SARS Antigen

Frequently Asked Questions

Summary
On May 8, 2020, Quidel received FDA Emergency Use Authorization for the Sofia SARS Antigen FIA for qualitative detection of nucleocapsid protein from SARS-CoV-2 in nasopharyngeal and nasal swab specimens directly, or after the swabs have been added to either Copan UTM or the CDC's formulation of VTM, from individuals who are suspected of COVID-19 by their healthcare provider.

On June 9, 2020, Quidel received FDA Emergency Use Authorization for the use of the Sofia immunofluorescence system with the Sofia SARS Antigen FIA, in addition to Sofia 2. Physician offices, hospitals and reference laboratories can run this assay using the Sofia and Sofia 2 immunofluorescence system as described below.

On June 23, 2020, Quidel received CE Mark for its Sofia SARS Antigen FIA to be used with Sofia or Sofia 2 instruments.

On July 17, 2020, Quidel amended its EUA performance data for its Sofia SARS Antigen FIA to 96.7% PPA versus RT-PCR when using nasal swabs within the first 5 days of symptoms.

How does the assay work?
The test employs immunofluorescence technology used with Sofia and Sofia 2 to detect nucleocapsid protein from SARS-CoV and SARS-CoV-2 virus 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 swab specimens, except for the Sofia or Sofia 2 instrument.

Does the test come with nasal swabs?
Yes, the test includes nasal 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?
Quidel is currently making an average of 1 million tests per week.

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 should contact a medical professional for evaluation. The test can be ordered by a medical professional if the patient meets the criteria for COVID-19 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 SARS Antigen FIA has a percent positive agreement (PPA) of 96.7% with RT-PCR using direct nasal swabs. The clinical samples were all collected from patients with symptom onset of 7 days or less.

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, Quidel is no longer supporting the use of transport media with the Sofia SARS Antigen FIA. The assay is authorized for use with a direct swab. If testing cannot be completed immediately, the sample swab should be placed in a clean, dry tube for storage up to 48-hours at room temperature (15°C to 30°C) or refrigerated (2°C to 8°C) after sample collection.

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?
Effective June 25, 2020 CPT® has released a new code for the SARS Antigen testing. The CPT code is 87426 and is for infectious agent antigen detection by immunoassay technique (eg, enzyme immunoassay (EIA), enzyme-linked immunosorbent assay (ELISA), immunochemiluminometric assay (IMCA) qualitative or semiquantitative, multiple-step method; severe acute respiratory syndrome coronavirus (eg, SARS-CoV, SARS-CoV-2 [COVID-19].)

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