

Assay Training: Xpert[®] Xpress SARS-CoV-2

For Use with GeneXpert Xpress System

For Use Under an Emergency Use
Authorization (EUA) Only



IVD In Vitro Diagnostic Medical Device



Training Agenda

- **Xpert® Xpress SARS-CoV-2**
 - Reagents
 - Sample collection
 - Kit storage and handling
 - Preparing the cartridge
 - Quality Controls
 - Results analysis
- **Discussion**



Training Objectives

At the end of the training, users will be able to:

Properly store and handle the Xpert[®] Xpress SARS-CoV-2* kit

Follow proper laboratory safety precautions

Collect and store appropriate specimen(s)

Prepare a cartridge and run the Xpert[®] Xpress SARS-CoV-2 test

Report the various software generated results

Understand the Xpert[®] Xpress SARS-CoV-2 control strategy

Xpert® Xpress SARS-CoV-2



For use under an Emergency Use Authorization (EUA) only



The Cepheid Solution



- Detection of SARS-CoV-2
- On-board internal controls for each sample
 - Probe Check Control (PCC)
 - Specimen Processing Control (SPC)
- Closed cartridge system minimizes risk of contamination
- On-demand results
- Random access

Intended Use

The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in upper respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and/or nasal wash/aspirate) collected from individuals suspected of COVID-19 by their healthcare provider.

Testing of nasopharyngeal, oropharyngeal, nasal, or mid-turbinate swab and nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Dx and GeneXpert Infinity systems is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high and moderate complexity tests.

Testing of nasopharyngeal, nasal, or mid-turbinate swab specimens using the Xpert Xpress SARS-CoV-2 test run on the GeneXpert Xpress System (Tablet and Hub Configurations) is authorized to be distributed and used in patient care settings outside of the clinical laboratory environment.

Intended Use (continued)

- Results are for the detection of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of active infection with SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.
- Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for treatment or other patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.
- Testing with the Xpert Xpress SARS-CoV-2 test is intended for use by trained operators who are proficient in performing tests using either GeneXpert Dx, GeneXpert Infinity and/or GeneXpert Xpress systems. The Xpert Xpress SARS-CoV-2 test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Xpert[®] Xpress SARS-CoV-2 Requirements

GeneXpert[®] Xpress System

- GeneXpert Xpress System with Xpress Software
 - Tablet software version 5.0 and 5.1 or Hub software version 6.1 or higher
- GeneXpert Xpress User's Guide

Test Kits

- XPRSARS-COV-2-10

Materials Required but not Provided

- 3mL viral transport media or 3mL saline
- Personal Protective Equipment (PPE)
- 1:10 dilution of bleach
- 70% ethanol or denatured ethanol

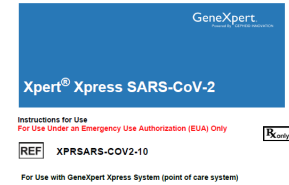
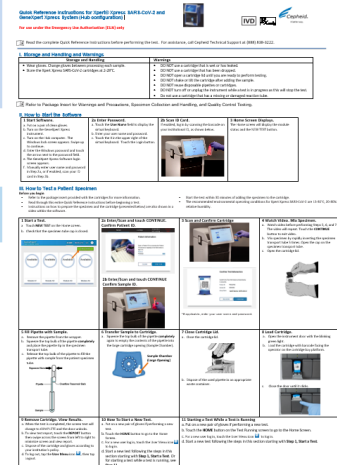
Optional

- Uninterruptible Power Supply/ Surge Protector
- Printer

Kit Components



	Xpert® Xpress SARS-CoV-2
Catalog Number	XPRSARS-COV2-10
Tests per kit	10
CD	Assay Definition File (ADF)
	Instructions to import ADF into GeneXpert software
Flyer	Directions to locate the Instructions For Use and Quick Reference Instructions on www.cepheid.com
Transfer pipettes	10
Storage	2-28°C



Cartridges contain chemically hazardous substances-please see Instructions for Use and Safety Data Sheet for more detailed information.

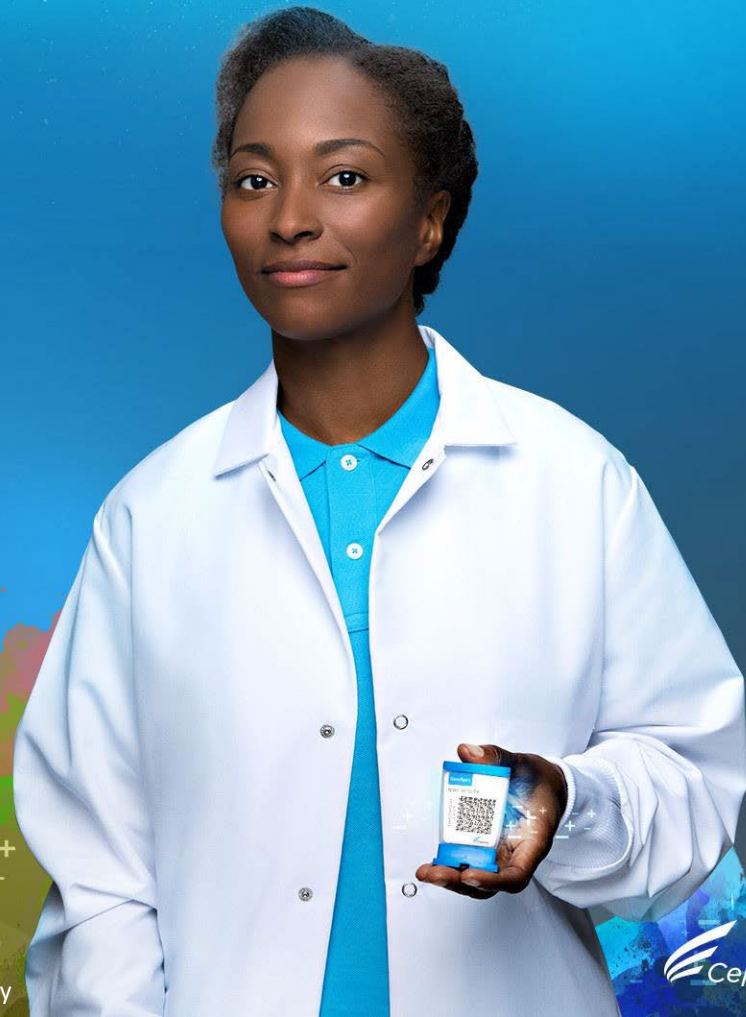
Cepheid, For use under an Emergency Use Authorization (EUA) only IVD 302-3750; Rev A, March 2020



Xpert[®] Xpress SARS-CoV-2 Kit Storage and Handling

- Store test kits at 2-28°C. Do not use expired cartridges.
- Each single-use cartridge is used to process one test. Do not reuse processed cartridges.
- Do not open a cartridge until ready to use.
 - Start the test within 30 minutes of adding the sample to the cartridge.
- To avoid cross contamination during sample handling steps, change gloves between samples

Specimen Collection



For use under an Emergency Use Authorization (EUA) only



Specimen Collection

Specimen Type:
nasopharyngeal swab, nasal swab, mid-turbinate swab

Place specimen into 3mL transport medium
or 3mL of saline



← Nasopharyngeal swab

Refer to the CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19)

<https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html>

Specimen Collection- Nasopharyngeal Swab


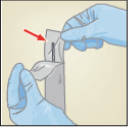
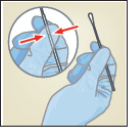


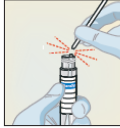
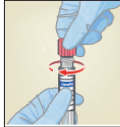
1. Insert the swab into either nostril, passing it into the posterior nasopharynx.
2. Rotate swab by firmly brushing against the nasopharynx several times.
3. Remove and place the swab into the tube containing 3 ml of viral transport medium or 3mL of saline.
4. Break swab at the indicated break line and cap the specimen collection tube tightly.



Specimen Collection- Nasopharyngeal Swab

Nasopharyngeal Specimen Collection

For use with Xpert® Nasopharyngeal Sample Collection Kit - Catalog # SWAB/B-100

- 1 Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.

- 2 Open the swab wrapper and remove the swab, taking care not to touch the tip of the swab to any surface.

- 3 Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.

- 4 Gently insert the swab into the nostril until you touch the posterior nasopharynx. Rotate swab several times.

- 5 Remove the cap from the tube. Insert the swab into the transport medium.

- 6 Break the swab shaft against the side of the tube at the scoreline. Avoid splashing contents on the skin. Wash with soap and water if exposed.

- 7 Replace the cap on the tube and close tightly.


For Xpert Xpress Flu and Xpert Xpress Flu/RSV:
Transport the specimen at 2-8°C.
Specimen may be stored for 24 hours at 15-30°C or up to 7 days at 2-8°C.

For Xpert Xpress SARS-CoV-2:
Specimen may be stored for 8 hours at 15-30°C or up to 7 days at 2-8°C.

* SWAB/B-100 contains Copan UTM 330C and Copan nylon swab 503CS01

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In Vitro Diagnostic Use 

In Vitro Diagnostic Use  

301-6052, Rev. D March 2020


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Specimen Collection- Nasal Swab

1. Insert the nasal swab 1 to 1.5cm into the nostril.
2. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.
3. Repeat on the other nostril with the same swab.
4. Remove and place the swab into the tube containing 3 ml of viral transport medium or 3mL of saline.
5. Break swab at the indicated break line and cap the specimen collection tube tightly.





Specimen Collection- Nasal Swab

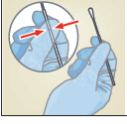
Nasal Swab Specimen Collection

For use with Xpert® Swab Sample Collection Kit - Catalog # SWAB/F-100


- 1 Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.


- 2 Open the swab wrapper and remove the swab, taking care not to touch the tip of the swab to any surface.



- 3 Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.

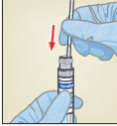

- 4 Rotate swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.

Do not insert the swabs more than 1-1.5 cm.

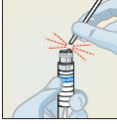

- 5 Repeat Step 4 on the other nostril with the same swab.

To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.


- 6 Remove the cap from the tube. Insert the swab into the transport medium.

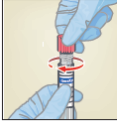

- 7 Break the swab shaft against the side of the tube at the scoreline.

Avoid splashing contents on the skin. Wash with soap and water if exposed.


- 8 Replace the cap on the tube and close tightly.

For Xpert Xpress Flu and Xpert Xpress Flu/RSV:
Specimen may be stored for 24 hours at 15-30°C or up to 7 days at 2-8°C.

For Xpert Xpress SARS-CoV-2:
Specimen may be stored for 8 hours at 15-30°C or up to 7 days at 2-8°C.



* SWAB/F-100 contains Copan UTM 330C and Copan nylon swab 502CS01

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In Vitro Diagnostic Use **IVD**

In Vitro Diagnostic Use **IVD**

301-9057, Rev. 8 April 2020

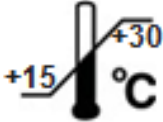
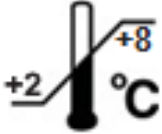
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Specimen Collection- Mid-Turbinate Swab

1. Insert the mid-turbinate swab into either nostril, passing it into the mid-turbinate area
2. Rotate swab by firmly brushing against the mid-turbinate area several times.
3. Remove and place the swab into the tube containing 3ml of viral transport medium or 3ml of saline.
4. Break swab at the indicated break line and cap the specimen collection tube tightly.



Specimen Transport and Storage

Sample type	Transport and Storage Conditions
Viral Transport Medium or saline containing nasopharyngeal swab, nasal swab, or mid-turbinate swab	 <p>Up to 8 hours</p>  <p>Up to 7 days</p>

Cartridge Preparation



For use under an Emergency Use Authorization (EUA) only



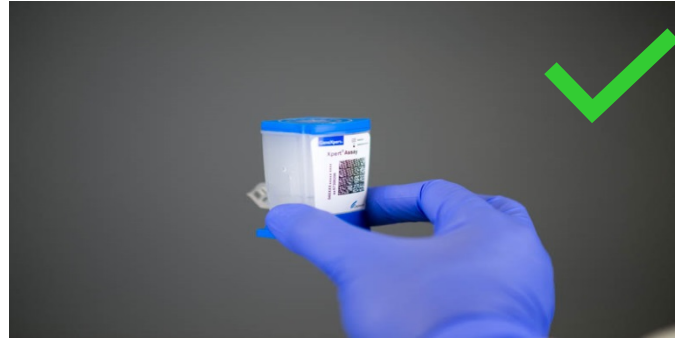
Warnings and Precautions

- Do not shake the cartridge
- Do not use a cartridge... :
 - if it appears wet, has leaked with signs of precipitate, or if the lid seal appears to have been broken
 - if it appears damaged
 - that has been dropped after removing it from packaging
 - that has been shaken. Shaking or dropping the cartridge after opening the cartridge lid may yield indeterminate results.
 - that has a damaged reaction tube (bent, missing, cracked)
 - that has been used: each cartridge is single-use to process one test
- Do not reuse pipettes
- Do not reuse swabs

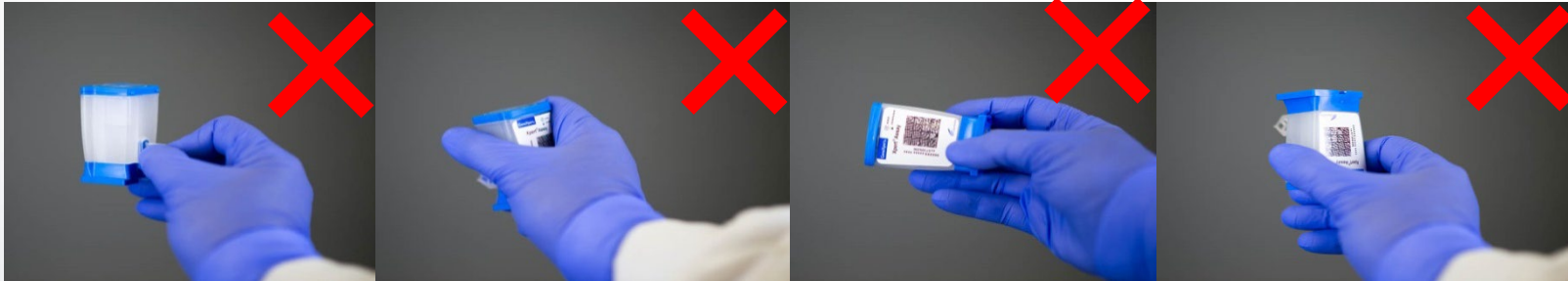
Proper Cartridge Handling Techniques

Correct

- Do not touch the reaction tube
- Keep the cartridge upright
- Do not tilt after sample is added



Incorrect



Xpert® Xpress SARS-CoV-2

Cartridge Preparation

Sample Qualification – check if all items below are present:

1. Transport media or saline containing swab
2. Patient name or identifier on the tube
3. Cartridges and transport media or saline are within the expiration date

Good Laboratory Practices:

- Wear clean gloves and lab coats.
- Change gloves between samples.
- Clean work surface with 1:10 dilution of bleach followed by 70% ethanol solution.

Xpert® Xpress SARS-CoV-2 Cartridge Preparation

Refer to the package insert for detailed instructions, precautions, and warnings.

For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

Contact information for all Cepheid Technical Support offices is available on our website: www.cepheid.com/en/CustomerSupport.



1 Take one Xpert cartridge for each sample.



2 Rapidly invert the tube 5 times.



3 Open the cartridge lid.



4 Using a clean 300 µL pipette (supplied), transfer 300 µL (one draw), of the sample to the opening of the cartridge.



5 Close the cartridge lid.



6 Start the test within the timeframe specified in the package insert.

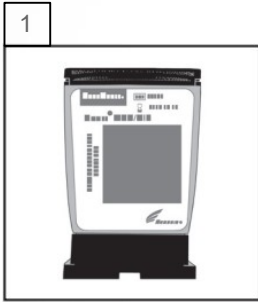
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302-3755, Rev. A March 2020

Xpert[®] Xpress SARS-CoV-2

Cartridge Preparation



Take one Xpert cartridge for each sample.



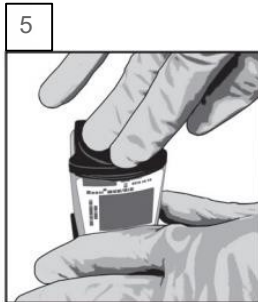
Rapidly invert the tube 5 times.



Open the cartridge lid.



Using a clean 300 μ L pipette (supplied), transfer 300 μ L (one draw) of the sample to the cartridge.



Close the cartridge lid.

6

Start the test within the timeframe specified in the Instructions For Use.

Automated Xpert[®] Xpress SARS-CoV-2



Waste Disposal

Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents and require use of standard precautions.

Follow your institution's environmental waste procedures for proper disposal of used cartridges and unused reagents. These materials may exhibit characteristics of chemical hazardous waste requiring specific national or regional disposal procedures.

If national or regional regulations do not provide clear direction on proper disposal, biological specimens and used cartridges should be disposed per WHO [World Health Organization] medical waste handling and disposal guidelines.

Quality Control

*Refer to the Instructions For Use
for complete details*



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Xpert[®] Xpress SARS-CoV-2 Cartridge Controls

- **Each Xpert cartridge is a self-contained test device.**
- A Sample Processing Control (SPC) and a Probe Check Control (PCC) are included in the cartridge.
- The SPC is present to:
 - verifies that sample processing is adequate
 - monitor for the presence of inhibitors in the PCR reaction
- The PCC verifies:
 - reagent rehydration
 - PCR tube filling in the cartridge
 - probe integrity
 - dye stability

If either control fails, a NO RESULT- REPEAT TEST result will be reported.

Commercially Available External Controls

Vendor	Description	Configuration	Storage
SeraCare AccuPlex™ SARS-CoV-2 Reference Material Kit Catalog # 0505-0126	Positive Control	5 x 1.5mL	2-8°C or -20°C
	Negative Control	5 x 1.5mL	2-8°C or -20°C

1. Open the cartridge lid.
2. Rapidly invert the external control tube 5 times.
3. Using a clean transfer pipette, transfer one draw of the external control sample into the large opening (Sample Chamber) in the cartridge.
4. Close cartridge lid.

To minimize degradation of the control material, return any unused sample to the recommended storage conditions immediately after use.

- Many other vendors for quality control material are also available in addition to the one outlined above.
- External controls should be used in accordance with local, state accrediting organizations, as applicable

External Controls should be performed:

- Each time a new lot of Xpert® Xpress SARS-CoV-2 Assay reagents is received.
- Each time a new shipment of Xpert Xpress SARS-CoV-2 Assay reagents is received even if it is the same lot previously received.
- Each time a new operator is performing the test (i.e., operator who has not performed the test recently).
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your institution's standard QC procedures.

If the QC lockout feature is enabled, follow the QC Lockout instructions detailed in the GeneXpert Xpress System User's Guide

Results Analysis

Refer to the Instructions For Use for complete details



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Early Assay Termination

- The Xpert Xpress SARS-CoV-2 test includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens.
- When SARS-CoV-2 titers are high enough to initiate the EAT function, the SPC amplification curve may not be seen and its results may not be reported.

Result Summary

Result	Interpretation
SARS-CoV-2 NEGATIVE	SARS-CoV-2 (coronavirus) target RNA is not detected.
SARS-CoV-2 POSITIVE	SARS-CoV-2 (coronavirus) target RNA is detected.
SARS-CoV-2 PRESUMPTIVE POS	If the result is SARS-CoV-2 PRESUMPTIVE POS , then retest with a new cartridge. If the retest is SARS-CoV-2 PRESUMPTIVE POS , collect new specimen and REPEAT TEST .
NO RESULT - REPEAT TEST	If the result is NO RESULT- REPEAT TEST with a new cartridge. If the retest is NO RESULT , collect new specimen and REPEAT TEST .
INSTRUMENT ERROR	Result is an instrument error. Touch CLEAR ERROR and follow the on-screen instructions. When the Home screen appears, repeat the test using a new cartridge.

Note: If an incorrect result is provided for the external control, repeat the external control run. If repeated control runs do not produce the expected results, contact Cepheid Technical Support at (888) 838-3222.

SARS-CoV-2 POSITIVE

Hub software version 6.1 or higher

The screenshot shows the GeneXpert Hub software interface. At the top, there is a blue navigation bar with the GeneXpert logo and the text "Powered by Cepheid Innovation". To the right of the logo are navigation links: HOME, RESULTS, QC, ADMIN, and a menu icon. The main content area is white and features a "Test Completed" heading. Below this heading, there is a table of test details. The "Result" field is highlighted in red and contains the text "SARS-CoV-2 POSITIVE". A blue "REPORT" button is located below the result. At the bottom of the page, there is a disclaimer: "For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA)."

Text	Value
Module D2	
Sample ID	200320 Pos-1
Test Type	
Specimen	Xpert Xpress SARS-CoV-2
User	Jun Zhang
Start Date	03/20/20 08:31:52

Result
SARS-CoV-2 POSITIVE

[REPORT](#)

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Tablet software version 5.0 and 5.1

The screenshot shows the GeneXpert Tablet software interface. At the top, there is a blue navigation bar with the GeneXpert logo and the text "XPRESS SOFTWARE". To the right of the logo are navigation links: VIEW PREVIOUS TESTS and HOME. The main content area is blue and features a "Test Result" heading. Below this heading, there is a table of test details. The "Result" field is highlighted in red and contains the text "SARS-CoV-2 POSITIVE". A green "PRINT RESULT" button is located at the bottom of the page. At the bottom right of the page, there is the Cepheid logo.

Text	Value
Patient/Sample ID	pos
Cartridge S/N	14559536
Assay	Xpert Xpress SARS-CoV-2
Result	SARS-CoV-2 POSITIVE
Start Time	03/20/20 11:53:06

[PRINT RESULT](#)

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SARS-CoV-2 Positive Test Report

SN 800xxx Institution Name

03/21/20 12:24:45

Test Report

Sample ID: 200320 Pos-1
Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
xpert Xpress SARS-CoV-2	1	In Vitro Diagnostic

Test Result: **SARS-CoV-2 POSITIVE**

User:
Status: Completed Start Time: 03/20/20 08:31:52
S/W Version: 6.1 End Time: 03/20/20 09:19:27
Expiration Date*: 12/24/90 Instrument S/N: 709003
Cartridge S/N*: 145598591 Module S/N: 749250
Reagent Lot*: 00100 Module Name: D2

Errors
<None>

Operator Initial/Date

Supervisor Initial/Date

* Indicates that a particular field is entered using a barcode scanner

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SARS-CoV-2 PRESUMPTIVE POS

Hub software version 6.1 or higher

The screenshot shows the GeneXpert Hub software interface. At the top, there is a blue header with the GeneXpert logo and navigation links for HOME, RESULTS, and QC. The main content area is titled "Test Completed" and displays the following information:

Module C3	Result
Sample ID 200320 PP-1	SARS-CoV-2 PRESUMPTIVE POS
Test Type	Assay Name
Specimen	Xpert Xpress SARS-CoV-
User Jun Zhang	Start I 03/20/20 08:32:33
Test Disclaimer	REPORT

At the bottom, there is a disclaimer: "For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA)."

Tablet software version 5.0 and 5.1

The screenshot shows the GeneXpert Tablet software interface. At the top, there is a blue header with the GeneXpert logo and navigation links for VIEW PREVIOUS TESTS and HOME. The main content area is titled "Test Result" and displays the following information:

Patient/Sample ID presump_pos	Cartridge S/N 14538801
Assay Xpert Xpress SARS-CoV-2	Start Time 03/20/20 11:54:31
Result SARS-CoV-2 PRESUMPTIVE POS	Test Disclaimer For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA).

At the bottom, there is a "PRINT RESULT" button and the Cepheid logo.

SARS-CoV-2 Presumptive Pos Test Report

SN 800xxx Institution Name 03/21/20 13:52:48

Test Report

Sample ID: 200320 PP-1
Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
Xpert Xpress SARS-CoV-2	1	In Vitro Diagnostic

Test Result: **SARS-CoV-2 PRESUMPTIVE POS**

User:
Status: Completed Start Time: 03/20/20 08:32:59
S/W Version: 6.1 End Time: 03/20/20 09:21:00
Expiration Date*: 12/24/90 Instrument S/N: 709002
Cartridge S/N*: 145598593 Module S/N: 638563
Reagent Lot*: 00100 Module Name: C3

Errors
<None>

Operator Initial/Date

Supervisor Initial/Date

* indicates that a particular field is entered using a barcode scanner

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SARS-CoV-2 NEGATIVE

Hub software version 6.1 or higher

The screenshot displays the GeneXpert Hub software interface. At the top, there is a blue navigation bar with the GeneXpert logo and the text "Powered by Cepheid Innovation". The navigation bar includes links for HOME, RESULTS, QC, and ADMIN, along with a menu icon. The main content area is titled "Test Completed" and contains the following information:

- Module D4
- Sample ID: 200320 Neg-2
- Test Type: Xpert Xpress SARS-CoV-2
- Specimen: Xpert Xpress SARS-CoV-2
- User: Jun Zhang
- Test Date/Time: 03/20/20 08:31:29
- Result: SARS-CoV-2 NEGATIVE (highlighted in green)
- REPORT button

At the bottom of the interface, there is a disclaimer: "For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA)." A footer bar at the bottom indicates "Hub software version 6.1 or higher".

Tablet software version 5.0 and 5.1

The screenshot displays the GeneXpert Tablet software interface. At the top, there is a blue navigation bar with the GeneXpert logo and the text "XPRESS SOFTWARE". The navigation bar includes links for VIEW PREVIOUS TESTS and HOME. The main content area is titled "Test Result" and contains the following information:

- Patient/Sample ID: neg
- Cartridge S/N: 145598641
- Assay: Xpert Xpress SARS-CoV-2
- Result: SARS-CoV-2 NEGATIVE (highlighted in green)
- Start Time: 03/20/20 11:50:37
- Test Disclaimer: For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA).
- PRINT RESULT button

At the bottom of the interface, there is a footer bar with the Cepheid logo and the text "Tablet software version 5.0 and 5.1".

SARS-CoV-2 Negative Test Report

SN 800xxx Institution Name 03/21/20 12:25:37

Test Report

Sample ID: 200320 Neg-2
Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
Xpert Xpress SARS-CoV-2	1	In Vitro Diagnostic

Test Result: SARS-CoV-2 NEGATIVE

User:
Status: Completed Start Time: 03/20/20 08:31:29
S/W Version: 6.1 End Time: 03/20/20 09:19:07
Expiration Date*: 12/24/90 Instrument S/N: 709003
Cartridge S/N*: 145598588 Module S/N: 724901
Reagent Lot*: 00100 Module Name: D4

Errors
<None>

Operator Initial/Date

Supervisor Initial/Date

* Indicates that a particular field is entered using a barcode scanner

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Reasons to Repeat the Assay

- A **PRESUMPTIVE POSITIVE** result indicates the 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present. Only one of the SARS-CoV-2 nucleic acid target was detected (E gene) while the other SARS-CoV-2 nucleic acid target (N2 gene) was not detected.
- An **INSTRUMENT ERROR** result could be due to, but not limited to, the maximum pressure limits were exceeded.
- A **NO RESULT- REPEAT TEST** indicates that insufficient data were collected. For example, Probe Check Control failed or a power failure occurred.

If an External Control fails to perform as expected, repeat external control test and/or contact Cepheid Technical Support for assistance.

INSTRUMENT ERROR

- If you encounter an INSTRUMENT ERROR, touch CLEAR ERROR and follow the on-screen instructions.
- When the Home screen appears, follow the retest procedure.
- If another INSTRUMENT ERROR occurs upon retest, contact Technical Support for assistance.

Hub software version 6.1 or higher

The screenshot shows the Hub software interface for version 6.1 or higher. At the top, there is a blue navigation bar with a back arrow, 'HOME', 'RESULTS' (underlined), and 'QC' with a menu icon. Below the navigation bar, the main content area is white and titled 'Test Completed'. It contains a table of test details and a 'REPORT' button. The 'Result' field is highlighted in yellow and displays 'INSTRUMENT ERROR'.

Module A1		Result
Sample ID	Patient ID	INSTRUMENT ERROR
SID5052	PID4638	
Test Type	Assay Name	
Specimen	Xpert Xpress Assay	
User	Start Date & Time	
Xpress User	09/05/19 12:51:00	
Test Disclaimer		
For In Vitro Diagnostic Use Only.		

Tablet software version 5.0 and 5.1

The screenshot shows the Tablet software interface for version 5.0 and 5.1. It features a dark blue background with a yellow banner at the top that reads 'INSTRUMENT ERROR'. To the right, there is a 'Start Time' field showing '05/13/14 13:13:57' and a 'Test Disclaimer' field with the text 'For In Vitro Diagnostic Use Only.'.

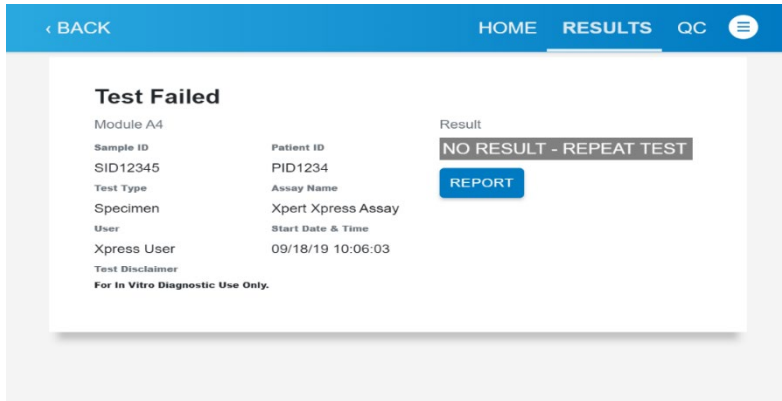
INSTRUMENT ERROR Test Report

Test Report			
Patient/Sample ID:			
Assay Information			
Assay	Assay Version	Assay Type	
Test Result: INSTRUMENT ERROR			
User:	<None>	Start Time:	11/16/17 09:39:28
Status:	Aborted	End Time:	11/16/17 09:42:13
Expiration Date*:	12/24/90	Instrument S/N:	804485
S/W Version:	5.0	Module S/N:	647385
Cartridge S/N*:	382691211	Module Name:	A2
Reagent Lot ID*:	20301		
Notes:			
Errors			
#	Description	Detail	Time
1	Operation terminated	Error 2125: Termination Error - Insufficient Volume: 12, 30, 0, 0	11/16/17 09:41:58
_____ Tech. Initial/Date		_____ Supervisor Initial/Date	
* indicates that a particular field is entered using a barcode scanner			

NO RESULT- REPEAT TEST

- If you encounter a NO RESULT - REPEAT TEST result, follow the retest procedure.
- If a NO RESULT- REPEAT TEST result occurs upon retest, contact Technical Support for assistance.

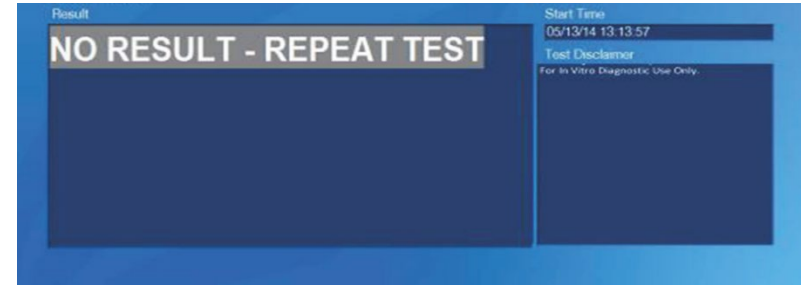
Hub software version 6.1 or higher



The screenshot shows the Hub software interface for version 6.1 or higher. At the top, there is a blue navigation bar with a '< BACK' button on the left, and 'HOME', 'RESULTS', and 'QC' tabs on the right, along with a menu icon. The main content area is titled 'Test Failed' and contains the following information:

Module A4		Result
Sample ID	Patient ID	NO RESULT - REPEAT TEST
SID12345	PID1234	REPORT
Test Type	Assay Name	
Specimen	Xpert Xpress Assay	
User	Start Date & Time	
Xpress User	09/18/19 10:06:03	
Test Disclaimer		
For In Vitro Diagnostic Use Only.		

Tablet software version 5.0 and 5.1



The screenshot shows the Tablet software interface for version 5.0 and 5.1. The interface is primarily dark blue. At the top, there is a 'Result' label on the left and a 'Start Time' label on the right. The main content area displays the following information:

NO RESULT - REPEAT TEST	Start Time
	05/13/14 13:13:57
	Test Disclaimer
	For In Vitro Diagnostic Use Only.

NO RESULT- REPEAT TEST Test Report

Test Report			
Patient/Sample ID:			
Assay Information			
Assay	Assay Version	Assay Type	
Test Result: NO RESULT - REPEAT TEST			
User:	<None>		
Status:	Done	Start Time:	12/13/17 08:22:54
Expiration Date*:	12/24/90	End Time:	12/13/17 08:45:43
S/W Version:	5.0	Instrument S/N:	804485
Cartridge S/N*:	306171426	Module S/N:	641283
Reagent Lot ID*:	06001	Module Name:	A1
Notes:			
Errors			
<None>			
_____ Tech. Initial/Date		_____ Supervisor Initial/Date	
* Indicates that a particular field is entered using a barcode scanner			

Retest Procedure

1

Discard used cartridge

Follow your institution's safety guidelines for disposal of cartridges

2



Obtain the residual specimen, mix according to Instructions For Use

If the leftover specimen volume is insufficient, or the retest continues to return an INSTRUMENT ERROR or NO RESULT, collect a new specimen.

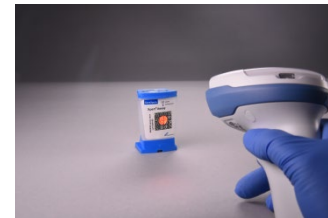
3



Obtain a new cartridge

Process the specimen per the Instructions For Use

4



Run the test on the System



Technical Assistance

- Before contacting Cepheid Technical Support, collect the following information:
 - Product name
 - Lot number
 - Serial number of the System
 - Error messages (if any)
 - Software version and, if applicable, Computer Service Tag number
- Log your complaint online using the following link <http://www.cepheid.com/us/support>
 - Create a Support Case
- Call: 1-888-838-3222
- Email: techsupport@cepheid.com



Thank You.



www.Cepheid.com