

# Xpert® Xpress CoV-2 plus Laboratory Information System Guidance

## **REF** XP3SARS-COV2-10

ADF: Xpert Xpress CoV-2 PLUS IVD

Version 1

Purpose: To provide information for enabling a Laboratory Information System (LIS) interface for the Xpert® Xpress CoV-2 plus test on GeneXpert® Systems.

Contents:

1. [Host Communication in GeneXpert System](#)
2. [Suggested LOINC Codes](#)
3. [Observation Language Translation Table](#)

If you need further assistance, please contact Cepheid Technical Support at <https://www.cepheid.com/en/about/contact-us> or email [techsupport@cepheid.com](mailto:techsupport@cepheid.com).

*This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.*

## 1 Host Communication in GeneXpert® System

### 1.1 Consult your LIS System Administrator:

Before making changes to your GeneXpert LIS interface settings, consult your LIS System Administrator.

### 1.2 Enable Host Communication:

If the GeneXpert system is not already configured for LIS host communication, follow the instructions in your GeneXpert System's User Guide: "Configuring Host Communications for a LIS."

### 1.3 Assay Host Test Code and Result Code Configuration:

Assay Host Test Code and Result Code must be defined in the GeneXpert system.

**Note:** When defining Host Test Codes and Result Codes, consider if your organization needs to use different codes for different versions of Cepheid tests so that the test versions can be distinguished in your LIS.

- A) If both assays must be enabled on a system simultaneously:
  - a. Create unique test codes for each Assay
- B) If only one Assay is enabled on a System:
  - a. Ensure all existing supplies of the prior Assay version are used
  - b. Delete the prior Assay (or disable/inactivate)
  - c. Add the new Assay with the same test codes as the previous Assay

### 1.4 Suggested Assay Host Test Codes

ADF Name / Assay Name	ADF Version	Assay Host Test Code	Analyte Name	Result Code	Possible Result Values
Xpress SARS-CoV-2 plus	1	<sup>1</sup> CoV2PLUS	CoV2PLUS	<sup>1</sup> N.A.	Negative Positive Error Invalid No Result

<sup>1</sup>**Note:** As a Single-Result Assay, the Assay Host Test Code will be the same as the Upload and Download Code.

## 2 Suggested LOINC Codes

Assay	Specimen <sup>1</sup>	Result Description	LOINC Code	Component	Property	Time	System	Scale	Method	Reference
Xpress CoV-2 plus	<ul style="list-style-type: none"> <li>NP Swabs</li> <li>Nasal Swabs</li> </ul>	Binary – Positive, Negative	94500-6	SARS coronavirus 2 RNA	PrThr	Pt	Respiratory	Ord	Probe.amp.tar	<a href="https://loinc.org/94500-6/">https://loinc.org/94500-6/</a>

<sup>1</sup>**Note:** The available LOINC codes do not differentiate specific respiratory specimen types. Refer to the Xpert Xpress CoV-2 *plus* Instructions for Use (IFU) for specific specimen type information.

## 3 LOINC Code Rationale

- Xpress CoV-2 *plus*

Please contact [us-ga@cepheid.com](mailto:us-ga@cepheid.com) with any questions regarding the use of this LOINC code.

#### 4 Observation Language Translations Table

The table below provides a consolidated translation of the analyte value strings for all the languages supported by the GeneXpert System.

#	Language	Positive	Negative	Error	Invalid	No Result
1	English	POSITIVE	NEGATIVE	ERROR	INVALID	NO RESULT
2	French	POSITIF	NÉGATIF	ERREUR	NON VALIDE	PAS DE RÉSULTAT
3	German	POSITIV	NEGATIV	FEHLER	UNGÜLTIG	KEIN ERGEBNIS
4	Spanish	POSITIVO	NEGATIVO	INCERTO	INDETERMINADA	SIN RESULTADO
5	Italian	POSITIVO	NEGATIVO	ERRORE	ERRO	NESSUN RISULTATO
6	Portuguese	POSITIVO	NEGATIVO	NON VALIDO	INVÁLIDO	SEM RESULTADO
7	Russian	ПОЛОЖИТЕЛЬНЫЙ	ОТРИЦАТЕЛЬНЫЙ	ОШИБКА	НЕДЕЙСТВИТЕЛЬНЫЙ	НЕТ РЕЗУЛЬТАТА
8	Ukrainian	ВИЯВЛЕНО	НЕ ВИЯВЛЕНО	НЕДІЙСНИЙ	НЕДІЙСНИЙ	НЕМАЄ РЕЗУЛЬТАТУ
9	Japanese	POSITIVE	NEGATIVE	ERROR	INVALID	NO RESULT