

Update to Field Safety Notice of August 05.2020

**Product: TaqPath™ COVID-19 CE-IVD RT-PCR kit (Catalog #A48067)
Applied Biosystems™ COVID-19 CE-IVD Interpretive Software v1.3 and v2.3**

19 August 2020

Dear Valued Customer,

This letter provides you additional information in support of Thermo Fisher Scientific's Field Safety Notice (FSN) dated on August 05.

The below information provides further details and does not alter the content of the initial Field Safety Notice related to the mandatory software upgrade.

In the previous FSN, we communicated that the MS2 assay which detects the Internal Positive Control (IPC), may produce inconclusive tests and may trigger the need to retest entire batches of samples. The software update to the MS2 settings is designed to reduce the risk of invalid, potential false negatives, or inconclusive tests and decrease the retest burden on customers. Analysis settings for other targets have not been changed. As a result, there is a mandatory upgrade for the Applied Biosystems COVID-19 Interpretive Software used with the TaqPath COVID-19 CE-IVD RT-PCR Kit.

The interpretive software update also addresses the risk of potential false negative results which are associated with RNA samples prepared by suboptimal extraction, and analyzed with former versions of Applied Biosystems™ COVID-19 CE-IVD Interpretive Software. As described under Assay Limitations, in publication number MAN0019215 Revision E and all translations of this publication:

"This kit [TaqPath™ COVID-19 CE-IVD RT-PCR kit (Catalog #A48067)] uses purified RNA as input sample for the analysis. The quality of the RNA recovered from biological samples is essential for the quality of the results generated with this kit."

If you have any technical questions or concerns, please contact Technical Support at 00 800 5345 5345 option 3 or email eurotech@thermofisher.com.

Sincerely,

Carol Bleakley
Senior Director of Quality
Genetic Sciences Division
Thermo Fisher Scientific