

[EUA, CE mark for Lyra Direct SARS-CoV-2 Assay](#)

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June 2020—Quidel announced it has received emergency use authorization for the Lyra Direct SARS-CoV-2 Assay from the Food and Drug Administration to allow direct sample processing.

Under the new EUA, the Lyra Direct SARS-CoV-2 Assay no longer requires an up-front sample extraction. The assay uses a reformulated buffer that replaces the extraction step with a 10-minute heat step, saving about 50 minutes in processing time. The assay runs on the Applied Biosystems 7500 Standard, Applied Biosystems 7500 Fast, Bio-Rad CFX96 Touch, Qiagen Rotor-Gene Q, Roche LightCycler 480, Roche Cobas z 480, and Thermo Fisher QuantStudio 7 Pro thermocyclers.

The Lyra Direct SARS-CoV-2 Assay received the CE mark on May 8.

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