

Date

Customer Name
Customer Title
Customer Company
Customer Address

Customer Communication

Mandatory Upgrade to TaqPath™ COVID-19 Interpretive Software CE-IVD Edition v1.2.

Dear Customer/Distributor,

This letter is to notify you of a mandatory upgrade for the TaqPath™ COVID-19 Interpretive Software. If you are using TaqPath™ COVID-19 Interpretive Software v1.0 or v1.1 please update the software to TaqPath™ COVID-19 Interpretive Software CE-IVD Edition v1.2.

A review of our analytical studies, which used contrived samples, shows that the Interpretive Software v1.0 and v1.1 may have a low potential to misidentify amplification of one of the targets (N-gene, S-gene, ORF1ab or the MS2 positive control). This misidentified amplification may cause the software to report a small percentage of false results.

The likelihood of false negative and false positive results is reduced through redundancy built into the design of the TaqPath™ COVID-19 CE-IVD RT-PCR Kit. The test requires two or more of the three targets (N-gene, S-gene, or ORF1ab) to be positive for the sample to be positive SARS-CoV-2. All three targets must be negative for the sample to be reported as SARS-CoV-2 Not Detected. Therefore, the likelihood of obtaining false results is very low (0.02% false negative and 0.08% false positive).

The potential for amplification misidentification has been addressed in TaqPath™ COVID-19 Interpretive Software CE-IVD Edition v1.2. All users performing COVID-19 diagnostic testing using v1.0 and v1.1 must upgrade the software to CE-IVD Edition v1.2.

Actions Requested:

- Notify all COVID-19 Interpretive Software users in your facility of this communication
- Discontinue use of COVID-19 Interpretive Software v1.0 and v1.1
- Contact your local Technical Support to discuss training and software upgrade procedures

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 contact Technical Support at 00 800 5345 5345 Option 3 or eurotech@thermofisher.com.

Sincerely,

XXXXXX
Sr Product Manager, qPCR Software
Genetic Sciences Division
Thermo Fisher Scientific