

Urgent Field Safety Notice

Product: Amplitude Platform with TaqPath™ COVID-19 HT Kit (Catalog #A50883)

21 September 2022

Institution:	«Customer Name»	«Address Line 2»
Address:	«Address Line 4»	«Address Line 3»
	«Address Line 1»	«City», «State» «Postal Code» «Country»

Dear Valued Customer,

This letter is to notify you of a mandatory software upgrade for the *Amplitude Platform with the TaqPath COVID-19 HT Kit* (Catalog #A50883) to version 2.2. Among other system improvements, v2.2 contains an algorithm update in the Interpretative Software Driver v1.3 to detect suspected instances of spatial crosstalk and to invalidate the affected wells.

Spatial crosstalk may result in false positive or inconclusive results when a sample well with either a valid negative result or an invalid result due to missing MS2 control is surrounded by multiple sample wells with valid high positive (Ct < 20) results. The spatial crosstalk phenomenon is typically observed in runs with high plate positivity (greater than 25% per plate) due to the increased regional density of positive samples present on the plate. We estimate the percent of samples potentially impacted by this issue to be 0.0006%.

In an effort of continuous improvement, Thermo Fisher Scientific is releasing a software upgrade to detect suspected instances of spatial crosstalk and to invalidate the affected wells. Until you receive the software upgrade, if you notice high rates of invalid or inconclusive results in conjunction with high plate positivity while using the instrument, please review amplification plots for evidence of spatial crosstalk, re-run any suspected impacted samples and report the issue to Thermo Fisher Scientific. It is not necessary to review retrospective results as the probability of this spatial crosstalk phenomenon leading to a false positive is extremely low.

Actions Required:

- Please contact your local Thermo Fisher Scientific representative to schedule an upgrade visit. Once scheduled, a Field Service Engineer will visit your site and complete the software updates for Amplitude Platform v2.2.
- Notify all Amplitude Platform with the TaqPath COVID-19 HT Kit users in your facility of this communication.
- Sign and return acknowledgement of Receipt – page 2 of this communication, to EU-customer-notification@thermofisher.com

Thermo Fisher Scientific is committed to supplying innovative, high-quality products. If you still have questions or concerns, please contact Technical Support at 00 800 5345 5345 option 3 or email eurotech@thermofisher.com. We thank you for the business partnership.

Sincerely,



Richard Lubin
Director, Site Quality
Genetic Sciences Division

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

Product Name	SKU Number	Number of Amplitude Platform systems available at facility (Customer to populate)
TaqPath™ COVID-19 HT Kit	A50883	

Customer Name and Address:

Institution:	«Customer_Name»	«Address_Line_2»
Address:	«Address_Line_4»	«Address_Line_3»
	«Address_Line_1»	«City», «State» «Postal Code» «Country»

I have read and understand the instructions provided in the letter dated 21 September 2022. YES NO

Acknowledgement that TFS (Thermo Fisher Scientific) Representative was contacted to schedule the software upgrade YES NO

I have notified all Amplitude Solution 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.
Due date for response is 30 September 2022.

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

Thermo Fisher Scientific Reference Number: PR (Problem Report) # 575094