Sofia®

QUIDEL

RSV FIA

Frequently Asked Questions

What is the CMS suggested CPT code and National Limit amount for the Sofia RSV FIA?
The suggested CPT code is 87807QW.* The Medicare National Limit amount** is $13.32.

What is the CLIA Complexity of the test?
This test is CLIA waived for children less than 7 years of age. This test is CLIA moderately complex for pediatric patients 7 to less than 19 years of age.

Who may be tested with this kit?
This test is intended for use with symptomatic pediatric patients under 19 years of age.

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

Can the Sofia RSV FIA cassettes 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.

Why does the test strip have a blue coloration after the test has been run?
The Sample Well on the Test Cassette is light blue in color. Once a sample is added to the Sample Well, it will begin to flow through the strip. By the end of the test's read time, the entire Read Result Area of the test strip will also be light blue in color. This blue color indicates to the user that the Test Cassette has already been used, and should therefore not be used again. **Note:** If a transport media is used, a pink or purple color will be observed on the test strip after it has been run. This is normal, and due to the coloration of certain transport medias.

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 (15°C to 30°C).

How should the specimens be transported when using the Sofia RSV 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 24 hours prior to testing: Copan UTM, Hank's Balanced Salt Solution, Liquid Amies, M4, M4-RT, M6, Modified Liquid Stuarts, Saline, Phosphate Buffered Saline and Starplex Multitrans. It is advised that a total volume of 1 mL or less of media be used for transport. When performing the Sofia RSV FIA, use the large, pink (250 µL) pipette supplied in the kit, to dispense 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?
For best performance, use the swabs provided in the kit to collect nasopharyngeal swab specimens. You may also use the Copan Nylon Flocked nasopharyngeal swab (Quidel catalog #20226).

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

How accurate is the Sofia RSV FIA?
The performance claims for this test were obtained comparing the test results with viral cell culture and DFA. Clinical performance characteristics are listed as follows:

Patient ages 0 to <7 years	
Sensitivity	87% – Nasopharyngeal swab 92% – Nasopharyngeal aspirate/wash
Specificity	96% – Nasopharyngeal swab 98% – Nasopharyngeal aspirate/wash

Patient ages 0 to <19 years	
Sensitivity	86% – Nasopharyngeal swab 89% – Nasopharyngeal aspirate/wash 87% – Nasopharyngeal swab in VTM 88% – Nasopharyngeal aspirate/wash in VTM
Specificity	97% – Nasopharyngeal swab 98% – Nasopharyngeal aspirate/wash 97% – Nasopharyngeal swab in VTM 98% – Nasopharyngeal aspirate/wash in VTM

Sofia vs. Sofia 2 Method Comparison

	Sofia	
	Pos	Neg
Sofia 2 Pos	314	10
Sofia 2 Neg	9	267
Total:	323	277

Positive % Agreement = 97% (314/323) (95%CI=94.7%-98.6%)

Negative % Agreement = 96% (267/277) (95% CI=93.4%-98.1%)

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 Sofia 2 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.

The performance of any rapid RSV 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 coding and payment levels can vary greatly from payer to payer and change over time. Quidel Corp. 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.

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