World Health Organization

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# WHO INFORMATION NOTICE FOR USERS

**Product name: TaqPath™ COVID-19 CE-IVD RT-PCR kit**
manufactured by **Thermo Fisher Scientific** (product code **A48067**) used with:

- Applied Biosystems COVID-19 Interpretive Software **v1.2** (used with the 7500 series Real-Time PCR instruments)
- Applied Biosystems COVID-19 Interpretive Software **v2.1 or v2.2** (used with the QuantStudio Real-Time PCR platforms)

**Date:** 1 September 2020

**WHO-identifier:** 2020/4, version 2 (see update in grey highlight)

**Type of action:** Advice to users

**Purpose of this notice:** To ensure users of Thermo Fisher Scientific TaqPath™ COVID-19 CE-IVD RT-PCR kit are aware of a mandatory software update and reinforce certain parts in the instructions for use that must be followed to avoid misclassification of test results.

**Description of the problem:** Thermo Fisher Scientific identified the need to conduct a field safety corrective action to reduce the risk related to use of their product, the issues were identified through customer feedback and internal review.

*Issue 1:*
Poorly extracted patient specimens were called valid using MS2 Assay. A cycle threshold (Ct) cutoff of 37 was not adequate to detect specimens with poor extraction efficiency or a large amount of impurities post-extraction. This issue *may* potentially cause a weakly positive specimen that sub-optimally extracted to be falsely called a valid negative specimen, thereby constituting a false negative. However, no customer has reported false negative results due to this issue to date.

*Issue 2:*
The MS2 assay, which detects the Internal Positive Control (IPC), was erroneously called amplified in a small percentage of Positive Control (PC) samples. This issue caused a plate to be designated incorrectly as invalid, thereby requiring unnecessary retesting of an entire batch of specimens.

As a result of the above two issues, Thermo Fisher Scientific recommends a mandatory upgrade for the Applied Biosystems COVID-19 Interpretive Software used with the TaqPath COVID-19 CE-IVD COVID-19 RT-PCR Kit:

- If you are using **Applied Biosystems COVID-19 Interpretive Software v1.2 (used with the 7500 series Real-Time PCR instruments**) you need to upgrade to **software v1.3**.
- If you are using **Applied Biosystems COVID-19 Interpretive Software v2.1 or v2.2 (used with the QuantStudio Real-Time PCR platforms**), you need to upgrade to **software v2.3**.

*Issue 3:*
Thermo Fisher Scientific has updated the Instructions for Use (IFU) to highlight the importance of vortexing the RT-PCR reaction plates to mitigate potential for false positive results. The vortexing instructions are detailed in the "Prepare RT-PCR reactions" step of the Instructions for Use, recorded under the publication number MAN0019215 Revision E and all translations of this publication.

Thermo Fisher Scientific strongly recommends that all users participate in training on how to properly run the workflow as offered by the local representative.

**Advice on action to be taken by users:**

1. Please check if your local representative for Thermo Fisher Scientific has communicated a field safety notice to your facility on this topic.
    a. If they have, please follow the instructions contained in the field safety notice specific for your regulatory jurisdiction. Thermo Fisher Scientific will provide a subscription code to access and complete e-learning. You will be required to pass an exam and acknowledge that you reviewed information to upgrade the Applied Biosystems COVID-19 Interpretive Software.
    b. If they have not, please contact your local representative for Thermo Fisher immediately, or the economic operator who provided you with the product.
2. **Stop using Applied Biosystems COVID-19 CE-IVD Interpretive Software v1.2, v2.1 and v2.2.**
3. **Do not test specimens until the mandatory e-learning and software upgrade has been conducted.**
4. Consider any positive result (SARS-CoV-2 detected) or negative results (SARS-CoV-2 not detected) in combination with clinical observations, patient history, and epidemiological information.
5. Ensure that you sign and return acknowledgement of receipt of the field safety notice issued by Thermo Fisher Scientific, as per their request.

**Transmission of this WHO Information Notice for Users:**
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected product has been deployed and used.

**Contact person for further information:**
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