Amplitude Solution FAQs

Frequently asked questions (FAQs) for the Thermo Fisher Scientific™ Amplitude™ Solution

Q: Can I run RUO reagents after upgrading to EUA?

A: No. You will not be able to switch back to RUO reagents after the EUA upgrade, since the software upgrade will only detect EUA barcodes moving forward. There will be a transition period where we'll work with you to switch over to the EUA product. RUO products can be used until the time of EUA software upgrade and successful transition of supply.

Leftover RUO reagents should either be consumed before the EUA upgrade or be replaced with EUA barcoded reagents.

Q: Are there any changes to the interpreted results format?

A: Yes, this upgrade enables a new output format with added regulatory text and additional columns corresponding to gene-level C_t values, result calls, and baseline analysis data in the output CSV file. Optionally, you may continue to use the original CSV format without the additional columns. Please note: you may have already received the feature enabling additional columns as a part of a previous upgrade. Please contact your service representative if you have any questions or to request example CSV output files.

Q: Does the new output CSV format affect the interpreted result calls?

A: No, the interpreted result call is not affected by the format change.

Q: Will the change in the interpreted results output format affect my downstream LIS/LIMS or EMR system integration?

A: We recommend that the switch to the new format is approved by your organization's IT personnel responsible for maintaining LIS/LIMS/EMR integration interface.

Q: What is the projected system downtime to perform the upgrade?

A: The projected system downtime is ~48 hours.

Q: How do I request and schedule an upgrade?

A: Your local Customer Success Manager (CSM) and Amplitude Solution Technical Sales Specialist (TSS) representative will contact you to discuss and schedule your upgrade.

Q: Are there any updates to the IFU?

A: Yes, please refer to the emergency-authorized Instructions for Use (IFU) for more details at **thermofisher.com/amplitude**.

Q: Are there any changes to the workflow?

A: Yes, there are minor changes to the workflow. Please refer to the emergency-authorized IFU at **thermofisher.com/amplitude** for details.

Q: What is included in the upgrade?

A: There are upgrades to software and hardware. For the detailed list of upgrades, please refer to the emergency-authorized IFU.

Q: Is re-validation required due to EUA?

A: Our certified Thermo Fisher representatives will perform the upgrade. Generally, additional validation is not required for customers who will follow the EUA Instructions for Use. Customers should work with their local regulatory authorities to determine what additional verification is required to maintain CLIA compliance and begin testing under the EUA. **Please refer to the emergency authorized IFU** for more details.

Find out more at **thermofisher.com/amplitude**

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