



JUNE 2025

NOW AVAILABLE

FDA Cleared Moderate Complexity and CLIA waived
Xpert® **Xpress** CoV-2/Flu/RSV **plus** and
Xpert **Xpress** CoV-2 **plus** for
GeneXpert® Dx Infinity and GeneXpert **Xpress** Systems

Dear Valued Customer,

Cepheid has recently received U.S. Food and Drug Administration (FDA) 510(k) Clearance for CLIA waived (CW) versions of the Xpert **Xpress** CoV-2 **plus** (XPRS-COV2-10) and Xpert **Xpress** CoV-2/Flu/RSV **plus** (XPRS4PLEX-10).

These products can now be used in both moderate complexity (MC) on GeneXpert Dx, GeneXpert with touchscreen and GeneXpert Infinity systems and on a CLIA waived (CW) environment on GeneXpert **Xpress**.

This clearance marks a major milestone, enabling Cepheid to advance its US-IVD Respiratory tests beyond Emergency Use Authorization (EUA) and enabling our customers to replace EUA-labeled tests with FDA Cleared versions compatible with GeneXpert **Xpress** on CLIA waived environments, in addition to the moderate complexity environment on the GeneXpert Dx, the GeneXpert with touchscreen, and the GeneXpert Infinity system.

The co-labeled CW and MC FDA Cleared tests are available for purchase now.

How this information impacts you depends on the test(s) you are currently using:

Current Users of the FDA Cleared Tests on Moderate Complexity Environment

Current users of the FDA Cleared moderate complexity tests can continue to use the Xpert **Xpress** CoV-2 **plus** (catalogue number XPRS-COV2-10) and/or the Xpert **Xpress** CoV-2/Flu/RSV **plus** (catalogue number XPRS4PLEX-10) in a moderate complexity environment. The CLIA waived 510(k) clearance does not affect the claims on the moderate complexity test.

Please note that lots greater than the numbers below will be co-labeled MC and CW:

Xpert Xpress CoV-2/Flu/RSV plus (XPRS4PLEX-10)	1001486113	Xpert Xpress CoV-2 plus (XPRS-COV2-10)	1001484410
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Important if you are using Xpert Xpress CoV-2/Flu/RSV plus (XPRS4PLEX-10)

In addition to the extension of the test label to CLIA waived environment a new version of the Assay Definition File (ADF) has been released and all users are requested to update to the most updated version of the ADF. Find resources to update your ADF can be found here: [Cepheid website | edoc](#)

Customers Currently Using Emergency Use Authorization (EUA) Tests

If you currently use Xpert **Xpress** CoV-2 **plus** (catalogue number XP3SARS-COV2-10) or Xpert **Xpress** CoV-2/Flu/RSV **plus** (catalogue number XP3COV2/FLU/RSV-10), we encourage you to transition to our FDA Cleared US-IVD versions of these tests before the end of sales date in December 2025. The tests are now co-labeled for moderate complexity and CLIA waived use, and both tests are available to be used with the GeneXpert Dx, GeneXpert Infinity, GeneXpert with touchscreen on an MC environment and GeneXpert **Xpress** systems on CW environments.

The EUA and US-IVD versions of Xpert **Xpress** CoV-2/Flu/RSV **plus** and Xpert **Xpress** CoV-2 **plus** tests are identical in design, chemistry, sample processing, and consumables, and have been shown to have equivalent performance.

However, there are some changes in the product claims between the EUA and US-IVD versions for each. The following table summarizes these differences:

Xpert Xpress CoV-2/Flu/RSV plus (XPRS4PLEX-10) differences with XP3COV2/FLU/RSV-10 (EUA)		Xpert Xpress CoV-2 plus (XPRS-COV2-10) claims differences with XP3SARS-COV2-10 (EUA)
ADF	5 combinatorial ADF options instead of 3	Updated ADF for GeneXpert Xpress users
Indications	N/A	Testing of asymptomatic patients no longer indicated
Sample Types	Nasal aspirate/wash no longer supported	Nasal aspirate/wash, mid-turbinate, oropharyngeal no longer supported
Transport Media	No differences	Saline no longer supported
Storage	Frozen (-20°C or -80°C) specimens in VTM/UTM or eNAT frozen/thawed x1 is now on label*	Frozen (-80°C) specimens in VTM/UTM or eNAT frozen/thawed x1 are now on label
Shelf Life	Extended to up to 17 months	Extended to up to 15 months

* Frozen specimens at -80°C were already on-claim for EUA version of Xpert **Xpress** CoV-2/Flu/RSV **plus** test.

See Instructions for Use (IFU) for details.

EUA obsolescence plans:

With the launch of the US-IVD tests, Cepheid plans to obsolete the EUA versions of our SARS-CoV-2 assays in the USA: Xpert **Xpress** CoV-2 **plus** (XP3SARS-COV2-10) and Xpert **Xpress** CoV-2/Flu/RSV **plus** (XP3COV2/FLU/RSV-10) by December 31st, 2025. Therefore, all customers who use the EUA versions will need to transition to the co-labeled FDA Cleared tests when commercially available.

Please see the below links to access supporting information:

Xpert Xpress CoV-2 *plus*



[Documentation](#)
(including [Instructions for Use](#), [Assay Definition File](#), [SDS](#))



[Verification Guide](#)



[Website](#)



[Datasheet](#)



[US-IVD EUA Comparison Document](#)



[US-IVD and EUA Equivalency letters](#)



[FAQs](#)



[Additional Resources](#)

Xpert Xpress CoV-2/Flu/RSV *plus*



[Documentation](#)
(including [Instructions for Use](#), [Assay Definition File](#), [SDS](#))



[Verification Guide](#)



[Website](#)



[Datasheet](#)



[US-IVD EUA Comparison Document](#)



[US-IVD and EUA Equivalency letters](#)



[FAQs](#)



[Additional Resources](#)

If you have any questions or concerns, please contact a Cepheid representative or Cepheid support.

US-IVD. *In Vitro* Diagnostic Medical Device.

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