Quidel Recalls Lyra SARS-CoV-2 Assay (M120) Due to Risk of False Negative Results

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- Lyra SARS-CoV-2 Assay (M120)
- Lot codes: 031620A, 031620B, 031620C, 032320, 032420, 032720, 032820A, 032820B, 040320, 040720, 040920, 041020, 174992, 175429, 175501, 175502, 175503, 176001, 176002, 176366, 176367, 176368, 178984, 178985, 180331, 180332, 180673, 180674, 180675, 182594, 184273, 185535, 185822, 186470, 186472, 187062, 187173, 187822, 189232, 189942, 190786, 193074, 193977
- Manufacturing Dates: March 17, 2020 to March 12, 2021
- Distribution Dates: March 17, 2020 to May 27, 2021
- Devices Recalled in the U.S.: 18385 (each kit contains 96 reactions)
- Date Initiated by Firm: April 26, 2021

Device Use

The Lyra SARS-CoV-2 Assay (M120) is a real-time polymerase chain reaction (https://www.cancer.gov/publications/dictionaries/cancer-terms/def/pcr) (RT-PCR) assay used to qualitatively detect nucleic acid from SARS-CoV-2, the virus that causes COVID-19. The test uses nasal, nasopharyngeal (NP), or oropharyngeal (OP) swab samples from patients suspected by their healthcare provider of illness caused by the COVID-19 virus. The SARS-CoV-2 virus is generally detectable in upper respiratory specimens during the onset of an infection. Positive results indicate the presence of SARS-CoV-2 RNA; however, patient history and other diagnostic information needs to be considered to determine if the patient has an infection. Positive results do not rule out bacterial infection or co-infection with other viruses.

Reason for Recall

Quidel is recalling the Lyra SARS-CoV-2 Assay (M120) due to a significant risk of false negative results for patients with relatively high amounts of SARS-CoV-2 virus potentially causing the PCR amplification to occur before a cycle-threshold (Ct) value ≤5 when using the following thermocyclers:

- ThermoFisher QuantStudio 7 Pro,
- Applied Biosystems 7500 Fast Dx,
- Applied Biosystems 7500,
- Bio-Rad CFX96 Touch,
- Roche LightCycler 480, or
- Qiagen RotorGene MDx

False negative results may lead to delayed diagnosis or inappropriate treatment of SARS-CoV-2 that may cause patient harm, serious illness, and death. False negative results can also lead to further spread of the SARS-CoV-2 virus, when presumed negative patients are introduced into groups within health care, long-term care, or other similar facilities. Actions to limit exposure based on false negative results might not be taken, such as isolating infected individuals.

Quidel has received five complaints about the Lyra SARS-CoV-2 Assay (M120), however, there have been no reports of injuries or death from this issue.

Who May be Affected?

- Patients, healthcare providers, family members, and others in the community who may be exposed, infected with, and have adverse outcomes due to infection with SARS-CoV-2 because of a false negative result.
- Laboratories who may have access to these tests.

What to Do

On April 26, 2021, Quidel sent all affected customers an "Urgent: Field Corrective Action" letter by email. The letter requested customers to:

- Review the revised Lyra SARS CoV 2 Assay Instructions for Use (IFU) for an updated Result Interpretation guidance: https://www.fda.gov/media/136820/download (/media/136820/download).
- For clinical specimens generating Ct values ≤5:
    - Perform 1:10 and 1:100 dilutions using uninoculated transport media.
    - Extract (process) and test the diluted samples according to the Lyra SARS CoV 2 IFU.
    - Refer to the Lyra SARS CoV 2 Assay IFU for full, detailed instructions and interpretation of results.
- Re-evaluate any data that was previously generated and re-test those samples, as needed, as noted above.

- Complete the Field Corrective Action Fax Back form enclosed in the Urgent Medical Device Correction notice acknowledging receipt and understanding of the recommended actions.
- Return the Fax Back form with the requested information to Quidel Technical Support by fax at 858.203.9297 or by email to customernotifications@quidel.com (mailto:customernotifications@quidel.com).

Contact Information

Customers with questions about this recall should contact Quidel Customer Service at 1-800-874-1517 (in the U.S.), or (858) 552-1100 (outside of U.S.), from Monday to Friday, 8:00 a.m. to 5:00 p.m. Eastern Time, or email at customerservice@quidel.com (mailto:customernotifications@quidel.com).

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187617)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.