Assay Training:
Xpert® Xpress SARS-CoV-2

For Use with GeneXpert Xpress System

For Use Under an Emergency Use Authorization (EUA) Only

Rx only

IVD In Vitro Diagnostic Medical Device

302-3762 Rev. C April 2020

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

* For use under an Emergency Use Authorization (EUA) only

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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

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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

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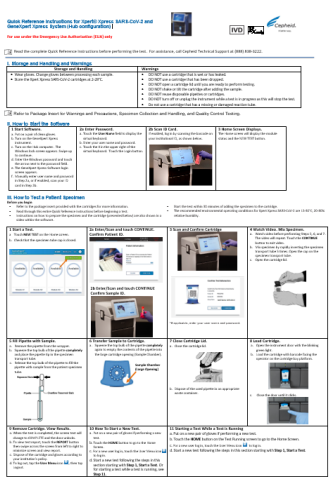
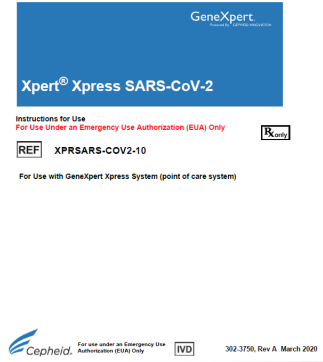
Kit Components

	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.

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

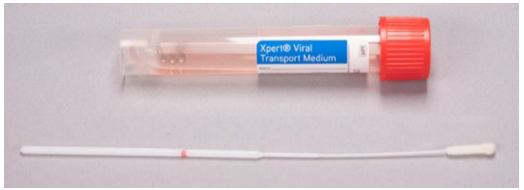
- Store test kits at 2-28ºC. Do not use expired cartridges.
- Each single-use cartridge is used to process one test. Do not reuse processed cartridges.
- Do not open a cartridge until ready to use.
  - Start the test within 30 minutes of adding the sample to the cartridge.
- To avoid cross contamination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

Specimen Collection

Specimen Collection

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

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

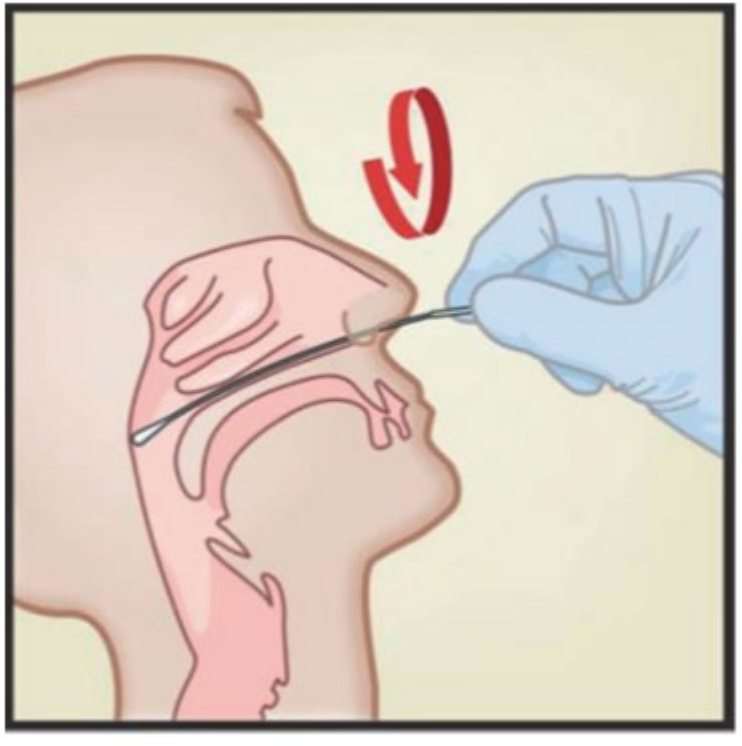


Nasopharyngeal swab

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.



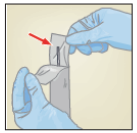
Specimen Collection- Nasopharyngeal Swab

Nasopharyngeal Specimen Collection

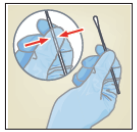
For use with Xpert® Nasopharyngeal Sample Collection Kit - Catalog # SWAB/B-100

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.



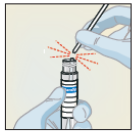
4. Gently insert the swab into the nostril until you touch the posterior nasopharynx.

   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

In Vitro Diagnostic Use IVD

In Vitro Diagnostic Use CE IVD

301-6052, Rev. D March 2020

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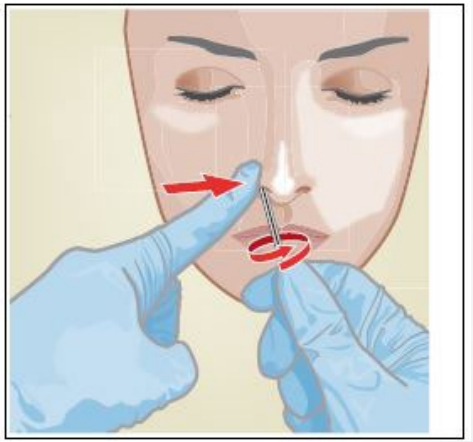
Specimen Collection- Nasal Swab

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.



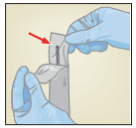
Specimen Collection- Nasal Swab

Nasal Swab Specimen Collection

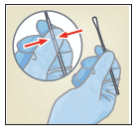
For use with Xpert® Swab Sample Collection Kit - Catalog # SWAB/F-100

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.



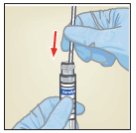
4. Rotate swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.

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

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

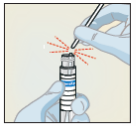
   To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.

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.

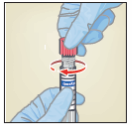
   Avoid splashing contents on the skin. Wash with soap and water if exposed.



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

In Vitro Diagnostic Use IVD

In Vitro Diagnostic Use CE IVD

301-9057, Rev. B April 2020

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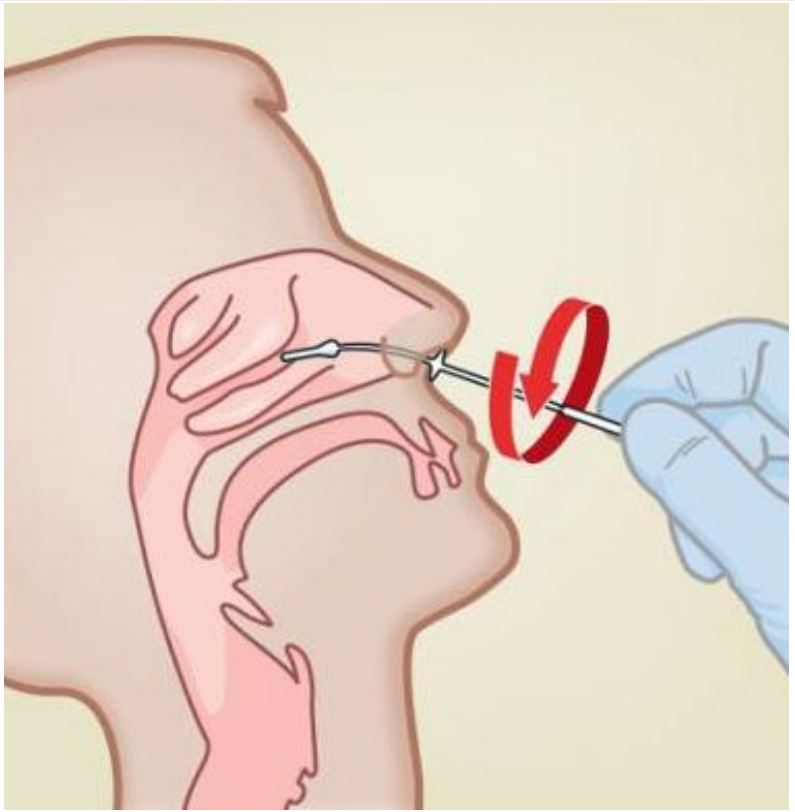
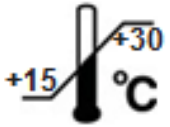
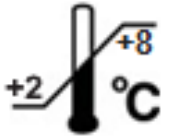
Specimen Collection- Mid-Turbinate Swab

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	 Up to 8 hours  Up to 7 days

Cartridge Preparation

Warnings and Precautions

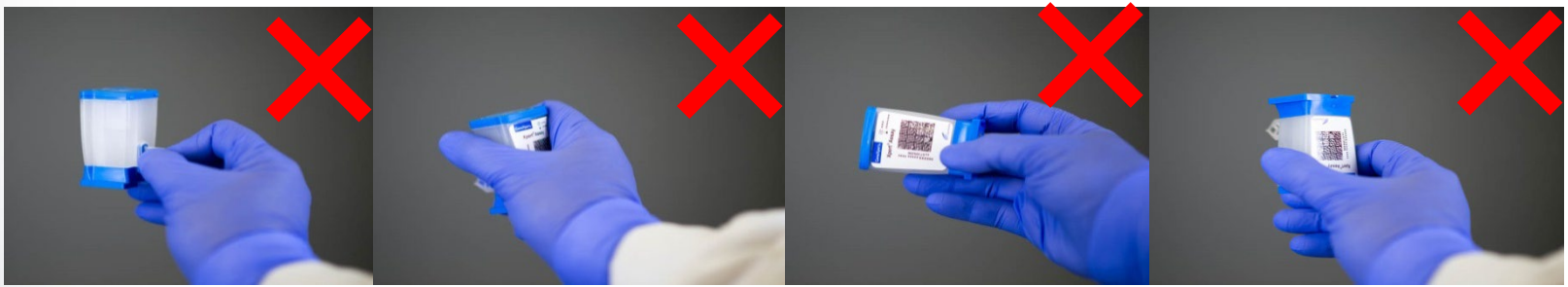
- Do not shake the cartridge
- Do not use a cartridge… :
  - if it appears wet, has leaked with signs of precipitate, or if the lid seal appears to have been broken
  - if it appears damaged
  - that has been dropped after removing it from packaging
  - that has been shaken. Shaking or dropping the cartridge 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.

Cepheid. A better way.

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

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Xpert® Xpress SARS-CoV-2

Cartridge Preparation

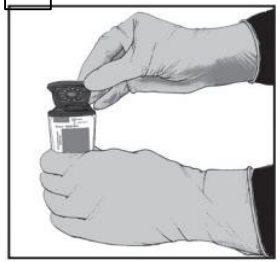
1

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 cartridge.

5

Close the cartridge lid.

6

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

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Automated Xpert® Xpress SARS-CoV-2

1. Add the sample to the cartridge.
2. Place the cartridge into the instrument.
3. Nucleic acids are purified.
4. Purified nucleic acids mix with PCR reagents.
5. Simultaneous amplification and detection occurs.
6. Results are ready to view.

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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.

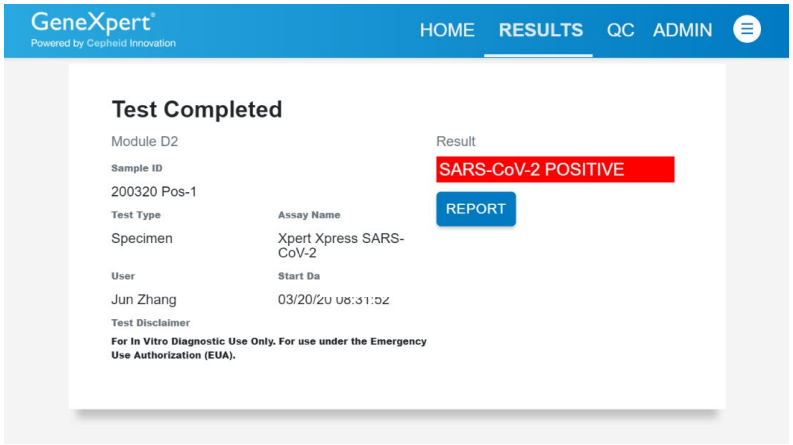
Result Summary

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.

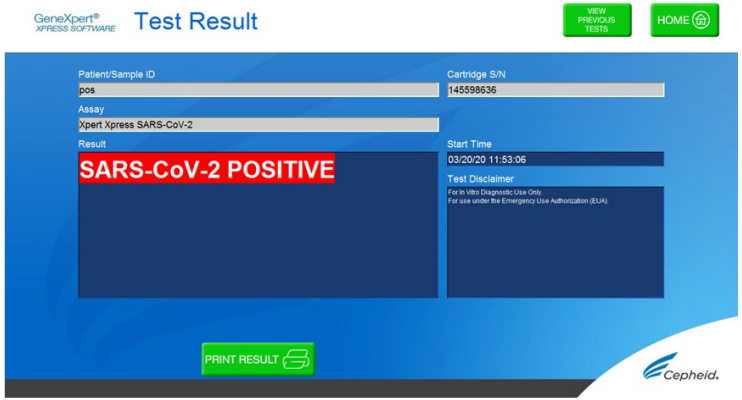
Note: If an incorrect result is provided for the external control, repeat the external control run. If repeated control runs do not produce the expected results, contact Cepheid Technical Support at (888) 838-3222.

SARS-CoV-2 POSITIVE

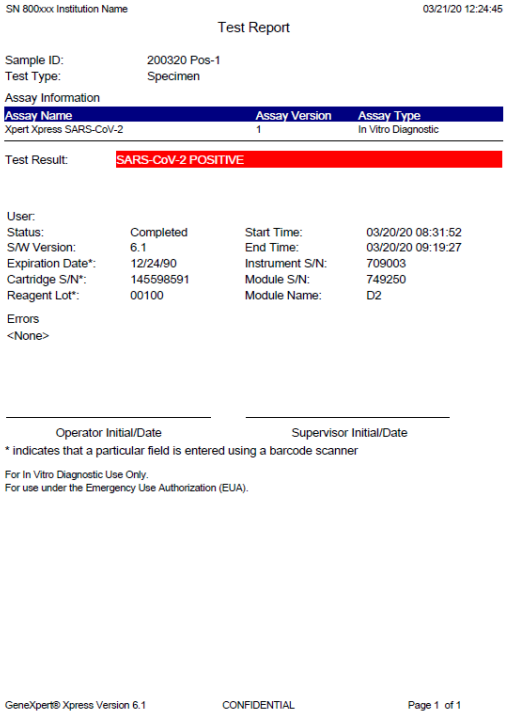
Hub software version 6.1 or higher



Tablet software version 5.0 and 5.1



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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GeneXpert® Xpress Version 6.1 CONFIDENTIAL Page 1 of 1

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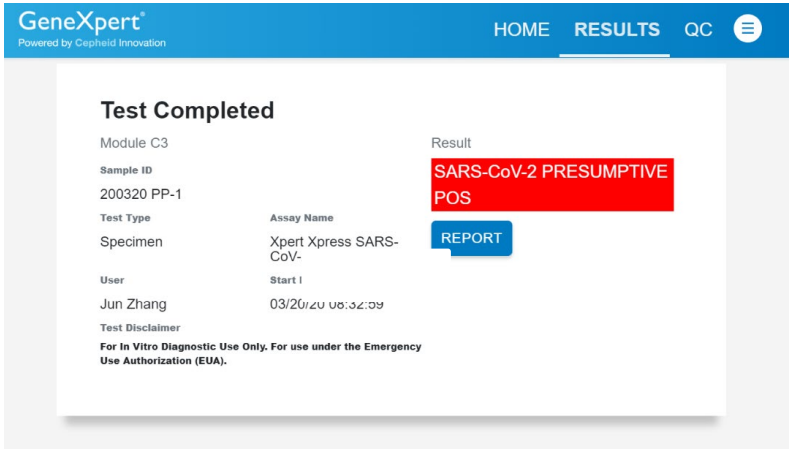
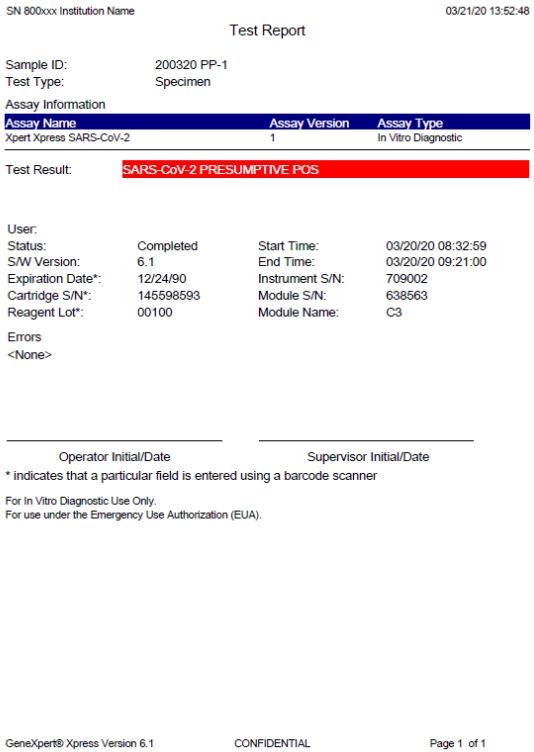
SARS-CoV-2 PRESUMPTIVE POS

Hub software version 6.1 or higher



Tablet software version 5.0 and 5.1

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

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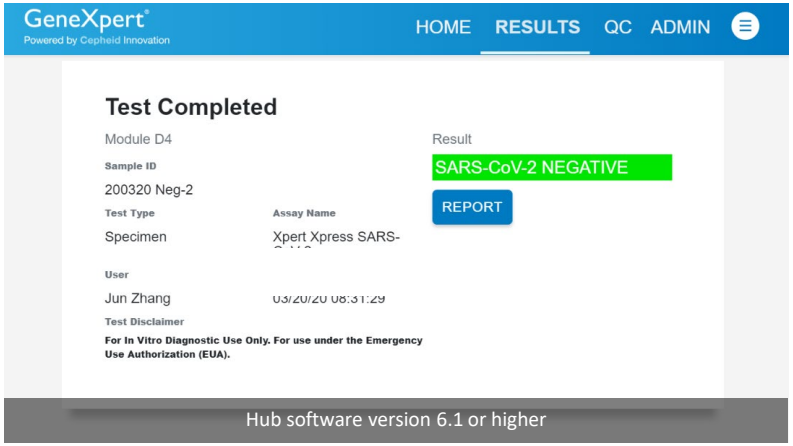
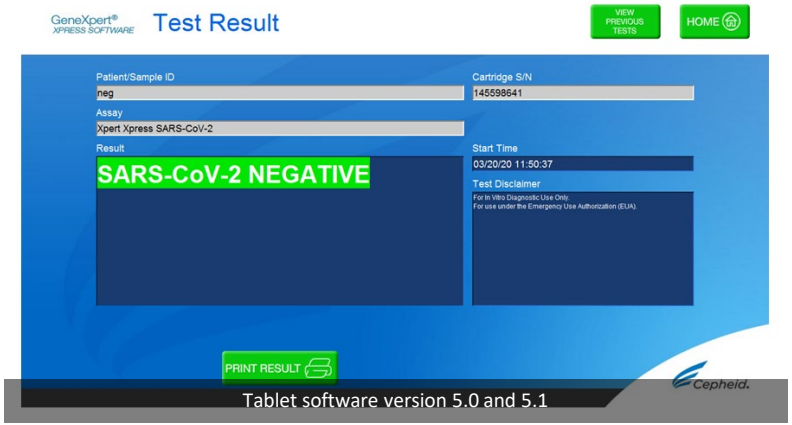
SARS-CoV-2 NEGATIVE

Hub software version 6.1 or higher



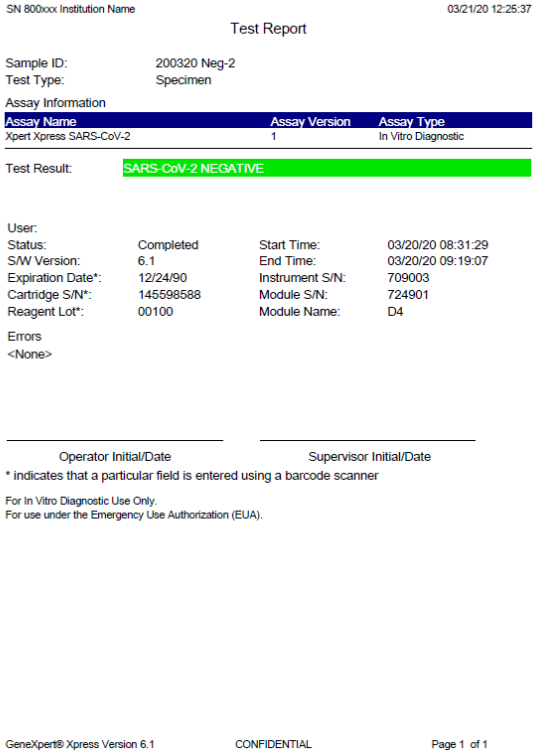
Hub software version 6.1 or higher

Tablet software version 5.0 and 5.1



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

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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.

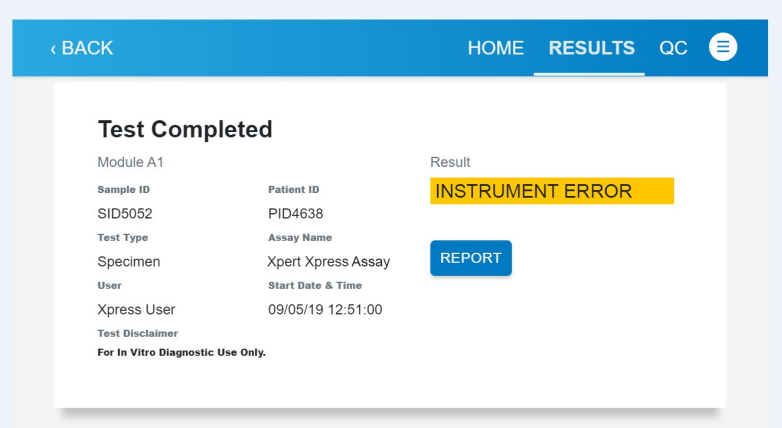
- A **NO RESULT- REPEAT TEST** indicates that insufficient data were collected. For example, Probe Check Control failed or a power failure occurred.

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

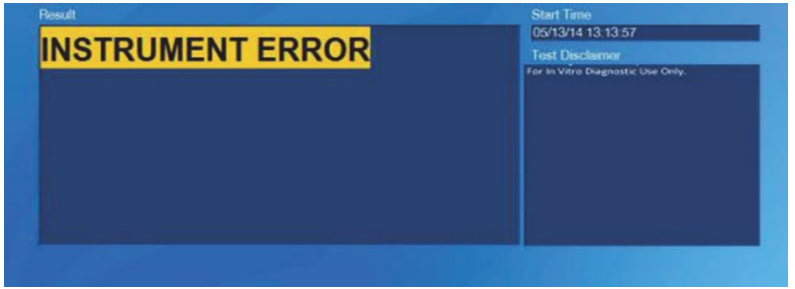
INSTRUMENT ERROR

- 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.

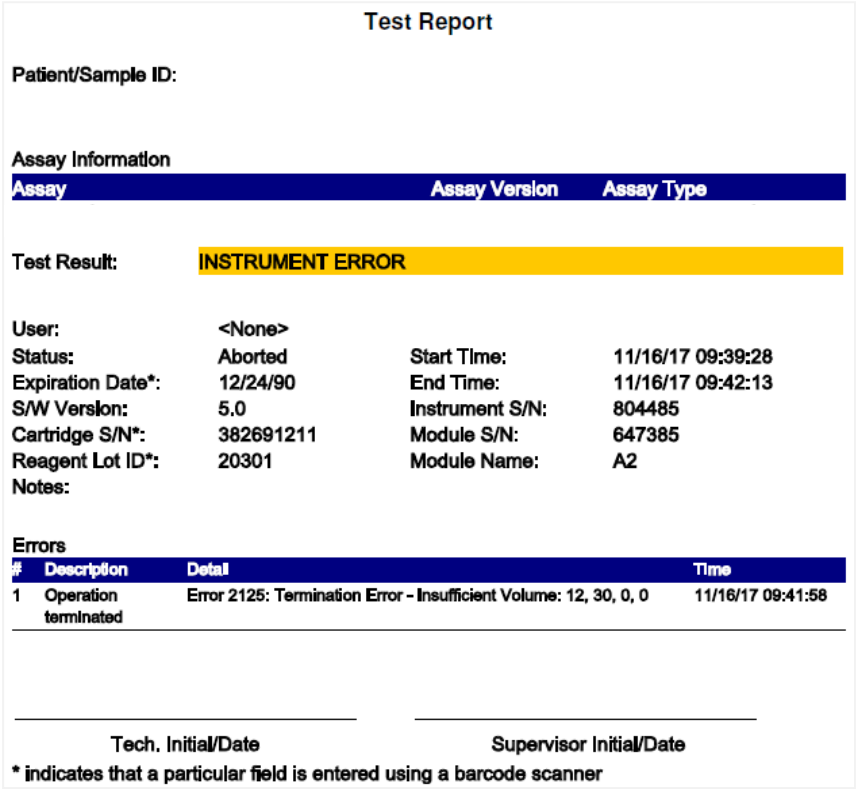
Hub software version 6.1 or higher



Tablet software version 5.0 and 5.1



INSTRUMENT ERROR Test Report



Test Report

Patient/Sample ID:

Assay Information

Assay	Assay Version	Assay Type

Test Result: INSTRUMENT ERROR

User:	<None>		
Status:	Aborted	**Start Time:**	11/16/17 09:39:28
Expiration Date*:	12/24/90	**End Time:**	11/16/17 09:42:13
S/W Version:	5.0	**Instrument S/N:**	804485
Cartridge S/N*:	382691211	**Module S/N:**	647385
Reagent Lot ID*:	20301	**Module Name:**	A2
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**

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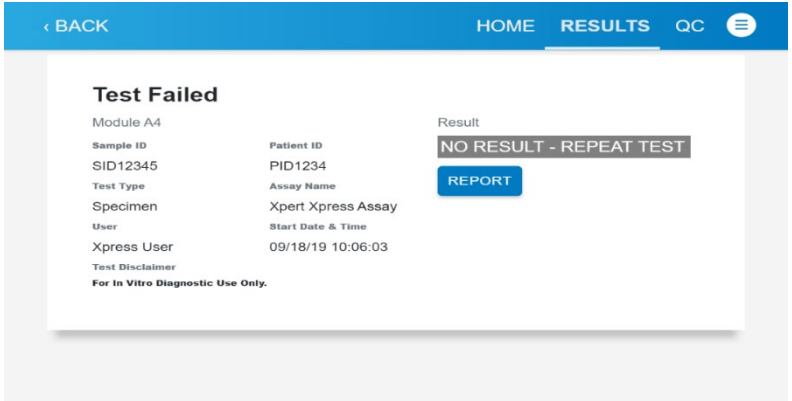
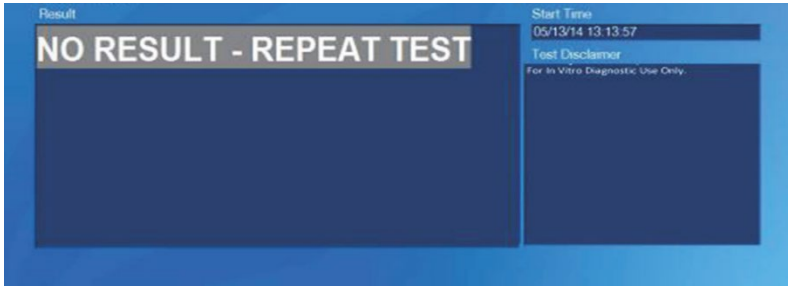
NO RESULT- REPEAT TEST

- 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



Tablet software version 5.0 and 5.1



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**

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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

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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.
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