

## **Urgent Field Safety Notice**

Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition Mandatory Upgrade to Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition v1.5 and 2.5

**Product: TaqPath™ COVID-19 CE-IVD RT-PCR kit (Ref. A48067)**

Date: March 3, 2021

Dear Valued Customer,

This letter is to notify you of a mandatory software upgrade for the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition, supplied for the interpretation of diagnostic tests performed with TaqPath™ COVID-19 CE-IVD RT-PCR kit (Ref. A48067).

- All versions of Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition (v1.3 or earlier, used with the 7500 series Real-Time PCR platforms) must be upgraded to software v1.5.
- All versions of Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition (v2.3 or earlier, used with the QuantStudio™ Real-Time PCR platforms), must be upgraded to software v2.5.

In Thermo Fisher Scientific's continuous improvement culture, a software upgrade has been released with new features to further mitigate for inadequate vortexing and offer additional functionalities.

- New analysis that is robust to high initial fluorescence caused by inadequate vortexing
- Amplification plot view that can be filtered by sample for manual review
- A new detailed sample report includes the amplification plot
- Comment field that will be included in the sample reports

### **Actions Required immediately:**

- Stop using Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition v1.3/v2.3 or any earlier version.
- Read and implement MAN0019215 revision F and its translations related to software upgrade.
- Go to [www.thermofisher.com/educationconnect](http://www.thermofisher.com/educationconnect) and sign in with your thermofisher.com username and password. You have or will be auto-enrolled into the training for the v1.5/v2.5 version of the software. Please look for the course "TaqPath™ COVID-19 CE-IVD RT-PCR Kit and COVID-19 Interpretive Software v1.5 and v2.5" in your "My Courses and Learning Plans" section and complete the training. You will be required to pass a quiz and acknowledge that you reviewed information to upgrade the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition. Re-registration is required for this upgrade.
- If any additional user in your lab has not been auto-enrolled, they can self-enroll in the training with the following Subscription Code: **TC19CEIVDFISW1525**. Refer to the online [Welcome Letter](#) and the [online video](#) for instructions on how to use the code, or contact your local instrument service team (go to <https://www.thermofisher.com/contactus>).
- Install the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition v1.5 or 2.5 as appropriate. For any assistance, contact your local instrument service team (go to <https://www.thermofisher.com/contactus>).
  - Note: Installation of this upgrade will require the uninstallation of any earlier version of the software but will not affect any report already published with earlier versions.
- Complete the [Response Form](#) online after successful software download and installation. Alternatively, this form is also available on page 3 of this letter.

**Transmission of this Field Safety Notice:**

- This notice needs to be passed on to all users of the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition within your organization or to any organization where the devices have been transferred.
- Please transfer this notice to other organizations on which this action has an impact.
- Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The undersign confirms that this notice has been notified to the appropriate Regulatory Agency.

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 visit [www.thermofisher.com/contactus](http://www.thermofisher.com/contactus) for your regional support team phone and email contact information.

Sincerely,

Carol Bleakley  
Sr. Director of Quality  
Genetic Sciences Division  
Thermo Fisher Scientific

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

<b>First Name *</b>	
<b>Surname *</b>	
<b>Work eMail (work domain) *</b>	
<b>Institution Name *</b>	
<b>Address</b>	
<b>Zip code *</b>	
<b>City *</b>	
<b>Country *</b>	
<b>Phone number *</b>	
<b>Fax</b>	
<b>email *</b>	

\* **Mandatory field**

- I have read and understand the instructions provided in the letter dated [Date].  YES  NO
- I have successfully upgraded and installed the Interpretive Software in my Institution.
  - YES
  - NO, I need Thermo Fisher Technical Support
  - N/A, the Software is not in use in my Institution

Please indicate how many instances (1, 2, 3, etc) you have upgraded the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD v 1.5/2.5, or indicate "none" if this Software version wasn't upgraded in your laboratory:

Product Name	SKU Number	Product Name	SKU Number	Number of Instances Upgraded
COVID19 INTPRTV CEIVD V1.3	100095578	COVID19 INTPRTV CEIVD V1.5	100098243	
COVID19 INTPRTV CEIVD V2.3	100095575	COVID19 INTPRTV CEIVD V2.5	100098246	

I have notified all users of the Applied Biosystems™ COVID-19 Interpretive Software CE-IVD Edition within my organization or to any organization where the devices have been transferred.	<input type="checkbox"/> YES <input type="checkbox"/> NO
If "No," please explain:	

Please return response sheet by email to [EU-customer-notification@thermofisher.com](mailto:EU-customer-notification@thermofisher.com)

For any questions or comments please contact Technical Support at 00 800 5345 5345 option 3 or email [eurotech@thermofisher.com](mailto:eurotech@thermofisher.com)

Thermo Fisher Scientific Reference Number: PR 476662