

March 23, 2020

Re: Special instructions for Xpert® Xpress SARS-CoV-2 Emergency Use Authorization (EUA) customers

Dear Valued Customer,

Cepheid has released the Xpert® Xpress SARS-CoV-2 (EUA) assay.

Part Number	ADF name
XPRSARS-COV2-10	Xpert Xpress SARS-CoV-2

This letter contains information to enable a laboratory information system interface for Xpert® Xpress SARS-CoV-2 (EUA) assay for GeneXpert Systems. It is intended to be used by people familiar with configuring interfaces between in vitro diagnostics instruments and a LIS. The letter contains the following information:

1. Enabling the Assay in GeneXpert
2. Suggested LOINC Code
3. Example GeneXpert Result Transmission Messages
 - a. ASTM
 - b. HL7
4. Observation Language Translation Table

If you need further assistance, please contact Cepheid Technical Support at https://www.cepheid.com/en_US/support/contact-us. You may also email techsupport@cepheid.com or open a support ticket directly.

Thank you for your continued business and interest in our products. We appreciate the partnership we have formed and will continue to strive to bring you the highest quality systems and tests in the industry.

Sincerely,

Cepheid

The Emergency Use Authorization (EUA) authority under section 564 allows FDA to facilitate availability and unapproved uses of medical countermeasures needed to prepare for and respond to Chemical, Biological, Radiological, or Nuclear emergencies.

[Emergency Use Authorization of Medical Products and Related Authorities](#)



Enabling the Assay in GeneXpert

- Please follow the instructions in your GeneXpert System’s User Guide for:
 - **‘Configuring Host Communications for an LIS’.**
 - **‘Configuring a Single-Result Assay for Order and Result Upload’.**
- Cepheid recommends using “SARSCOV2” as the Assay Host Test Code on the GeneXpert system.
- Please confirm with your LIS administrator to ensure compatibility with your LIS.

Suggested LOINC Code

Assay	Specimen ¹	Result Description	LOINC Code	Long Descriptor	Component	Property	Time	System	Scale	Method
Xpert® Xpress SARS-CoV-2	<ul style="list-style-type: none"> • Nasopharyngeal (NP) swab • Nasal wash /Aspirate 	Binary - Positive, Negative	94500-6		SARS Coronavirus 2 RNA	PrThr	Pt	Respiratory	Ord	Probe.amp.tar

<https://loinc.org/94500-6/>

¹**Note:** the available LOINC Codes do not differentiate specific respiratory specimen types. Refer to the Xpert® Xpress SARS-CoV-2 Package Insert for specific specimen type information.

LOINC Code Rationale

Xpert® Xpress SARS-CoV-2 is a single NAA test with probe detection from a respiratory specimen for the detection of SARS-CoV-2. The final decision regarding the appropriate code(s) is the responsibility of the testing laboratory.

<https://loinc.org/sars-coronavirus-2>

Please contact ga@cepheid.com with any questions regarding the use of this LOINC code with Xpert® Xpress SARS-CoV-2.

Example GeneXpert Result Transmission Messages

These example messages can be used by an LIS interface analyst to understand the structure and content of Xpert Xpress SARS-CoV-2 from the GeneXpert system.

Example ASTM Messages

Example ASTM Message: Positive

```
H|@^|URM-XjvI5DXA-27||ACME Health System SN 802108^GeneXpert^5.3||||LIS|P|1394-97|20200320110943
.P|1|||||
.O|1|200320 pos-2||^SARSCOV2|R|20200320082844|||||ORH|||||F
.R|1|^SARSCOV2^Xpert Xpress SARS-CoV-2^1^|POSITIVE^||||F|John Doe|20200320082844|20200320091711|DOEJ-
840G3^708995^688024^145598634^00100^20901224
.R|2|^SARSCOV2^E^|POS^||
.R|3|^SARSCOV2^E^Ct|^28.3||
.R|4|^SARSCOV2^E^EndPt|^407.0||
.R|5|^SARSCOV2^N2^|POS^||
.R|6|^SARSCOV2^N2^Ct|^30.8||
.R|7|^SARSCOV2^N2^EndPt|^256.0||
.R|8|^SARSCOV2^SPC^|NA^||
.R|9|^SARSCOV2^SPC^Ct|^28.3||
.R|10|^SARSCOV2^SPC^EndPt|^385.0||
.L|1|N.
```

Example ASTM Message: Negative

```
H|@^|URM-bz6I5DXA-31||ACME Health System SN 802108^GeneXpert^5.3||||LIS|P|1394-97|20200320111029
.P|1|||||
.O|1|200320 neg-2||^SARSCOV2|R|20200320083015|||||ORH|||||F
.R|1|^SARSCOV2^Xpert Xpress SARS-CoV-2^1^|NEGATIVE^||||F|John Doe|20200320083015|20200320091814|DOEJ-
840G3^708993^619334^145598631^00100^20901224
.R|2|^SARSCOV2^E^|NEG^||
.R|3|^SARSCOV2^E^Ct|^0.0||
.R|4|^SARSCOV2^E^EndPt|^3.0||
.R|5|^SARSCOV2^N2^|NEG^||
.R|6|^SARSCOV2^N2^Ct|^0.0||
.R|7|^SARSCOV2^N2^EndPt|^1.0||
.R|8|^SARSCOV2^SPC^|PASS^||
.R|9|^SARSCOV2^SPC^Ct|^28.6||
.R|10|^SARSCOV2^SPC^EndPt|^329.0||
.L|1|N.
```

Example ASTM Message: Presumptive Positive

```
H|@^|URM-QN6I5DXA-29||ACME Health System SN 802108^GeneXpert^5.3||||LIS|P|1394-97|20200320111027
.P|1|||||
.O|1|200320 PP-2||^SARSCOV2|R|20200320082926|||||ORH|||||F
.R|1|^SARSCOV2^Xpert Xpress SARS-CoV-2^1^|PRESUMPTIVE POS^||||F|John
Doe|20200320082926|20200320091816|DOEJ-840G3^708994^673327^145598632^00100^20901224
.R|2|^SARSCOV2^E^|POS^||
.R|3|^SARSCOV2^E^Ct|^26.5||
.R|4|^SARSCOV2^E^EndPt|^424.0||
.R|5|^SARSCOV2^N2^|NEG^||
.R|6|^SARSCOV2^N2^Ct|^0.0||
.R|7|^SARSCOV2^N2^EndPt|^3.0||
.R|8|^SARSCOV2^SPC^|NA^||
.R|9|^SARSCOV2^SPC^Ct|^28.2||
.R|10|^SARSCOV2^SPC^EndPt|^434.0||
.L|1|N.
```



Example HL7 Messages

Example HL7 Message: Positive

```
MSH|^~\&|ACME Health System SN 802108^GeneXpert^5.3||LIS||20200320111817||ORU^R32^ORU_R30|URM-W8sK5DXA-37|P|2.5
.PID|1|||^^^|
.ORG|RE|1|||20200320083015
.OBR|1||SARSCOV2|F
.TQ1|||20200320083015|20200320091814|R
.OBX|1|ST|&SARSCOV2&Xpert Xpress SARS-CoV-2&1||POSITIVE^||||F||||^JohnDoe||20901224~00100~145598631~619334~708993~DOEJ-840G3
.OBX|2|ST|&SARSCOV2|E|NEG^||
.OBX|3|ST|&SARSCOV2|E&Ct|^0.0||
.OBX|4|ST|&SARSCOV2|E&EndPt|^3.0||
.OBX|5|ST|&SARSCOV2|N2|NEG^||
.OBX|6|ST|&SARSCOV2|N2&Ct|^0.0||
.OBX|7|ST|&SARSCOV2|N2&EndPt|^1.0||
.OBX|8|ST|&SARSCOV2|SPC|PASS^||
.OBX|9|ST|&SARSCOV2|SPC&Ct|^28.6||
.OBX|10|ST|&SARSCOV2|SPC&EndPt|^329.0||
.SPM|1|200320 neg-2^||ORH||||P.
```

Example HL7 Message: Negative

```
MSH|^~\&|ACME Health System SN 802108^GeneXpert^5.3||LIS||20200320111817||ORU^R32^ORU_R30|URM-W8sK5DXA-37|P|2.5
.PID|1|||^^^|
.ORG|RE|1|||20200320083015
.OBR|1||SARSCOV2|F
.TQ1|||20200320083015|20200320091814|R
.OBX|1|ST|&SARSCOV2&Xpert Xpress SARS-CoV-2&1||NEGATIVE^||||F||||^JohnDoe||20901224~00100~145598631~619334~708993~DOEJ-840G3
.OBX|2|ST|&SARSCOV2|E|NEG^||
.OBX|3|ST|&SARSCOV2|E&Ct|^0.0||
.OBX|4|ST|&SARSCOV2|E&EndPt|^3.0||
.OBX|5|ST|&SARSCOV2|N2|NEG^||
.OBX|6|ST|&SARSCOV2|N2&Ct|^0.0||
.OBX|7|ST|&SARSCOV2|N2&EndPt|^1.0||
.OBX|8|ST|&SARSCOV2|SPC|PASS^||
.OBX|9|ST|&SARSCOV2|SPC&Ct|^28.6||
.OBX|10|ST|&SARSCOV2|SPC&EndPt|^329.0||
.SPM|1|200320 neg-2^||ORH||||P.
```

Example HL7 Message: Presumptive Positive

```
MSH|^~\&|ACME Health System SN 802108^GeneXpert^5.3||LIS||20200320111814||ORU^R32^ORU_R30|URM-0WsK5DXA-35|P|2.5
.PID|1|||^^^|
.ORG|RE|1|||20200320082926
.OBR|1||SARSCOV2|F
.TQ1|||20200320082926|20200320091816|R
.OBX|1|ST|&SARSCOV2&Xpert Xpress SARS-CoV-2&1||PRESUMPTIVE POS^||||F||||^JohnDoe||20901224~00100~145598632~673327~708994~DOEJ-840G3
.OBX|2|ST|&SARSCOV2|E|POS^||
.OBX|3|ST|&SARSCOV2|E&Ct|^26.5||
.OBX|4|ST|&SARSCOV2|E&EndPt|^424.0||
.OBX|5|ST|&SARSCOV2|N2|NEG^||
.OBX|6|ST|&SARSCOV2|N2&Ct|^0.0||
.OBX|7|ST|&SARSCOV2|N2&EndPt|^3.0||
.OBX|8|ST|&SARSCOV2|SPC|NA^||
.OBX|9|ST|&SARSCOV2|SPC&Ct|^28.2||
.OBX|10|ST|&SARSCOV2|SPC&EndPt|^434.0||
.SPM|1|200320 PP-2^||ORH||||P.
```



Observation Language Transaction Table

ENGLISH	POSITIVE	PRESUMPTIVE POS	NEGATIVE	ERROR	INVALID	NO RESULT
FRENCH	POSITIF	PRESUMPTIVE POS	NÉGATIF	ERREUR	NON VALIDE	PAS DE RÉSULTAT
GERMAN	POSITIV	PRESUMPTIVE POS	NEGATIV	FEHLER	UNGÜLTIG	KEIN ERGEBNIS
SPANISH	POSITIVO	PRESUMPTIVE POS	NEGATIVO	ERROR	NO VÁLIDO	SIN RESULTADO
ITALIAN	POSITIVO	PRESUMPTIVE POS	NEGATIVO	ERRORE	NON VALIDO	NESSUN RISULTATO
PORTUGUESE	POSITIVO	PRESUMPTIVE POSIT	NEGATIVO	ERRO	INVÁLIDO	SEM RESULTADO
RUSSIAN	ПОЛОЖИТЕЛЬНЫЙ	ПРЕДПОЛОЖИТЕЛЬНО ПОЛ	ОТРИЦАТЕЛЬНЫЙ	ОШИБКА	НЕДЕЙСТВИТЕЛЬНЫЙ	НЕТ РЕЗУЛЬТАТА
UKRAINIAN	ПОЗИТИВНИЙ	НЕГАТИВНИЙ	ПОМИЛКА	НЕДІЙСНИЙ	НЕДІЙСНИЙ	НЕМАЄ РЕЗУЛЬТАТУ
INDONESIAN	POSITIF	PRADUGA POS	NEGATIF	KESALAHAN	TIDAK VALID	TANPA HASIL
POLISH	DODATNI	PRZYPUSZCZALNEGO	UJEMNY	BŁĄD	NIEWAŻNY	BRAK WYNIKU