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September 2023

TO: Customers of the U.S. FDA EUA Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** Test

RE: Similarity of U.S. FDA EUA and 510(k) Cleared Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** Tests for Verification Study Decisions

The purpose of this letter is to provide information regarding the U.S. Food and Drug Administration (FDA) 510(k) cleared version of the Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** test to aid in the laboratory's decision regarding the need to perform a new verification study when transitioning from the U.S. FDA Emergency Use Authorization (EUA) version of the test.

The Xpert **Xpress** CoV-2/Flu/RSV ***plus*** EUA and 510(k) cleared tests are identical in design, however, there are some differences in the product claims.

The following attributes have not changed between the EUA and 510(k) version of the tests.

- General Intended use (symptomatic patients) and patient population claimed
- Claimed specimen types of anterior nasal (NS) and nasopharyngeal swabs (NPS) collected in 3 mL of VTM/UTM or 2 mL of eNAT
- Sample processing
- Test chemistry or design
- Targets detected

Notable differences for 510(k) version are:

- The following sample types are NO longer supported: nasal aspirate/wash
- The following collection media are NO longer supported: saline
- Modifications of the Assay Definition File (ADF) algorithm (as compared to the earlier version of the **Xpress** CoV-2/Flu/RSV ***plus*** EUA ADF) to:
    1. Return a positive result for non-SARS-CoV-2 analytes when SPC and SARS-CoV-2 are not detected. This update was designed to reduce the number of invalid results obtained by the 510(k) version of the test.

       NOTE: This updated ADF will also be available for the EUA test by October 2023.
    2. Offer 5 combinational ADF options, instead of 3.
- Frozen (-20º or -80ºC) NPS and NS specimens in VTM/UTM and eNAT that have undergone one freeze/thaw are on claim. See IFU for details.

A traditional 510(k) submission for the Xpert **Xpress** CoV-2/Flu/RSV ***plus*** to be performed on the GeneXpert Instrument Systems (Dx and Infinity) for use in a laboratory setting was filed with the FDA with all required analytical and clinical performance data. Based on the data submitted, the FDA provided clearance of the Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test on August 17, 2023. Additionally, invalid rates, positive percent agreement (PPA) and negative performance agreement (NPA) using the updated ADF setting were compared to the test's performance when using the old ADF settings. This showed no significant difference in the PPA/NPA and no significant differences in the invalid rate in the dataset analyzed when using the updated ADF.

As per Centers for Medicare & Medicaid Services (CMS), a verification study is required prior to reporting patient results whenever an unmodified FDA cleared or approved non-waived test system is introduced into the laboratory. Additionally, as long as the EUA and 510k products are the same from an intended use, design, chemistry, sample processing, consumables, and procedures standpoint, and as long as the manufacturer's instructions regarding performance verification remain the same, the lab does not need to re-verify the test once the manufacturer receives FDA 510(k) clearance of that test.

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Given the high similarity between the EUA and 510(k) versions of the test, specifically no changes in the test targets, RT-PCR chemistry, sample processing, and no significant performance differences between the EUA and 510(k) ADFs, if the laboratory has previously verified the EUA version (un-modified) of the Xpert **Xpress** CoV-2/Flu/RSV ***plus*** test, a verification of the 510(k) version of the product may not be required. However, it is the laboratory's decision to determine if a new verification is needed. If the laboratory decides to perform a verification, a verification guide is available.

Thank you for being a valued customer of Cepheid.

Best regards,

Mike Loeffelholz, Ph.D.
Vice President, Scientific Affairs
Cepheid

Xpert **Xpress** CoV-2/Flu/RSV ***plus*** (**XPRS4PLEX-10**) is a US-IVD. For *In Vitro* Diagnostic Use in laboratories that are CLIA certified to perform moderate or high complexity tests.

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