

Xpert[®] Xpress CoV-2 *plus* (US-IVD) Laboratory Information System Guidance

REF XPRS-COV2-10

ADF: Xpert Xpress CoV-2 plus IVD

Version 1

Purpose: To provide information that is helpful when enabling a Laboratory Information System (LIS) interface for the Xpert[®] Xpress CoV-2 *plus* (US-IVD) test on GeneXpert[®] Systems.

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

1 Summary of Cepheid Products with SARS-CoV-2

Xpert® Xpress CoV-2 *plus* (XPRS-COV2-10) is the newest Cepheid test for the GeneXpert® System that performs SARS-CoV-2 testing. The table below summarizes ALL of the tests that Cepheid has marketed with a SARS-CoV-2 assay to help clarify important differences related to LIS setup.

Product Name	Catalog Number	ADF	Launch Date
Xpert® Xpress SARS-CoV-2 (EUA/CE-IVD)	XPRSARS-COV2-10	Xpert Xpress SARS-CoV-2	March 2020
Xpert® Xpress SARS-CoV-2/Flu/RSV (EUA/CE-IVD)	XPCOV2/FLU/RSV-10	Xpert Xpress_SARS-CoV-2_Flu_RSV	October 2020
		Xpert Xpress_SARS-CoV-2_Flu	
		Xpert Xpress_SARS-CoV-2	
Xpert® Xpress CoV-2/Flu/RSV <i>plus</i> (EUA/CE-IVD)	XP3COV2/FLU/RSV-10	Xpress SARS-CoV-2_Flu_RSV plus	November 2023 (version 2)
		Xpress SARS-CoV-2_Flu plus	
		Xpress SARS-CoV-2_+plus	
Xpert® Xpress CoV-2 <i>plus</i> (EUA/CE-IVD)	XP3SARS-COV2-10	Xpert Xpress CoV-2 plus	May 2022
Xpert® Xpress CoV-2/Flu/RSV <i>plus</i> (US-IVD)	XPRS4PLEX-10	Xpress SARS-CoV-2 Flu RSV plus	September 2023
		Xpress SARS-CoV-2 Flu plus	
		Xpress SARS-CoV-2 plus	
		Xpress Flu RSV plus	
		Xpress Flu plus	
Xpert® Xpress CoV-2 <i>plus</i>* (US-IVD)	XPRS-COV2-10	Xpert Xpress CoV-2 plus IVD	January 2024

*The remainder of this document will focus on the newest version of the Xpert® Xpress CoV-2 *plus* (US-IVD) test, **bolded above**.

2 Enabling the Test and Host Communication in GeneXpert® System

2.1 Consult your LIS System Administrator:

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

2.2 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 an LIS.”

2.3 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 whether your organization needs to use different codes for different versions of Cepheid tests. This ensures that test versions can be distinguished in your LIS.

Note: If the Xpert Xpress CoV-2 plus (EUA) test has already been configured on a GeneXpert System with the suggested Codes below, then 1 of 2 (two) options must be taken as an Assay Host Test Code can only be associated with a single ADF/Assay:

- A) If both Tests are to be used simultaneously:
 - a. Create unique test codes for each Test
- B) If only using the US-IVD test:
 - a. Ensure all existing supplies of the prior Test version are used
 - b. Delete the prior Test
 - c. Add the new Test with the same test codes as the previous Test

2.4 Suggested Assay Host Test Codes

ADF Name / Assay Name	ADF Version	Assay Host Test Code	Analyte Common Name	Result Code	Possible Result Values
Xpert Xpress CoV-2 plus IVD	1	¹ COV2PLUS	COV2PLUS	¹ N.A.	NEGATIVE POSITIVE ERROR INVALID NO RESULT

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

3 Example Messages

These example messages can be used by an LIS interface analyst to understand the structure and content of Xpert Xpress CoV-2 plus (XPRS-COV2-10) test results.

3.1 ASTM Example Messages:

ASTM - Xpert Xpress CoV-2 plus IVD: POSITIVE

```
H|@^\|GXM-67312614772||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20231020130414
P|1||||^^^|||||||||||||||||||||||||||||||||
O|1|230913_P1153_A_POS_02||^^SARSCOV2|R|20230913112831|||||||ORH|||||||F
R|1|^^SARSCOV2^Xpert Xpress CoV-2 plus
IVD^1^^|POSITIVE^||||F||User|20230913112831|20230913115616|WinDev2006Eval^700415^672401^137496246^06000^20901224|
R|2|^^SARSCOV2^^E^|POS^|||
R|3|^^SARSCOV2^^E^Ct|^30.7|||
R|4|^^SARSCOV2^^E^EndPt|^497.0|||
R|5|^^SARSCOV2^^N2^|POS^|||
R|6|^^SARSCOV2^^N2^Ct|^34.1|||
R|7|^^SARSCOV2^^N2^EndPt|^94.0|||
R|8|^^SARSCOV2^^RdRP^|POS^|||
R|9|^^SARSCOV2^^RdRP^Ct|^33.9|||
R|10|^^SARSCOV2^^RdRP^EndPt|^196.0|||
R|11|^^SARSCOV2^^SPC^|NA^|||
R|12|^^SARSCOV2^^SPC^Ct|^35.4|||
R|13|^^SARSCOV2^^SPC^EndPt|^55.0|||
L|1|N
```

ASTM - Xpert Xpress CoV-2 plus IVD: NEGATIVE

```
H|@^\|GXM-16865207172||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20231020130416
P|1||||^^^|||||||||||||||||||||||||||||||||
O|1|230913_P1153_A_NEG_02||^^SARSCOV2|R|20230913112758|||||||User|20230913112758|20230913115746|WinDev2006Eval^700042^625000^1374
96248^06000^20901224|
R|2|^^SARSCOV2^^E^|NEG^|||
R|3|^^SARSCOV2^^E^Ct|^0.0|||
R|4|^^SARSCOV2^^E^EndPt|^1.0|||
R|5|^^SARSCOV2^^N2^|NEG^|||
R|6|^^SARSCOV2^^N2^Ct|^0.0|||
R|7|^^SARSCOV2^^N2^EndPt|^0.0|||
```

R|8|^^SARSCOV2^^RdRP^|NEG^||
R|9|^^SARSCOV2^^RdRP^Ct|^0.0||
R|10|^^SARSCOV2^^RdRP^EndPt|^1.0||
R|11|^^SARSCOV2^^SPC^|PASS^||
R|12|^^SARSCOV2^^SPC^Ct|^30.8||
R|13|^^SARSCOV2^^SPC^EndPt|^152.0||
L|1|N

ASTM - Xpert Xpress CoV-2 plus IVD: INVALID

H|@^|GXM-53570555652||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20231020130410
P|1||||^^^||||||||||||||||||||||||||
O|1|230913_P1153_A_INVALID_01||^^SARSCOV2|R|20230913151750||||||ORH|||||||F
R|1|^^SARSCOV2^Xpert Xpress CoV-2 plus
IVD^1^^|INVALID^||||F||User|20230913151750|20230913154719|WinDev2006Eval^700415^912777^137496214^06000^20901224|
R|2|^^SARSCOV2^^E^|INVALID^||
R|3|^^SARSCOV2^^E^Ct|^0.0||
R|4|^^SARSCOV2^^E^EndPt|^1.0||
R|5|^^SARSCOV2^^N2^|INVALID^||
R|6|^^SARSCOV2^^N2^Ct|^0.0||
R|7|^^SARSCOV2^^N2^EndPt|^1.0||
R|8|^^SARSCOV2^^RdRP^|INVALID^||
R|9|^^SARSCOV2^^RdRP^Ct|^0.0||
R|10|^^SARSCOV2^^RdRP^EndPt|^1.0||
R|11|^^SARSCOV2^^SPC^|FAIL^||
R|12|^^SARSCOV2^^SPC^Ct|^0.0||
R|13|^^SARSCOV2^^SPC^EndPt|^11.0||
L|1|N

ASTM - Xpert Xpress CoV-2 plus IVD: NO RESULT

H|@^|GXM-18468833758||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20231020130412
P|1||||^^^||||||||||||||||||||||||||
O|1|230913_P1153_A_NO RESULT2||^^SARSCOV2|R|20230913113008||||||ORH|||||||F
R|1|^^SARSCOV2^Xpert Xpress CoV-2 plus IVD^1^^|NO
RESULT^||||F||User|20230913113008|20230913113141|WinDev2006Eval^700054^746477^137496242^06000^20901224|
R|2|^^SARSCOV2^^E^|NO RESULT^||
R|3|^^SARSCOV2^^E^Ct|^0.0||

R|4|^^SARSCOV2^^E^EndPt|^0.0||
R|5|^^SARSCOV2^^N2^|NO RESULT^||
R|6|^^SARSCOV2^^N2^Ct|^0.0||
R|7|^^SARSCOV2^^N2^EndPt|^0.0||
R|8|^^SARSCOV2^^RdRP^|NO RESULT^||
R|9|^^SARSCOV2^^RdRP^Ct|^0.0||
R|10|^^SARSCOV2^^RdRP^EndPt|^0.0||
R|11|^^SARSCOV2^^SPC^|NO RESULT^||
R|12|^^SARSCOV2^^SPC^Ct|^0.0||
R|13|^^SARSCOV2^^SPC^EndPt|^0.0||
L|1|N

ASTM - Xpert Xpress CoV-2 plus IVD: ERROR

H|@^|GXM-77635151877||GeneXpert PC^GeneXpert^6.4||||LIS||P|1394-97|20231020130413
P|1||||^^^|||||||||||||||||||||||||||
O|1|230913_P1153_A_ERROR_02|^SARSCOV2|R|20230913112913||||||ORH|||||||F
R|1|^SARSCOV2^Xpert Xpress CoV-2 plus
IVD^1^|ERROR^||||F||User|20230913112913|20230913113115|WinDev2006Eval^700062^730297^137496244^06000^20901224|
C|1||Error^2125^Operation terminated^Error 2125: Termination Error - Insufficient Volume: 12, 50, 0, 13^20230913113101|N
R|2|^SARSCOV2^E^|NO RESULT^||
R|3|^SARSCOV2^E^Ct|^0.0||
R|4|^SARSCOV2^E^EndPt|^0.0||
R|5|^SARSCOV2^^N2^|NO RESULT^||
R|6|^SARSCOV2^^N2^Ct|^0.0||
R|7|^SARSCOV2^^N2^EndPt|^0.0||
R|8|^SARSCOV2^^RdRP^|NO RESULT^||
R|9|^SARSCOV2^^RdRP^Ct|^0.0||
R|10|^SARSCOV2^^RdRP^EndPt|^0.0||
R|11|^SARSCOV2^^SPC^|NO RESULT^||
R|12|^SARSCOV2^^SPC^Ct|^0.0||
R|13|^SARSCOV2^^SPC^EndPt|^0.0||
L|1|N ASTM - NEGATIVE results

3.2 HL7 Example Messages:

HL7 - Xpert Xpress CoV-2 plus IVD: POSITIVE

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20231020132252||ORU^R32^ORU_R30|GXM-11302258276|P|2.5|||||||
PID|1|||^^^||||^^^|||||
ORC|RE|1|||||20230913112831
OBR|1||SARSCOV2|||||||F
TQ1|||||20230913112831|20230913115616|R
OBX|1|ST|&SARSCOV2&Xpert Xpress CoV-2 plus IVD&1|&|POSITIVE^|||||F||||^User||20901224~06000~137496246~672401~700415~WinDev2006Eval
OBX|2|ST|&SARSCOV2&&|E&|POS^||
OBX|3|ST|&SARSCOV2&&|E&Ct|^30.7||
OBX|4|ST|&SARSCOV2&&|E&EndPt|^497.0||
OBX|5|ST|&SARSCOV2&&|N2&|POS^||
OBX|6|ST|&SARSCOV2&&|N2&Ct|^34.1||
OBX|7|ST|&SARSCOV2&&|N2&EndPt|^94.0||
OBX|8|ST|&SARSCOV2&&|RdRP&|POS^||
OBX|9|ST|&SARSCOV2&&|RdRP&Ct|^33.9||
OBX|10|ST|&SARSCOV2&&|RdRP&EndPt|^196.0||
OBX|11|ST|&SARSCOV2&&|SPC&|NA^||
OBX|12|ST|&SARSCOV2&&|SPC&Ct|^35.4||
OBX|13|ST|&SARSCOV2&&|SPC&EndPt|^55.0||
SPM|1|230913_P1153_A_POS_02^||ORH|||||P
```

HL7 - Xpert Xpress CoV-2 plus IVD: NEGATIVE

```
MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20231020132253||ORU^R32^ORU_R30|GXM-06101686172|P|2.5|||||||
PID|1|||^^^||||^^^|||||
ORC|RE|1|||||20230913112758
OBR|1||SARSCOV2|||||||F
TQ1|||||20230913112758|20230913115746|R
OBX|1|ST|&SARSCOV2&Xpert Xpress CoV-2 plus IVD&1|&|NEGATIVE^|||||F||||^User||20901224~06000~137496248~625000~700042~WinDev2006Eval
OBX|2|ST|&SARSCOV2&&|E&|NEG^||
OBX|3|ST|&SARSCOV2&&|E&Ct|^0.0||
OBX|4|ST|&SARSCOV2&&|E&EndPt|^1.0||
OBX|5|ST|&SARSCOV2&&|N2&|NEG^||
OBX|6|ST|&SARSCOV2&&|N2&Ct|^0.0||
OBX|7|ST|&SARSCOV2&&|N2&EndPt|^0.0||
OBX|8|ST|&SARSCOV2&&|RdRP&|NEG^||
```

OBX|9|ST|&SARSCOV2&&|RdRP&Ct|^0.0||
OBX|10|ST|&SARSCOV2&&|RdRP&EndPt|^1.0||
OBX|11|ST|&SARSCOV2&&|SPC&|PASS^||
OBX|12|ST|&SARSCOV2&&|SPC&Ct|^30.8||
OBX|13|ST|&SARSCOV2&&|SPC&EndPt|^152.0||
SPM|1|230913_P1153_A_NEG_02^||ORH|||||P

HL7 - Xpert Xpress CoV-2 plus IVD: INVALID

MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20231020132248||ORU^R32^ORU_R30|GXM-86841724232|P|2.5|||||||
PID|1||||^|||||||||^|||||||
ORC|RE|1||||||20230913151750
OBR|1|||SARSCOV2|||||||||||||F
TQ1||||||20230913151750|20230913154719|R
OBX|1|ST|&SARSCOV2&Xpert Xpress CoV-2 plus IVD&1|&|INVALID^|||||F|||||^User||20901224~06000~137496214~912777~700415~WinDev2006Eval
OBX|2|ST|&SARSCOV2&&|E&|INVALID^||
OBX|3|ST|&SARSCOV2&&|E&Ct|^0.0||
OBX|4|ST|&SARSCOV2&&|E&EndPt|^1.0||
OBX|5|ST|&SARSCOV2&&|N2&|INVALID^||
OBX|6|ST|&SARSCOV2&&|N2&Ct|^0.0||
OBX|7|ST|&SARSCOV2&&|N2&EndPt|^1.0||
OBX|8|ST|&SARSCOV2&&|RdRP&|INVALID^||
OBX|9|ST|&SARSCOV2&&|RdRP&Ct|^0.0||
OBX|10|ST|&SARSCOV2&&|RdRP&EndPt|^1.0||
OBX|11|ST|&SARSCOV2&&|SPC&|FAIL^||
OBX|12|ST|&SARSCOV2&&|SPC&Ct|^0.0||
OBX|13|ST|&SARSCOV2&&|SPC&EndPt|^11.0||
SPM|1|230913_P1153_A_INVALID_01^||ORH|||||P

HL7 - Xpert Xpress CoV-2 plus IVD: NO RESULT

MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20231020132249||ORU^R32^ORU_R30|GXM-55642246124|P|2.5|||||||
PID|1||||^|||||||||^|||||||
ORC|RE|1||||||20230913113008
OBR|1|||SARSCOV2|||||||||||||F
TQ1||||||20230913113008|20230913113141|R
OBX|1|ST|&SARSCOV2&Xpert Xpress CoV-2 plus IVD&1|&|NO RESULT^|||||F|||||^User||20901224~06000~137496242~746477~700054~WinDev2006Eval
OBX|2|ST|&SARSCOV2&&|E&|NO RESULT^||
OBX|3|ST|&SARSCOV2&&|E&Ct|^0.0||

OBX|4|ST|&SARSCOV2&&|E&EndPt|^0.0||
OBX|5|ST|&SARSCOV2&&|N2&|NO RESULT^||
OBX|6|ST|&SARSCOV2&&|N2&Ct|^0.0||
OBX|7|ST|&SARSCOV2&&|N2&EndPt|^0.0||
OBX|8|ST|&SARSCOV2&&|RdRP&|NO RESULT^||
OBX|9|ST|&SARSCOV2&&|RdRP&Ct|^0.0||
OBX|10|ST|&SARSCOV2&&|RdRP&EndPt|^0.0||
OBX|11|ST|&SARSCOV2&&|SPC&|NO RESULT^||
OBX|12|ST|&SARSCOV2&&|SPC&Ct|^0.0||
OBX|13|ST|&SARSCOV2&&|SPC&EndPt|^0.0||
SPM|1|230913_P1153_A_NO RESULT2^||ORH|||||P

HL7 - Xpert Xpress CoV-2 plus IVD: ERROR

MSH|^~\&|GeneXpert PC^GeneXpert^6.4||LIS||20231020132250||ORU^R32^ORU_R30|GXM-16543470348|P|2.5|||||||
PID|1||||^^^||||^^^|||||||
ORC|RE|1|||||20230913112913
OBR|1||SARSCOV2|||||||||||F
TQ1|||||20230913112913|20230913113115|R
OBX|1|ST|&SARSCOV2&&Xpert Xpress CoV-2 plus IVD&1|&|ERROR^|||||F||||^User||20901224~06000~137496244~730297~700062~WinDev2006Eval
NTE|1|L|Error^2125^Operation terminated^Error 2125: Termination Error - Insufficient Volume: 12, 50, 0, 13^20230913113101
OBX|2|ST|&SARSCOV2&&|E&|NO RESULT^||
OBX|3|ST|&SARSCOV2&&|E&Ct|^0.0||
OBX|4|ST|&SARSCOV2&&|E&EndPt|^0.0||
OBX|5|ST|&SARSCOV2&&|N2&|NO RESULT^||
OBX|6|ST|&SARSCOV2&&|N2&Ct|^0.0||
OBX|7|ST|&SARSCOV2&&|N2&EndPt|^0.0||
OBX|8|ST|&SARSCOV2&&|RdRP&|NO RESULT^||
OBX|9|ST|&SARSCOV2&&|RdRP&Ct|^0.0||
OBX|10|ST|&SARSCOV2&&|RdRP&EndPt|^0.0||
OBX|11|ST|&SARSCOV2&&|SPC&|NO RESULT^||
OBX|12|ST|&SARSCOV2&&|SPC&Ct|^0.0||
OBX|13|ST|&SARSCOV2&&|SPC&EndPt|^0.0||
SPM|1|230913_P1153_A_ERROR_02^||ORH|||||P

3.3 General Examples of Order Download Messages:

ASTM - Xpert Xpress CoV-2 plus IVD: Order Download

```
H|@^|67a63f37-179c-42d4-afb0-4d1bbae29fe4||LIS^||||GeneXpert||P|1394-97|
P|1||||^^^
O|1|230913_P1153_A_POS_02||^^SARSCOV2|R|20231020125534||||||ORH||^|||||
L|1|N
```

HL7 - Xpert Xpress CoV-2 plus IVD: Order Download

```
MSH|^~\&|LIS^||GeneXpert||||564760b7-f1ac-4459-a72a-16b09ecfc9e6|P|2.5
PID|1||||^^^
ORC|RE|1|||||20231020132123
OBR|1||SARSCOV2|||||||
TQ1||||||R
SPM|1|230913_P1153_A_NEG_02^||ORH|||||P
```

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	ERROR	INDETERMINADA	SIN RESULTADO
5	Italian	POSITIVO	NEGATIVO	ERRORE	NON VALIDO	NESSUN RISULTATO
6	Portuguese	POSITIVO	NEGATIVO	ERRO	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