

Urgent Field Safety Notice

Products: **TaqPath™ COVID-19 CE-IVD RT-PCR Kit , 1000 reactions (Catalog #A48067)**
 TaqPath™ COVID-19 CE-IVD RT-PCR Kit, 100 reactions (Catalog #A51738)

MMM DD, YYYY

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 important updates to the Instructions for Use of our TaqPath COVID-19 CE-IVD RT-PCR Kit used with our QuantStudio™ 5 (QS5 and QS5 Dx) instruments due to an issue brought to our attention through customer feedback and our post market surveillance program.

While evaluating the feedback from customers, we identified remote occurrences (~0.0002%) of signal discontinuity in the multicomponent plots from QuantStudio 5 (QS5 and QS5 Dx) instruments, for 96-well, 0.2-mL block and a MicroAmp™ Optical 96-Well Reaction Plate (with or without barcode). Our investigation has determined that the observed signal discontinuities are likely caused by inadequate sealing of the PCR plate. If signal discontinuity occurs in two or more viral targets, and the signal discontinuity results in the amplification curve crossing the threshold, a false positive result could occur.

To reduce the potential for false positive results and unnecessary retesting, **we are adding use of a compression pad to the Instructions for Use of the TaqPath COVID-19 CE-IVD RT-PCR Kit when using QuantStudio 5 instruments (QS5 and QS5 Dx) with 96-well, 0.2-mL block and a MicroAmp Optical 96-Well Reaction Plate (with or without barcode).** For additional information please refer to the attached Frequently Asked Questions (FAQs).

Actions Required:

- The probability of the previous results obtained without the compression pad being false positive is remote (~0.0002%) and the results generated using previous versions of our TaqPath COVID-19 IFUs are still valid.
- Going forward, if you are using a QuantStudio 5 (QS5 or QS5 Dx) instrument, for 96-well, 0.2-mL block and a MicroAmp Optical 96-Well Reaction Plate (with or without barcode) with TaqPath COVID-19 CE-IVD RT-PCR Kits (Catalog #A48067 and #A51738):
 1. Share this communication letter with all individuals in your facility who use Thermo Fisher's QuantStudio 5 and TaqPath products in the above configuration.
 2. Follow the instructions on the latest version of the Instructions for Use document with the addition of compression pad to the workflow (Figure 1). Instructions for Use documents are available to download at <https://www.thermofisher.com/findyourifu>.
 3. Please note that the user needs to purchase MicroAmp Optical Film Compression Pad pack (Catalog #4312639) separately from the COVID-19 testing kits.
 4. Kits that were purchased prior to this notification can continue to be used, provided the users follow the latest version of the Instructions for Use.



Figure 1: MicroAmp Optical Film Compression Pad (left) and placement of the Compression Pad on a 96-well MicroAmp Reaction Plate (right). The gray side should always be placed down and the brown side up.

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 a live training.

- Go to www.thermofisher.com/educationconnect and sign in with your thermofisher.com username and password. Type in the subscription code **TC19CE/VDJ/SW1525** in the box on the left to access and complete the training.
- Read and implement the compression pad workflow updates that have been added to the latest release of the Instructions for Use – available at <https://www.thermofisher.com/findyourifu>, to help prevent signal discontinuity events and potential resultant false calls.
- Sign and return acknowledgement of receipt on page 3 of this communication, to EU-customer-notification@thermofisher.com no later than MMM DD, YYYY.

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 euotech@thermofisher.com.

Sincerely,

A handwritten signature in black ink, appearing to read "Richard A. Lubin", written over a horizontal line.

Richard A. Lubin
Director, Site Quality
Genetic Sciences Division
Thermo Fisher Scientific

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

Product Name	SKU Number
TaqPath™ COVID-19 CE-IVD RT-PCR Kit, 1000 reactions	A48067
TaqPath™ COVID-19 CE-IVD RT-PCR Kit, 100 reactions	A51738

Customer Name and Address:

I have read and understand the instructions provided in the letter dated MMM DD, YYYY. ☐ YES ☐ NO

I have notified all TaqPath COVID-19 kit 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 **within 10 working days of receiving this notification.**For any questions or comments please contact Technical Support at 00 800 5345 5345 option 3 or via email: eurotech@thermofisher.com**Thermo Fisher Scientific Reference Number:** PR 518365