SARS-CoV-2 Assay

Frequently Asked Questions

Summary
On March 17, 2020, Quidel received FDA Emergency Use Authorization for the Lyra SARS-CoV-2 assay to detect the virus that causes COVID-19. Hospitals and reference laboratories can run this assay using the bioMérieux NucliSENS® easyMAG® system or EMAG® system for extraction and the ABI 7500 Fast Dx for amplification and detection. Additional validated instruments are further described below. As with our other respiratory assays, the kits can be ordered with swabs/Viral Transport Media (VTM) or with reagents alone.

Update: On March 25, 2020, Quidel received CE Mark for the Lyra SARS-CoV-2 assay, authorizing Quidel to market and sell the assay in Europe and in countries that accept the CE Mark, and COVID-19 Medical Device Authorization from Health Canada to sell the assay in Canada. Also, on March 23, 2020, the EUA was extended, allowing the assay to run on four (4) additional thermocyclers: Applied Biosystems® 7500 Standard, Applied Bioscience® 7500 Fast, Roche LightCycler® 480, and Qiagen Rotor-Gene Q. Additionally, the Centers for Disease Control and Prevention has expanded the list of acceptable specimens to include nasal and nasal turbinate swabs.

Where will the Quidel-made assay be available for testing, and how soon will it be deployed?
We are currently shipping and on allocation to several of our customers throughout the United States. As we ramp up production, it is our goal to meet the needs of all our customers.

How many tests are currently available? What is the timeline to get to maximum production? What number of tests does maximum production entail?
Quidel began shipping tests to U.S. labs immediately. Due to demand, we are currently allocating this product in order to serve as many customers as possible. We are working on ramping our production and now anticipate being able to generate approximately 50,000 tests/day by mid-April. This maximum production is an estimate and could be affected by any potential supply chain disruptions.

Are you experiencing any supply chain issues that may impact assay production? Do you anticipate any further issues in testing once the assays are available?
Currently, we are manufacturing test kits for the assay. There is an industry-wide supply chain issue with swabs and UTM, and Quidel is affected as well, although the shortages of these components currently do not affect the manufacture of our test kits.

Where will this test be used?
Hospitals and reference laboratories can run this assay using the bioMérieux NucliSENS® easyMAG® system or EMAG® system for extraction and the ABI 7500 Fast Dx for amplification and detection. As with our other respiratory assays, the kits can be ordered with swabs/Viral Transport Media (VTM) or with reagents alone.

We have recently received an expansion of our EUA allowing us to run the assay on the ABI 7500 Standard, the ABI 7500 Fast, Qiagen's Rotor-Gene Q and the Roche LC480. We are continuing to explore and validate other thermocyclers and will continue to update this list as quickly as possible

In addition to the platforms included in our EUA, we have also received an expansion of our EUA to include the Roche MagnaPur system for extraction. We are continuing to validate other extraction systems and will update this list as quickly as possible.

How will Quidel determine who gets the test kits and ancillary materials (kits with swabs/VTM)?
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. Our goal is to be able to have tests available to all our customers and we will continue to work with the regulatory bodies on implementing a strategy to help provide tests as well as ancillary materials such as swabs and transport media to our customers.

Please note current swab/VTM customers: We are out of stock from our swab/VTM vendor and are currently unable to determine when we will have a restocking position in order to provide swabs/VTM. We will continue to update this information as we receive it.

How does this compare to the other COVID-19 tests on the market?
Extraction takes approximately 1 hour, and amplification and detection take 75 minutes. The assay features:

- A one-step reagent set-up by rehydrating the lyophilized Master Mix
- Refrigerated storage (instead of frozen storage)
- Room temperature setup (instead of using ice or a cooling block)
- Flexible 96-test format

Should the public have any concerns about this type of research work in their community?
The virus that we use to test for coronavirus in our R&D facility uses an inactivated form of the virus.

From reading the press release, it is my understanding this is a PCR reagent kit. Is that correct? How long does it take for this test to come back with results?
Yes, this is a PCR reagent kit. Diagnostic answers are usually provided in a few hours, however the results of the test may not come back immediately if the test sample was sent out to a lab.

How does the assay work?
The test detects the RNA that is specific for the SARS-CoV-2 virus in nasopharyngeal (NP) or oropharyngeal (OP) swab specimens collected by a healthcare provider. More recently, the CDC has expanded the list of acceptable specimens to include nasal and nasal turbinate swabs. Our Lyra SARS-CoV-2 Assay can provide a diagnostic answer from these sample types.

Has Quidel received federal funding to develop and produce this assay?
Quidel has not received any federal funding to develop and produce this assay.

Is Quidel affected by government-imposed isolation policies stemming from the global pandemic?
This situation is constantly changing, however Quidel's employees that work in operations, distribution and R&D are authorized to continue their work at our facilities in order to make and deliver the products needed.

Where can patients get a test?
Anyone with symptoms consistent with COVID-19 should contact a medical professional for evaluation and the test can be ordered by a laboratory professional if the patient meets the criteria for COVID-19 testing.

Laboratory professionals may order these tests through their Cardinal Health representative or contact Quidel directly at 1.800.874.1517, Option 1 for Customer Service.

Are these tests available outside of the U.S.?
As of March 25, 2020, we've received authorization to market and sell the test to Canada through Health Canada, and have received the CE Mark, which allows Quidel to sell the test into the EU, as well as any other countries that accept the CE Mark.

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