Risk of Inaccurate Results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit - Letter to Clinical Laboratory Staff and Health Care Providers

The U.S. Food and Drug Administration (FDA) is alerting clinical laboratory staff and health care providers of a risk of false results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit based on two issues related to the test kit and the associated Applied Biosystems COVID-19 Interpretive Software. The test is a molecular assay for the detection of COVID-19 from respiratory specimens.

The first issue is related to inadequate vortexing and centrifugation of RT-PCR reaction plates. Thermo Fisher Scientific's conclusion from investigations of customer complaints indicate that inadequate vortexing or centrifugation can lead to false positive results. Thermo Fisher Scientific has updated these instructions to reduce the risk of inaccurate results. The updated instructions related to vortexing and centrifugation are important for both laboratories performing testing according to the authorized instructions for use and laboratories who are performing validated modifications outside of the authorization.

The second issue is related to the assay Internal Positive Control (IPC) and requires laboratory staff to upgrade their software to reduce the risk of invalid, potential false negatives, or inconclusive tests and to decrease the potential need to retest.

Recommendations

The FDA recommends clinical laboratory staff and health care providers using the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit:

- **Implement promptly the software updates and updated instructions for use from Thermo Fisher Scientific.**
    - Stop using Applied Biosystems COVID-19 Interpretive Software v1.2, v2.0 and v2.2.
    - Upgrade your Applied Biosystems COVID-19 Interpretive Software to version 1.3 or 2.3. Go to www.thermofisher.com/educationconnect (http://www.thermofisher.com/educationconnect) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) and sign in with your thermofisher.com username and password.
        - Type in the subscription code **C19CKEUAFIS1323** to access and complete the training. You will need to pass an exam and acknowledge that you reviewed

information to upgrade the Applied Biosystems COVID-19 Interpretive Software.

- Re-registration is needed for this upgrade.
- Read Thermo Fisher Scientific's EducationConnect welcome letter (https://www.brainshark.com/thermofisher/educationconnect_welcomeEUA) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) or watch the video tutorial (https://www.brainshark.com/1/player/thermofisher?&fb=0&r3f1=&custom=educationconnect_tutorial) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for full instructions to learn how to access the new version of the software.

- Read and implement the vortexing and centrifugation instructions Thermo Fisher Scientific added to the latest release of the Instructions for Use (https://assets.thermofisher.com/TFS-Assets/LSG/manuals/MAN0019181_TaqPath_COVID-19_IFU_EUA.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) to prevent insufficient mixing and/or centrifugation.

- **For all positive results, review the amplification curves within the instrument software for controls and patient specimens to determine whether the plate should be retested due to inadequate vortexing and centrifugation. Contact your local Thermo Fisher Scientific Field Applications Scientist for additional information on viewing amplification curves and performing plate level checks.**
  - **Implement routine plate level checks of the amplification curves to ensure your laboratory appropriately adheres to specimen processing instructions for vortexing and centrifugation.**
- **Healthcare providers should consider positive results in combination with clinical observations, patient history, and epidemiological information.**
- Notify all Thermo Fisher Scientific TaqPath COVID-19 Combo Kit and Applied Biosystems COVID-19 Interpretive Software users in your facility of this letter.
- Contact Thermo Fisher Scientific's Technical Support at 800-955-6288 option 2 or techsupport@thermofisher.com (mailto:techsupport@thermofisher.com) for technical questions.
- Report any issues with using the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit and the Applied Biosystems COVID-19 Interpretive Software to Thermo Fisher Scientific and the FDA. See Reporting Problems to the FDA below.

Background

The FDA authorized the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit for use only in laboratories in the United States certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to perform moderate and high complexity tests. The test initially received an Emergency Use Authorization (/media/136113/download) on March 13, 2020 and has been granted several modifications (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) through supplemental EUA requests between March and July 2020.

The test is designed to detect viral nucleic acid from SARS-CoV-2, the virus that causes COVID-19, in upper respiratory specimens, such as nasal swabs.

FDA Actions

The FDA is working with Thermo Fisher Scientific and our public health partners to resolve these issues. The FDA will continue to keep clinical laboratory staff, health care providers, manufacturers, and the public informed of new or additional information.

Additional Resources

- FAQs on Testing for SARS-CoV-2 (/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2)
- In Vitro Diagnostics EUAs (/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas)

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit and the Applied Biosystems COVID-19 Interpretive Software.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact COVID19DX@fda.hhs.gov (mailto:COVID19DX@fda.hhs.gov).