



Sofia[®]

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.

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?

We are ramping up manufacturing to go from 200,000 tests on the week of May 11 to more than a million a week within several weeks.

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.

We first intend to take on-board customers in the traditional professional segment, in particular, those that would help in addressing testing for hospital health care providers, and first responders. During this initial time, we will continue to perform studies and further establish the clinical utility of the product. We expect to be at full manufacturing volume as mentioned above in the near-term and can expand testing to other facilities to address other demands, as appropriate.

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?

We have met the sensitivity hurdle required by the FDA for Emergency Use Authorization on a small number of clinical samples. Over the next few weeks we will be conducting further studies with clinical specimens collected using nasal swabs to better understand the performance of the Sofia SARS Antigen FIA.

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

Yes, VTM may be used with this assay in accordance with the package insert, however, we recommend running direct swabs for the best performance.

What viral transport medias (VTM) are allowed with the assay?

Internal validation of all medias is ongoing. The data in the package insert supports use with Universal Transport Media (UTM) and internal validation supports use of CDC's Formulation Media. **Remel M4 and M4RT should not be used as some lots have been demonstrated to generate false positive results.**

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

We are currently focused on the US professional segment, followed by entry into the Canadian market, and also have an initial focus on customers that are addressing the testing needs of hospital health care providers and first responders. We are planning to expand globally as our inventory and manufacturing position progresses.

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