SARS-CoV-2 Assay

Frequently Asked Questions

Summary:
On May 18, 2020, Quidel received FDA Emergency Use Authorization for the Lyra Direct SARS-CoV-2 Assay to allow direct sample processing in nasal (NS), nasopharyngeal (NP), or oropharyngeal (OP) direct swab specimens from individuals suspected of COVID-19 by their healthcare provider.

Under the new EUA, hospital and reference laboratories no longer have to depend on an upfront sample extraction. Lyra Direct SARS-CoV-2 Assay utilizes a reformulated buffer that replaces the extraction step with a simple 10-minute heat step, saving approximately 50 minutes in processing time.

On May 8, 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.

How does the assay work?
The Lyra Direct SARS-CoV-2 Assay detects SARS-CoV-2 viral RNA that has been extracted from a patient sample using a simple heat step. A multiplex real-time RT-PCR reaction is carried out under optimized conditions in a single tube generating amplicons for the targeted virus (if present) and the Process Control (PRC) present in the sample.

This reaction is performed utilizing one of seven thermocyclers: Applied Biosystems® 7500 Fast Dx, Applied Biosystems® 7500 Standard, Roche LightCycler® 480 Instrument II, Roche cobas® z 480, Qiagen Rotor-Gene® Q, Bio-Rad CFX96 Touch™, Thermo Fisher QuantStudio™ 7 Pro. Identification of the SARS-CoV-2 virus occurs by the use of target specific primers and fluorescent-labeled probes that hybridize to a conserved region of the non-structural polyprotein of the SARS-CoV-2 virus.

Does the test come with everything needed to perform the assay?
The assay with the controls included is available as a standalone kit or with the ancillary materials such as swabs and transport tubes.

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.

Can viral transport media (VTM) be used with this assay?
No, VTM may not be used with this assay in accordance with the Package Insert. Use of specimens in transport media will adversely impact the sensitivity of the assay.

If utilizing a direct swab specimen what are the storage requirements?
Nasal, nasopharyngeal, or oropharyngeal swab specimens should be collected and placed in a clean, dry transport tube. Specimens should be transported and tested as soon as possible after collection.

Specimens are stable for up to 24 hours at room temperature or up to 72 hours when stored at 2°C to 8°C. If specimens cannot be tested within 72 hours of collection, they should be frozen at –70°C or colder until tested.

How fast is the test?
Sample preparation time varies depending on format utilized and the number of samples being processed. The amplification and detection take approximately 70 minutes.

How does this compare to Lyra SARS-CoV-2 Assay?
The Lyra Direct SARS-CoV-2 Assay differs from the Lyra SARS-CoV-2 Assay in that the Direct Assay detects COVID-19 directly from samples without prior need for RNA purification. In a comparative LoD study for the Lyra Direct SARS-CoV-2 Assay and the Lyra SARS-CoV-2 Assay it was determined that the LoD for the two versions of the Lyra Assay (Lyra SARS-CoV-2 Assay and Lyra Direct SARS-CoV-2) have an input LoD of 1.28×10^4 genome equivalents/mL showing the equivalent performance between the two assays.

How does this compare to the other COVID-19 tests on the market?
There are many features and benefits of the Lyra Direct SARS-CoV-2 Assay

- Detects COVID-19 directly from samples without a prior RNA purification process.
- Flexibility in storage of direct swab specimens can be stored at room temperature for 24 hours or up to 72 hours when stored at 2°C to 8°C.
- Accommodates to varying test volumes with different workflow formats
- Open platform solution to provide flexibility in implementation with multiple thermocyclers

How many tests can you supply?
Currently, we are manufacturing approximately 96,000 tests per day.

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.

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.

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