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 NucliSSENS® 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.

How does the assay work?
The test detects the RNA that is specific for the SARS-CoV-2 virus in nasopharyngeal (NP) or oropharyngeal swab specimens collected by a healthcare provider.

Where is the test performed?
Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Where is the test made?
The test was designed in San Diego, California and manufactured in Athens, Ohio.

How fast is the test?
Extraction takes approximately 1 hour, and amplification and detection takes 75 minutes.

What about other thermocyclers?
We have been working to validate additional equipment with our assay. In addition to the systems included in our EUA, We have currently validated this 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.

What about other extraction platforms?
In addition to the platforms included in our EUA, we have validated the Roche MagnaPur system. We are continuing to validate other extraction systems and will update this list as quickly as possible.

How many tests can you supply?
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.
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 of 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.

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 medical professional if the patient meets the criteria for COVID-19 testing.

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