

Urgent Field Safety Notice

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

5 August 2020

Dear Valued Customer,

This letter is to notify you of two issues we have observed through internal review and customer feedback and as a result we have made important updates to our Software and Instructions for Use (IFU).

1. The first issue is related to the MS2 assay which detects the Internal Positive Control (IPC). We have made a software update to the MS2 settings to reduce the risk of invalid or inconclusive tests and to 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

- 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.
2. The second issue is related to instructions for vortexing RT-PCR reaction plates. For this issue, we have updated the Instructions for Use (IFU) to highlight the importance of vortexing the RT-PCR reaction plates to mitigate potential 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.

We strongly recommend that all users participate in training on how to properly run the workflow. Our training team walks through the entire end-to-end process, including the vortexing step and its importance. Please access the training that is available 24/7 via the Education Connect link provided below. If you have additional training needs, please contact your local Thermo Fisher Scientific representative to schedule live training.

Actions Required:

- Notify all Applied Biosystems COVID-19 CE-IVD Interpretive Software users in your facility of this communication.
- Stop using Applied Biosystems COVID-19 CE-IVD Interpretive Software v1.2, v2.1 and v2.2.
- Go to www.thermofisher.com/educationconnect and sign in with your thermofisher.com username and password. Type in the subscription code **COVID19CEIVDISW1323** to access and complete the training. You will be required to pass an exam and acknowledge that you reviewed information to upgrade the COVID-19 Interpretive Software. Re-registration is required for this upgrade. For full instructions to learn how to access the new version of the software please read our [EducationConnect welcome letter](#) or [watch this quick video tutorial](#).
- Read and implement the vortexing recommendations added to the latest release of the Instructions for Use – available on the product page [TaqPath COVID-19 CE IVD IFU](#) to prevent insufficient mixing and/or centrifugation.

- Sign and return acknowledgement of Receipt – page 3 of this communication, to EU-customer-notification@thermofisher.com

Thermo Fisher Scientific is committed to supplying innovative, high-quality products. If you have any technical questions or concerns, please refer to the Frequently Asked Questions document provided with this communication. If you still have 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

CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)

* (Customer to populate)

Institution *	
Customer Name *	
Address * City * Post Code * Country *	
Email *	

Product Name	SKU Number	Number of Instances Upgraded (Customer to populate)
COVID19 INTPRTV CEIVD V1.2	100093771	
COVID19 INTPRTV CEIVD V2.1	100094143	
COVID19 INTPRTV CEIVD V2.2	100094318	

I have read and understand the instructions provided in the letter dated 5 August 2020. YES NO

I have notified all software users in my facility:	<input type="checkbox"/> YES <input type="checkbox"/> NO
If "No," please explain:	

Customer Signature of Receipt: _____ **Date:** _____

Please return response sheet by email to EU-customer-notification@thermofisher.com

For any questions or comments please contact Technical Support at 00 800 5345 5345 option 3 or email euotech@thermofisher.com

Thermo Fisher Scientific Reference Number: PR 430820

Urgent Field Safety Notice

Mandatory Upgrade to TaqPath™ COVID-19 CE-IVD Interpretive Software v1.3 and v2.3

Date:

Institution:	<<Customer_Name>>	<<Address_Line_2>>
Address:	<<Address_Line_4>>	<<Address_Line_3>>
	<<Address_Line_1>>	<<City>>, <<State>> <<Post Code>> <<Country>>

Dear Valued Customer,

This letter is to notify you of a mandatory upgrade for the TaqPath™ COVID-19 CE-IVD Interpretive Software.

- If you are using TaqPath COVID-19 CE-IVD 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 TaqPath COVID-19 CE-IVD Interpretive Software v2.1, or v2.2 (used with the QuantStudio Real-Time PCR platforms), you need to upgrade to software v2.3.

An internal review of a cross-section of customer data and feedback from using the TaqPath™ COVID-19 CE-IVD RT-PCR Kit resulted in two observed issues:

1. The previous interpretive software versions may not recognize suboptimal extractions (poorly extracted samples). The development team initially determined that if the extraction failed, the MS2 Ct would be >37. However, a review of customer data has shown that suboptimal extractions can result in lower MS2 Ct values than expected. This issue could potentially cause a weakly positive sample that is prepared by suboptimal extraction to be falsely called a valid negative sample, thereby constituting a false negative.
2. The MS2 assay, which detects the Internal Positive Control (IPC), may be erroneously called amplified in a small percentage of Positive Control (PC) samples. This issue could cause a plate to be designated invalid, thereby requiring unnecessary retesting of an entire batch of samples.

Software Algorithm Improvements

Versions 1.3 and 2.3 address both issues by applying an optimized Ct cutoff for MS2. Our investigation indicates that most users will not experience these errors. However, given that errors could occur, we have optimized the MS2 settings to reduce the risk of false test outcomes and to decrease the retest burden on customers. No other analysis settings have been changed.

Instructions for Use Clarifications

In addition to these software algorithm improvements, we have updated the Instructions for Use to highlight the importance of mixing the RT-PCR reaction plates to further mitigate potential false positives. Insufficient mixing of qPCR plates could produce a “waterfall” effect in which decreasing signal in the baseline region ultimately produces erroneous Ct values, potentially leading to an incorrect positive call for one or more targets.

Actions Required:

- Notify all COVID-19 CE-IVD Interpretive Software users in your facility of this communication.
- Stop using COVID-19 CE-IVD Interpretive Software v1.2, v2.1, and v2.2.
- Go to www.thermofisher.com/COVID19EUATraining-ISWv13-33 to complete the training and upgrade the COVID-19 CE-IVD Interpretive Software. Re-registration is required for this upgrade.
- Sign and return acknowledgement of Receipt – page **3** of this communication.

We apologize for any inconvenience. Thermo Fisher Scientific is committed to supplying innovative, high-quality products. If you have any technical questions or concerns, please refer to the Frequently Asked Questions document provided with this communication. If you still have questions or concerns, please contact Technical Support at [\[800-955-6288 option 4 or techsupport@thermofisher.com\]](tel:800-955-6288) *add your country TS info here*.

Sincerely,

Genetic Sciences Division
Thermo Fisher Scientific

DRAFT

CUSTOMER RESPONSE SHEET
Acknowledgement and Receipt Form
(Customer response is required)

Product Name	SKU Number	Number of Instances Upgraded (Customer to populate)
COVID19 INTRPTV CEIVD V1.2	100093771	
COVID19 INTPRTV CEIVD V2.1	100094143	
COVID19 INTPRTV CEIVD V2.2	100094318	

Customer Name and Address:

I have read and understand the instructions provided in the letter dated <enter date>. YES NO

I have notified all software users in my facility:	<input type="checkbox"/> YES <input type="checkbox"/> NO
If "No," please explain:	

Customer Signature of Receipt: _____ Date: _____

Please return response sheet by email to xxx.xxxx@thermofisher.com.

For any questions or comments please contact Technical Support at 1-XXX-XXX-XXXX.

Thermo Fisher Scientific Reference Number: PR XXXXX