



Assay Training: Xpert[®] Xpress CoV-2 *plus*

Catalog Number XP3SARS-COV2-10

For Use with GeneXpert[®] Dx or GeneXpert Infinity Systems



 In Vitro Diagnostic Medical Device

302-8260 Rev. B November 2022

Training Agenda

- 1 Reagents
- 2 Sample collection
- 3 Kit storage and handling
- 4 Preparing the cartridge
- 5 Quality controls
- 6 Results analysis
- 7 Discussion



Training Objectives

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

- Properly store and handle the Xpert[®] Xpress CoV-2 *plus* kit
- Follow proper laboratory safety precautions
- Collect and store appropriate specimen(s)
- Prepare a cartridge and run the Xpert Xpress CoV-2 *plus* test
- Report the various software generated results
- Understand the Xpert Xpress CoV-2 *plus* control strategy

The Cepheid Solution



- Detection of SARS-CoV-2 RNA
- On-board internal controls for each sample
- Probe Check Control (PCC)
- Sample Processing Control (SPC)
- Closed cartridge system minimizes risk of contamination
- Results in **30** minutes with EAT of 20 minutes
- On-demand results
- Random access

Intended Use

- The Xpert® Xpress CoV-2 *plus* test is a real-time, RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab, or nasal swab specimen obtained from individuals meeting COVID-19 clinical and/or epidemiological criteria, as well as individuals without symptoms or other reasons to suspect COVID-19 infection. Results are for the identification of SARS-CoV-2 RNA.
- Positive results are indicative of the presence of SARS-CoV-2 RNA; 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.
- 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.

Good Laboratory Practice Review

Personal Protective Equipment (PPE)

- Wear clean lab coats, safety glasses, and gloves
- Change gloves between processing samples

Lab Bench Area

- Clean work surfaces routinely with:
 - ✓ 1:10 dilution of household bleach*
 - ✓ 70% Ethanol Solution
- After cleaning, ensure work surfaces are dry

Specimens, Samples, and Kits Storage

- Store specimens and samples away from the kits to prevent contamination

Equipment

- Use filtered pipette tips when recommended
- Follow the manufacturer's requirements for calibration and maintenance of equipment

* Final active chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Specimen Collection, Storage and Handling

Specimen Collection

Specimen Type	Storage Type
Nasopharyngeal swab	Place specimen into 3 mL of viral transport medium, 3 mL of saline, or 2 mL of eNAT™
Anterior nasal swab	

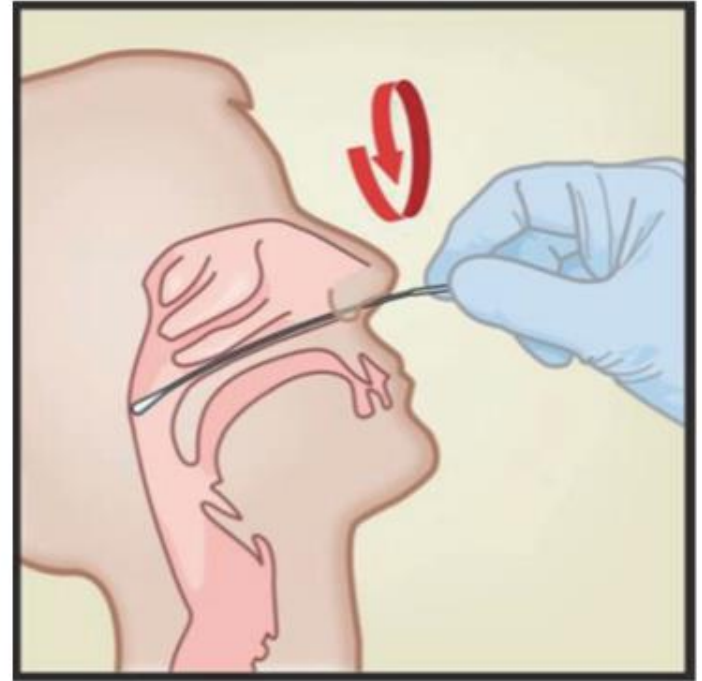


Nasopharyngeal swab

Nasal swab

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 transport tube.
4. Break swab at the indicated break line.
5. Cap the specimen collection tube tightly.




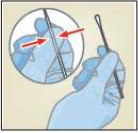
Specimen Collection- Nasopharyngeal Swab


Nasopharyngeal Specimen Collection


- 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.



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301-6052, Rev. H September 2021



Specimen Collection- Nasal Swab

1. Insert the nasal swab 1 to 1.5 cm 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 transport tube.
5. Break swab at the indicated break line.
6. Cap the specimen collection tube tightly.



Specimen Collection- Nasal Swab

Nasal Swab Specimen Collection

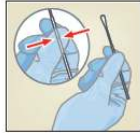
- 1 Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.



- 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.

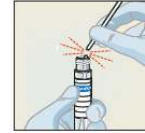
- 5 Repeat Step 4 on the other nostril with the same swab.
To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.



- 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.

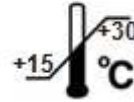


Specimen Transport and Storage

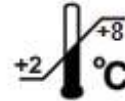
Sample Type

Transport and Storage Conditions

Transport tube containing nasopharyngeal swab or nasal swab in viral transport medium or saline or eNAT™ *



≤ 48 hours



≤ 7 days

*Nasopharyngeal and anterior nasal swab samples collected into saline and eNAT should not be frozen.

Kit Storage and Handling

Xpert® Xpress CoV-2 *plus* Requirements

GeneXpert® Dx and GeneXpert Infinity System

- GeneXpert Dx software version **4.7b** or higher
- For GeneXpert Infinity-80 and Infinity-48s systems: Xpertise software version **6.4b** or higher

Test Kits

- XP3SARS-COV2-10

Materials Required but not Provided

- Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent
- Viral transport medium, 3 mL
- 0.85-0.9% (w/v) saline, 3 mL
- Nasopharyngeal and Nasal (Copan Part Number 50 units : 305C & 346C) or equivalent

Optional

- Uninterruptible Power Supply/ Surge Protector
- Printer

Kit Components

Xpert® Xpress CoV-2 plus

Catalog Number **XP3SARS-COV2-10**

Tests per Kit 10

Transfer Pipettes 10-12

Storage Temperature 2-28°C

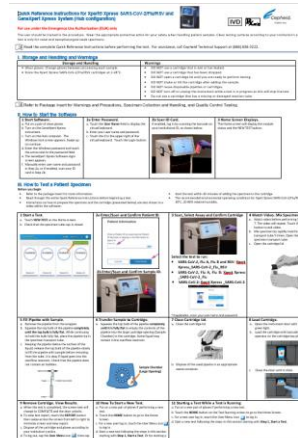
Flyer

Instructions to locate (and import) the ADF documentation such as the Product Insert on www.cepheid.com

The kit also includes two printed copies of the Quick Reference Instructions, which should **only** be used with the GeneXpert® Xpress System.

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

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REF: XP3SARS-COV2-10

Instructions for Use
For Use with GeneXpert® Dx or GeneXpert® Infinity Systems
IVD | CE



For In-Vitro Diagnostic Use Only

9027142 Rev. A, December 2021



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.

Cartridge Preparation

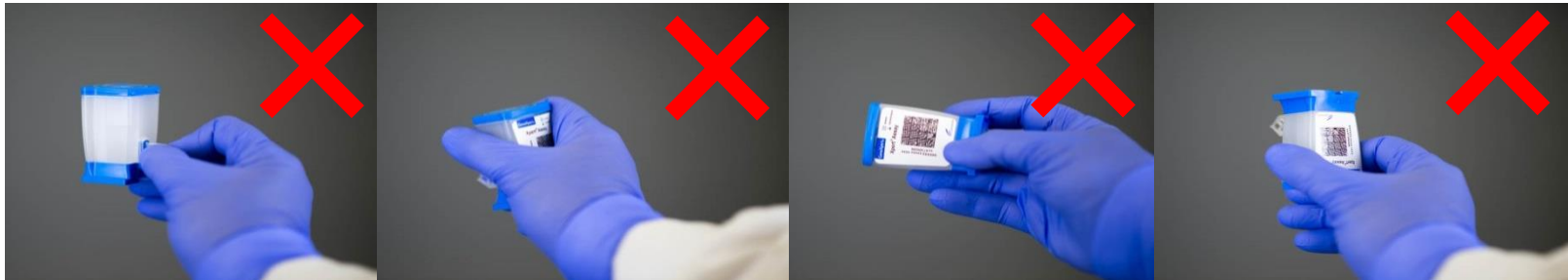
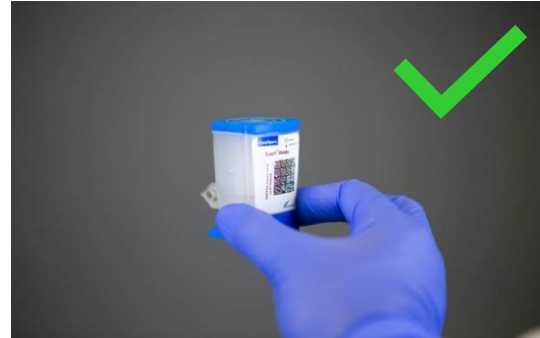


Warning and Precautions

- Do not shake the cartridge.
- Do not use a cartridge...
 - if it appears wet, has leaked, 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 dropped or shaken after you have added the sample.
 - that has a damaged reaction tube.
 - that has been used; each cartridge is single-use to process one test.
 - that has expired.
- Do not reuse pipettes.
- Do not reuse swabs.

Proper Cartridge Handling Techniques

- Do not touch the reaction tube.
- Keep the cartridge upright after seal has been broken.
- Do not tilt when scanning the cartridge.



Xpert® Xpress CoV-2 *plus* Cartridge Preparation

Check if all items below are present:

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

Good Laboratory Practices:

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

Xpert® Cartridge Preparation

- Xpert Xpress SARS-CoV-2
- Xpert Xpress SARS-CoV-2/Flu/RSV
- Xpert Xpress CoV-2/Flu/RSV *plus*
- Xpert Xpress CoV-2 *plus*

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.

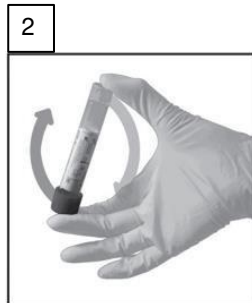


6 Start the test within the timeframe specified in the package insert.

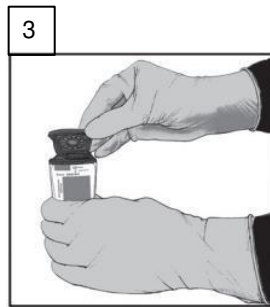
Xpert[®] Xpress CoV-2 *plus* Cartridge Preparation



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.

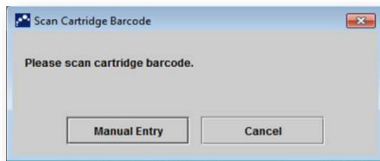
Run a Test on GeneXpert[®] Dx

1 Create a test.



Start the test **within 30 minutes** after adding the sample to the cartridge.

2 Scan barcode for Patient and/or Sample ID.



Do not click on Manual Entry or Cancel.

3 Scan the cartridge.



Run a Test on GeneXpert® Dx (continued)

4 Complete the fields as required.

5 Xpert® Xpress CoV-2 *plus* is selected automatically.

6 The module is selected automatically.

7 Click on Start Test.

8 A green light will flash on the module.
Load the cartridge into module and close the door.

The screenshot shows the 'Create Test' window with the following fields and values:

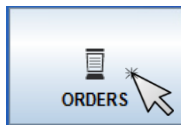
- Patient ID: [Empty]
- Sample ID: [Empty]
- Patient ID 2: [Empty]
- Last Name: [Empty]
- Name: [Empty]
- Select Assay: Xpert Xpress CoV-2 *plus*
- Select Module: A3
- Reagent Lot ID*: 16119
- Expiration Date*: 2016/1/17
- Test Type: Specimen
- Sample Type: Other
- Notes: [Empty]

The 'Start Test' button is highlighted with an orange box, and a mouse cursor is pointing at it.



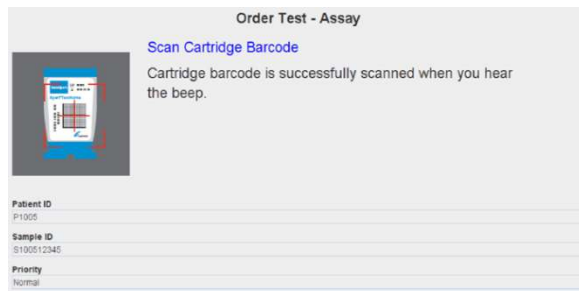
Run a Test on GeneXpert® Infinity

1 Create a test.



Place the cartridge on the conveyor **within 30 minutes** of adding the sample.

2 Scan barcode for Patient and/or Sample ID.



3 Scan the cartridge.

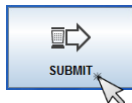


Run a Test on GeneXpert® Infinity (continued)

4 Complete the fields as required. →

5 Xpert® Xpress CoV-2 *plus* is selected automatically. →

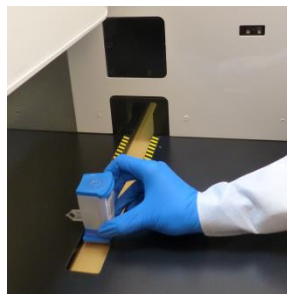
6 Click SUBMIT.



7 Place the cartridge onto the conveyor belt.

Order Test - Test Information

Patient ID patientid	
Sample ID sampleid	
Last Name patient	First Name id
Accuracy Xpert Xpress CoV-2 plus	
Reagent Lot ID 12102	Cartridge S/N* 282769448
Expiration Date* 2018/11/04	Priority Normal
Test Type Specimen	Other Sample Type
Sample Type Other	
Notes	



Automated Xpert® Xpress CoV-2 *plus*



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 Controls

Xpert® Xpress CoV-2 *plus* Quality Controls

- Each Xpert cartridge is a self-contained test device.
- Cepheid designed specific molecular methods to include internal controls that enable the system to detect specific failure modes within each cartridge.
 - Probe Check Controls (PCC)
 - Sample Processing Control (SPC)

Refer to 301-4868 GeneXpert Quality Control features for all Cepheid assays.

Internal Quality Controls

- **Probe Check Controls (PCC)**

- Before the PCR step, fluorescence signal is measured on all probes and compared with default factory settings to monitor:
 - Reagent rehydration
 - PCR tube filling
 - Probe integrity
 - Dye stability

- **Sample Processing Controls (SPC)**

- SPC ensures that the sample was processed correctly and verifies that sample processing was adequate.
 - Verifies adequate extraction and amplification of the sample
 - Detects PCR inhibition
 - Ensures appropriate PCR conditions for amplification
 - Verifies that PCR reagents are functional
 - Must be positive in a negative sample to be a valid test
 - Can be positive or negative in a positive sample

Commercially Available External Controls

ZeptoMetrix®	Description	Configuration	Storage
NATSARS(COV2)- ERC	Positive Control	6 x 0.5 mL	2-8°C or -20°C
NATSARS(COV2)- NEG	Negative Control	6 x 0.5 mL	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 (300 µL) 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.

Result Interpretation

Assay Targets

- SARS-CoV-2 RNA
- E, N2 and RDRP
- SPC

Early Assay Termination

- The Xpert[®] Xpress CoV-2 *plus* test includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the target nucleic acid reaches a predetermined threshold before the full 45 PCR cycles have been completed.
- When SARS CoV-2 titers are high enough to initiate the EAT function, the SPC and/or additional target amplification curves may not be seen, and their results may not be reported.

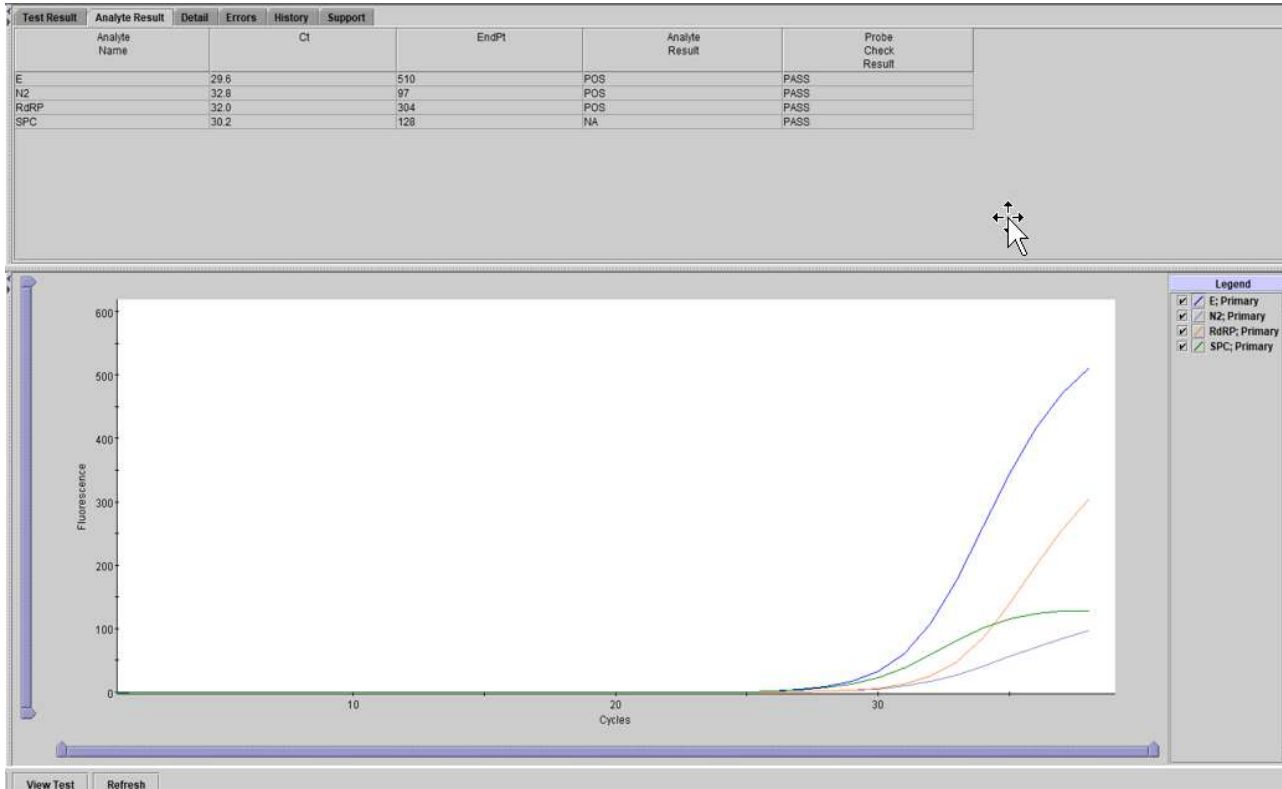
Results Summary SARS-CoV-2 ADF

Result Displayed	SARS- CoV-2	SPC
SARS-CoV-2 POSITIVE	+	+/-
SARS-CoV-2 NEGATIVE	-	+
INVALID	-	-
ERROR	NO RESULT	NO RESULT
No Result	NO RESULT	NO RESULT

SARS-CoV-2 POSITIVE

Test Result

SARS-CoV-2 POSITIVE



- SARS-CoV-2 target RNA is detected
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 POSITIVE Test Report

Test Report

Patient ID:
Sample ID: POS
Test Type: Specimen
Sample Type:

Assay Information

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

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

Analyte Result

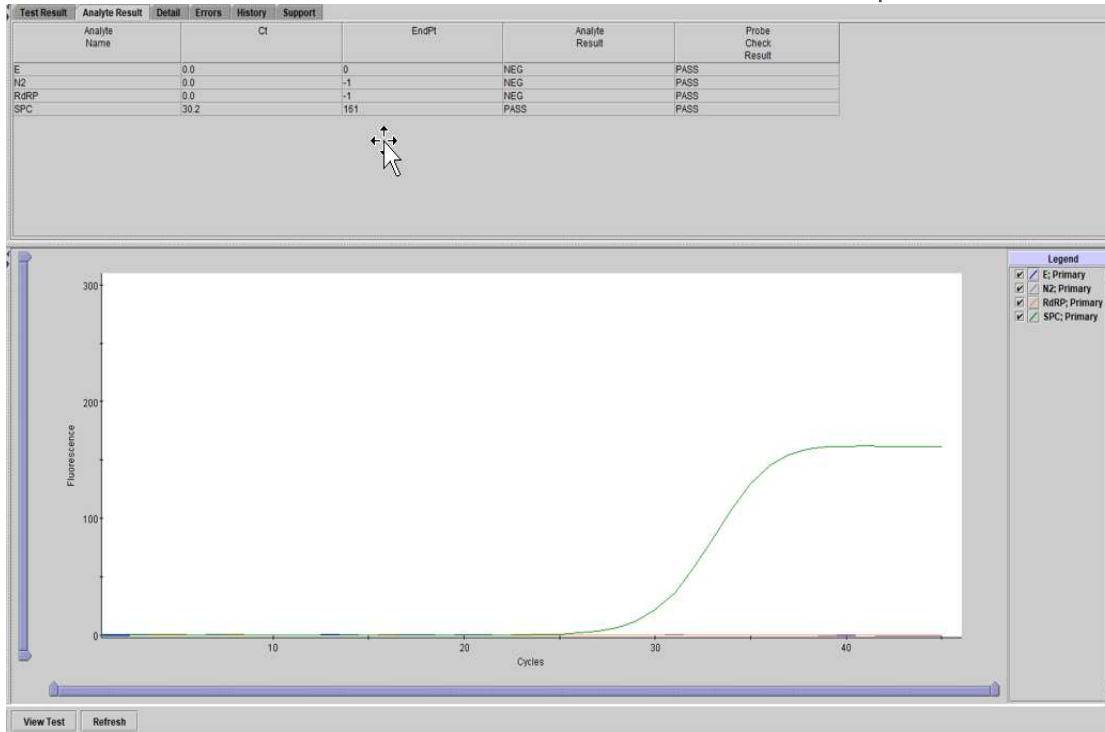
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	29.6	510	POS	PASS
N2	32.8	97	POS	PASS
RdRP	32.0	304	POS	PASS
SPC	30.2	128	NA	PASS

User: Jane Doe
Status: Done
Expiration Date*: 12/25/22
S/W Version: 5.1
Cartridge S/N*: 418295643
Reagent Lot ID*: 00100
Notes:
Error Status: OK

Start Time: 12/02/21 14:41:49
End Time: 12/02/21 15:08:22
Instrument S/N: 742612
Module S/N: 619392
Module Name: B2

SARS-CoV-2 NEGATIVE

Test Result SARS-CoV-2 NEGATIVE



- SARS-CoV-2 not detected
- N2, E and RdRP do not have a Ct within the valid range and endpoint above the minimum setting
- SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 NEGATIVE Test Report

Test Report

Patient ID:
Sample ID: NEG
Test Type: Specimen
Sample Type:

Assay Information

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

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	0.0	0	NEG	PASS
N2	0.0	-1	NEG	PASS
RdRP	0.0	-1	NEG	PASS
SPC	30.2	161	PASS	PASS

User: Jane Doe
Status: Done
Expiration Date*: 12/25/22
S/W Version: 5.1
Cartridge S/N*: 418295645
Reagent Lot ID*: 00100
Notes:
Error Status: OK

Start Time: 12/02/21 15:49:26
End Time: 12/02/21 16:19:32
Instrument S/N: 742611
Module S/N: 723610
Module Name: A1

Limitations

- Performance characteristics of this test have been established with the specimen types listed in the Intended Use Section only. The performance of this assay with other specimen types or samples has not been assessed and performance characteristics are unknown.
- Erroneous test results might occur from improper specimen collection; failure to follow the recommended sample collection, handling, and storage procedures; technical error; or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.
- False negative results may occur if virus is present at levels below the analytical limit of detection.
- As with any molecular test, mutations within the target regions of Xpert® Xpress CoV-2 *plus* could affect primer and/or probe binding and result in failure to detect the presence of virus or the virus being detected less predictably.

Limitations

- Results from the Xpert® Xpress CoV-2 *plus* test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient. This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.
- Viral nucleic acid may persist in vivo, independent of virus infectivity. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
- Performance has not been established with media containing guanidine thiocyanate (GTC) other than eNAT™.

Troubleshooting

Factors That Negatively Affect Results

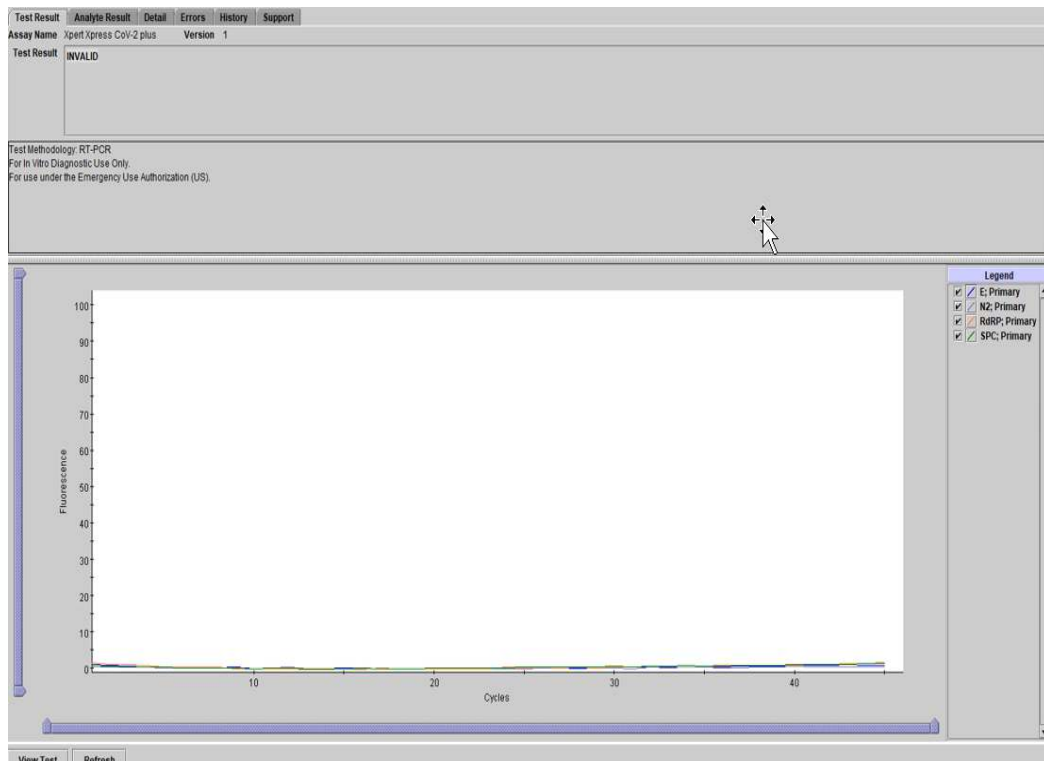
- Improper specimen collection.
 - The performance of this assay with other specimen types or samples has not been evaluated.
- Inadequate numbers of organisms are present in the specimen.
- Improper transport or storage of collected specimen.
 - Storage and transport conditions are specimen specific.
 - Refer to the Instructions For Use for the appropriate handling instructions.
- Improper testing procedure.
 - Modification to the testing procedures may alter the performance of the test.
 - Careful compliance with the Instructions For Use is necessary to avoid erroneous results.

Reasons to Repeat the Test

- An **INVALID** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- An **ERROR** result could be due to, but not limited to, Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.
- A **NO RESULT** indicates that insufficient data were collected. For example, cartridge failed integrity test, the operator stopped a test that was in progress, or a power failure occurred.

INVALID Result

Test Result **INVALID**



- SPC does not meet acceptance criteria. Presence or absence of the target RNA cannot be determined.

- SPC: FAIL;

- SARS-CoV-2 signals do not have a Ct within valid range and endpoint below minimum setting

- Probe Check – PASS; all probe check results pass

Possible Causes

- Improper sample collection or preparation
- Presence of interfering substances in the sample

Solution

- Repeat the test with a new cartridge

ERROR Result



Test Result	Analyte Result	Detail	Errors	History	Support
	Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E		0.0	0	NO RESULT	NA
N2		0.0	0	NO RESULT	NA
RdRP		0.0	0	NO RESULT	NA
SPC		0.0	0	NO RESULT	NA

<No Data Available>

View Test Refresh

- Presence or absence of the target RNAs cannot be determined.
- SARS-CoV-2: NO RESULT
- SPC: NO RESULT
- Probe Check: FAIL; all or one of the probe check results fail
- If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.
- Solution
 - Repeat the test with a new cartridge.

NO RESULT

Test Result **NO RESULT**

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	0.0	0	NO RESULT	NA
NZ	0.0	0	NO RESULT	NA
RdRP	0.0	0	NO RESULT	NA
SFC	0.0	0	NO RESULT	NA

<No Data Available>

- Presence or absence of the target RNAs cannot be determined.
- A **NO RESULT** indicates that insufficient data was collected. For example, the operator stopped a test that was in progress.

Possible Causes

- Test was stopped with stop test button
- Electrical failure

Solution

- Secure the power
- Repeat the test with a new cartridge.

Retest Procedure

1

Discard used cartridge. Follow your institution's safety guidelines for disposal of cartridges.

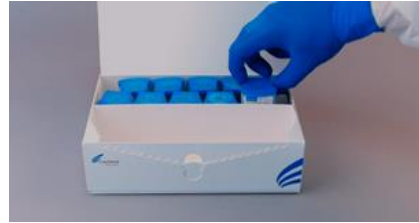
2



Obtain the residual specimen. Prepare according to Instructions For Use.

If the leftover specimen volume is insufficient, or the retest returns an INVALID, ERROR, or NO RESULT, collect a new specimen.

3



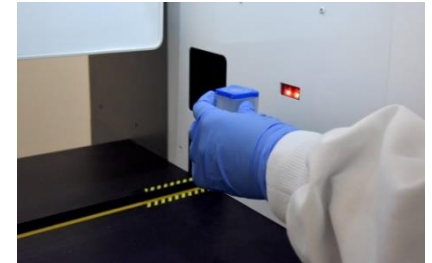
Obtain a new cartridge.

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 case online using the following link
<http://www.cepheid.com/en/support>: *Create a Support Case*



Thank You

www.cepheid.com