbursement?

According to CMS guidelines, the payment for CPT codes 87804 and 87804-59 includes the use of the reader or analyzer.

What is the CLIA complexity of this test?

This test is CLIA waived for direct nasal swab, nasopharyngeal swab, and nasopharyngeal aspirate/wash specimens. It is moderately complexed for all specimens eluted in transport media.

Can the Sofia Influenza A+B FIA be visually interpreted without Sofia?

No, the fluorescence-based chemistry is not detectable without Sofia. Do not try to interpret the results without proper use of Sofia. This is an important feature and ensures objectivity.

What are Quidel's recommendations for external quality control and calibration testing for this kit?

The Calibration Check Procedure should be performed every 30 days. Refer to the Sofia User Manual for calibration instructions. If the Calibration Check does not perform as expected, contact Quidel Technical Support.

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

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 Sofia Influenza A+B FIA?

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 8°C or 25°C for up to 72 hours prior to testing: Copan UTM, M4, M4-RT, M5, M6 and Starplex Multitrans. Alternatively, samples may be stored for up to 24 hours at 2°C to 8°C in Hank's Balanced Salt Solution. Samples in Saline may be stored for up to 24 hours at 2°C to 8°C or 4 hours at 25°C. Customers choosing to use Modified Liquid Stuarts may store samples at 2°C to 8°C for up to 6 hours. It is advised that a total volume of 1 mL or less of media be used for transport. When performing the Sofia Influenza A+B FIA, use 250 µL of the sample suspended in the media per the Nasopharyngeal Aspirate/Wash or Viral Transport Media test procedure. **Note:** All clinical specimens must be at room temperature before beginning the assay.

Can I use a different type of swab to collect the sample?

Use the swabs provided in the kit to collect nasal swab specimens. To order additional nasal swabs use Quidel Catalog #20103. For nasopharyngeal swab samples, we recommend using the Copan Nylon Flocked swab (Quidel Catalog #20226).

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 Sofia Influenza A+B FIA detects the highly conserved antigens in the viral nucleoproteins. These antigens currently appear to be unaffected by the variations in new strains.

Does the Sofia Influenza A+B FIA detect the 2009 H1N1 Influenza A virus?

Performance characteristics for influenza A and B were established during February through March 2011 when influenza viruses **A/California/7/2009 (2009 H1N1)**, A/Perth/16/2009 (H3N2), and B/Brisbane/60/2008 (Victoria-Like) were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled "Update: Influenza Activity--United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

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) has archived information for historical purposes on their website at: <http://www.cdc.gov/h1n1flu/update.htm>.

Does the Sofia Influenza A+B FIA detect H5N1 or other strains of "avian" influenza viruses?

The Sofia Influenza A+B FIA has been shown to detect cultured human isolates of H5N1; as with other rapid tests for influenza, the ability of the Sofia Influenza A+B FIA to detect influenza Type A in patients infected with H5N1 has not been established.

Where can I find up-to-date news and information on avian influenza?

The World Organisation for Animal Health and the Centers for Disease Control and Prevention (CDC) post information on their websites:

<http://www.oie.int/for-the-media/press-releases/detail/article/avian-influenza-h5n1-clade-2321/>

<http://www.cdc.gov/flu/avian>

Will the Sofia Influenza A+B FIA specify that a patient has 2009 H1N1 or an H3N2 Influenza A virus?

No. The Sofia Influenza A+B FIA can distinguish between influenza A and B viruses, but it does not differentiate influenza subtypes.

Will the Sofia Influenza A+B FIA show a positive test result after someone has had a nasally administered vaccine?

Individuals who received nasally administered influenza vaccine may have positive test results for up to 3 days after vaccination.

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 paired divergent strains occurred in 2003 between the Panama and Fujian variants.¹

How accurate is the Sofia Influenza A+B FIA?

In a clinical study, sensitivity with nasopharyngeal swab samples was 97% for Type A and 90% for Type B. Specificity was 95% for Type A and 97% for Type B. Additional clinical performance characteristics are listed as follows:

Sofia Influenza A+B FIA Performance compared to Culture

Sensitivity	A-90%, B-89% – Nasal swab A-97%, B-90% – Nasopharyngeal swab A-99%, B-88% – Nasopharyngeal aspirate/wash
Specificity	A-95%, B-96% – Nasal swab A-95%, B-97% – Nasopharyngeal swab A-96%, B-96% – Nasopharyngeal aspirate/wash

Sofia Influenza A+B FIA – Sofia vs. Sofia 2 Method Comparison

	TYPE A				TYPE B			
	Sofia				Sofia			
	Pos	Neg			Pos	Neg		
Sofia 2 Pos	304	15**	Positive % Agreement/ (95% C.I.) 304/311 = 98% (95.4%-98.9%)	Sofia 2 Pos	154	5**	Positive % Agreement/ (95% C.I.) 154/157 = 98% (94.5%-99.4%)	
Sofia 2 Neg	7*	423	Negative % Agreement/ (95% C.I.) 423/438 = 97% (94.4%-97.9%)	Sofia 2 Neg	3*	587	Negative % Agreement/ (95% C.I.) 587/592 = 99% (98.1%-99.6%)	
Total:	311	438		Total:	157	592		

*There were 7 discordant Sofia 2 negative/Sofia positive results for Influenza A which included 1 low positive (C₉₅) specimen and the rest high negative (C₅) specimens.

*There were 3 discordant Sofia 2 negative/Sofia positive results for Influenza B which included all high negative (C₅) specimens.

**There were 15 discordant Sofia 2 positive/Sofia negative results for Influenza A which included 3 low positive (C₉₅) specimens and the rest high negative (C₅) specimens.

**There were 5 discordant Sofia 2 positive/Sofia negative results for Influenza B which included all high negative (C₅) specimens.

Why does Sofia 2 read the results before the full 15 minutes in the WALK AWAY mode?

The Sofia 2 has Advance Result Technology (ART) which allows for an early read time for samples that are positive. Negative results will take the full 15 minutes to read results.

Does Advance Result Technology apply to the Quality Control as well in the WALK AWAY mode?

No, the early read result time does not apply to Quality Control samples. Quality Control samples in the WALK AWAY mode will take 15 minutes to read the results.

¹Smith, 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.

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

FQ2021803EN00 (01/18)