



Sofia[®]2

Flu + SARS Antigen

Frequently Asked Questions

Summary

On October 2, 2020, Quidel received FDA Emergency Use Authorization for the Sofia 2 Flu + SARS Antigen FIA for the simultaneous qualitative detection and differentiation of nucleocapsid protein from SARS-CoV-2, influenza A and influenza B. Sofia 2 Flu + SARS Antigen FIA is intended for the qualitative detection of the nucleocapsid protein antigens in direct nasopharyngeal (NP) and nasal (NS) swab specimens from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider within the first five days of the onset of symptoms.

How does the assay work?

The test employs immunofluorescence technology used with Sofia 2 to detect nucleocapsid protein from SARS-CoV-2 virus and influenza A and B in nasopharyngeal (NPS) and nasal swab (NS) specimens.

Does the test come with everything needed to perform the assay?

The test comes with all the materials necessary to perform the test with nasal (Cat. #20377) or nasopharyngeal swab specimens (Cat. #20390), except for the Sofia 2 instrument.

Does the test come with swabs?

Yes. Kit Cat. #20377 comes with nasal swabs, while kit Cat. #20390 comes with nasopharyngeal swabs.

Where is the test performed?

Testing is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate complexity/high complexity tests, or at the Point of Care (POC) in patient care settings operating under a CLIA Certificate of Waiver.

Where is the test made?

The test was designed and is manufactured in San Diego, California.

How fast is the test?

The test includes approximately 1 minute of extraction with a 15-minute run time.

How many tests can you supply?

We are currently manufacturing 2.1 million Sofia SARS-related tests per week on average and are continuing to build our capacity.

How will Quidel determine who gets the test kits?

Quidel is doing everything possible to produce as many tests as we can during this developing situation with the understanding that during a global health emergency demand may exceed supply at times. The need for testing remains unchanged with exceptional demand. We recently doubled our production of Sofia rapid antigen tests to

the current rate of approximately 2.1 million tests per week. We are constructing additional product manufacturing lines that we expect will more than double our current capacity once again by the summer of 2021. Until that time, we continue to do our best to position products to the accounts that are best situated to address this global pandemic with our systems.

Where can patients get a test?

Anyone with symptoms consistent with COVID-19 or Influenza should contact a medical professional for evaluation. The test can be ordered by a medical professional if the patient meets the criteria for testing.

Medical professionals may order these tests through their select distributor representative.

What is the sensitivity of the assay?

The performance data in the Package Insert for Sofia 2 Flu + SARS Antigen FIA has a percent positive agreement (PPA) of 95.2% with RT-PCR using direct nasal swabs for SARS-CoV-2. The clinical samples were all collected from patients with symptom onset of 5 days or less. Based on a 2011 multi-center clinical field study, the PPA for influenza A is 90%/97.1% for nasal/nasopharyngeal specimens and the PPA for influenza B is 89%/90%, respectively.

Please refer to the Package Insert for full details on the performance of the assay.

Can viral transport media (VTM) be used with this assay?

Because of the clinical benefit of employing the most sensitive method during the critical 0-5 day window for SARS Antigen, Quidel is not supporting the use of transport media with the Sofia 2 Flu + SARS test.

Are these tests available outside of the U.S.?

We are currently focused on the North American professional segment, providing our COVID products preferentially to laboratories that are addressing the testing needs of hospital health care providers and first responders. As our manufacturing capacity has increased we have begun to provide a limited number of instruments and test cartridges to a small number of other ministries of health, including Israel, and we hope to do more globally in the coming months as we further expand our ability to manufacture and distribute these critical products.

What CPT code should be used?

We are currently working with AMA to confirm appropriate coding for reimbursement and will update this information as it becomes available.

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