



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

For use with GeneXpert[®] Systems with Touchscreen



CE IVD In Vitro Diagnostic Medical Device

302-8255 Rev. B, Nov 2022

Training Agenda

Xpert® Xpress SARS-CoV-2

- 1 Reagents
- 2 Kit Storage and Handling
- 3 Specimen Collection, 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** 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



The Cepheid Solution



Detection of SARS-CoV-2

- On-board internal controls for each sample
 - Probe Check Control (PCC)
 - Sample 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 real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimen collected from individuals who are suspected of 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.
- The Xpert® Xpress SARS-CoV-2 test is intended to be performed by trained users in both laboratory and near patient testing settings.

Good Laboratory Practice Review

Personnel 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



- Store specimens and sample away from kit to prevent contamination

Specimens, Samples, and Kits Storage

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

Equipment

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

Kit Storage and Handling

Xpert[®] Xpress SARS-CoV-2 Requirements

GeneXpert[®] Systems

- For GeneXpert[®] System with Touchscreen:
Cepheid OS 1.0



Test Kits

- XPRSARS-COV2-10

Materials Required by Not Provided

- Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent
- Viral transport medium, 3 mL (Copan P/N 330C) or equivalent
- 0.9% (w/v) saline, 3 mL
- Sample Collection Kit for Viruses (Copan P/N 305C, Copan P/N 346C) or equivalent
- Personal Protective Equipment (PPE)
- 1:10 Bleach
- 70% ethanol or denatured ethanol

Optional

- Uninterruptible Power Supply/Surge Protector
- Printer

Xpert® Xpress SARS-CoV-2 Kit Components

Catalog Number	XPRSARS-COV2-10
Tests per Kit	10
Kit CD	Assay Definition File (ADF) Assay Import Instructions Flyer: Instructions to access on-line reference materials including the Product Insert
Disposal Transfer Pipettes	10 to 12
Storage	2–28°C







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

Xpert[®] Xpress SARS-CoV-2

Kit Storage and Handling

- Store Xpert[®] Xpress SARS-CoV-2 cartridges and reagents at **2–28°C**.
- Follow your institution's safety procedures for working with chemicals and handling biological samples
- Do not use collection devices that have not been validated by Cepheid
- Open the cartridge lid only when adding the sample, close the lid, and proceed with processing
 - Start the test within **30 minutes** of adding the sample to the cartridge.

Warnings 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
 - appears damaged
 - has been dropped after removing it from packaging
 - has been dropped or shaken after you have added the sample
 - has a damaged reaction tube
 - has been used; each cartridge is single-use to process one test
 - has expired
-  Do not reuse pipettes
-  Dispose of cartridges and reagents according to your institution's and country's guidelines for disposal of hazardous materials

Warnings and Precautions

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, the biological specimens and used cartridges should be disposed of per WHO (World Health Organization) medical waste handling and disposal guidelines.



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 evaluated.
- A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.
- As with any molecular test, mutations within the target regions of Xpert[®] Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

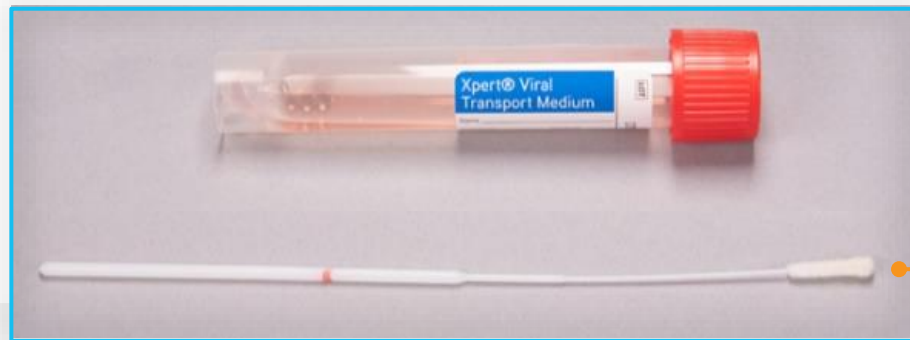
For detailed information, refer to the current Instructions For Use.

Specimen Collection, Storage and Handling

Specimen Collection

Specimen Type: Nasopharyngeal swab nasal swab, and/or nasal wash/aspirate specimens

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



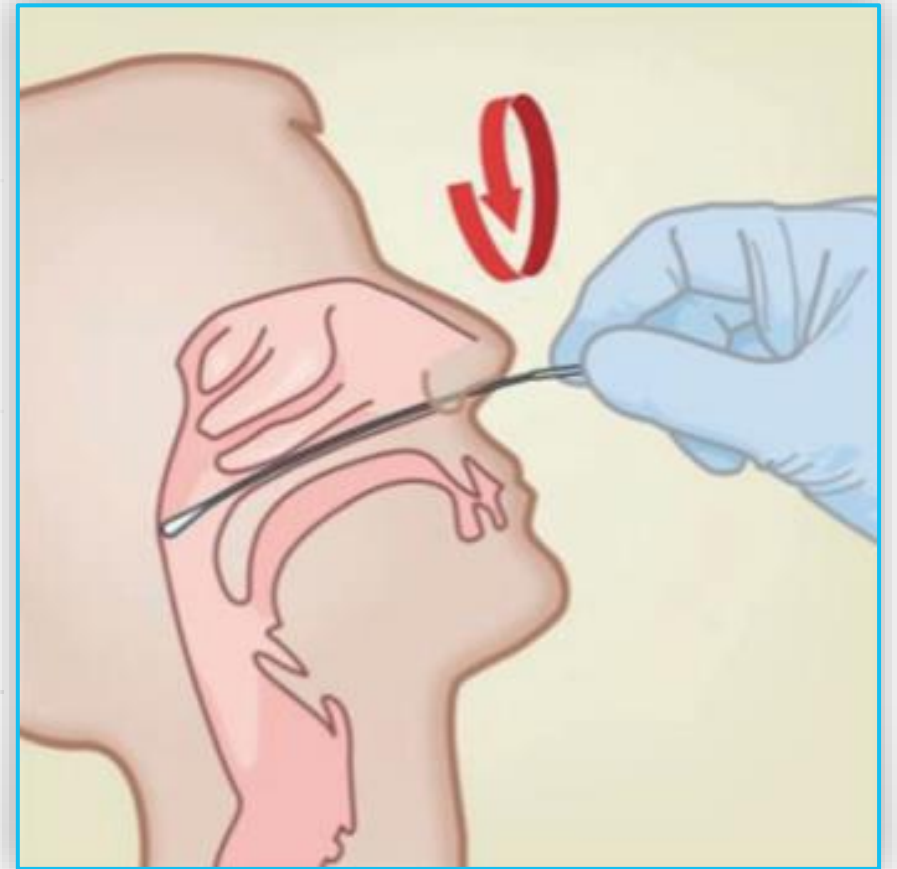
Nasopharyngeal swab

➔ Refer to the WHO Laboratory Biosafety Guidance Related to the Coronavirus Disease 2019 (COVID-19):

[https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-\(covid-19\)](https://www.who.int/publications-detail/laboratory-biosafety-guidance-related-to-coronavirus-disease-2019-(covid-19))

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 3mL of viral transport medium or 3mL of saline.
- 4 Break swab at the indicated break line and cap the specimen collection tube tightly.

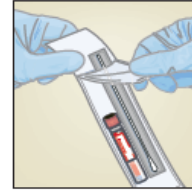


Specimen Collection: Nasopharyngeal Swab

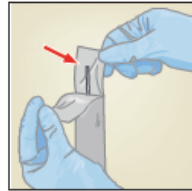
Nasopharyngeal Specimen Collection

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

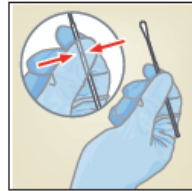
1 Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.



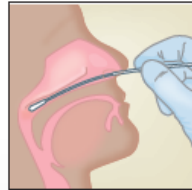
2 Open the swab wrapper and remove the swab, taking care not to touch the tip of the swab to any surface.



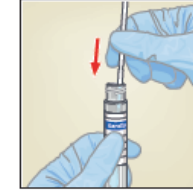
3 Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.



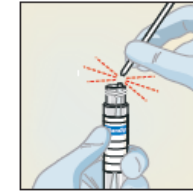
4 Gently insert the swab into the nostril until you touch the posterior nasopharynx. Rotate swab several times.



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 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 3mL of viral transport medium or 3mL of saline.

5 Break swab at the indicated break line and cap the specimen collection tube tightly.

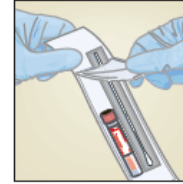


Specimen Collection: Nasal Swab

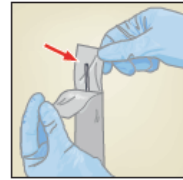
Nasal Swab Specimen Collection

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

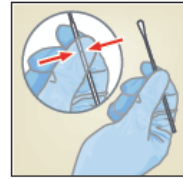
1 Open the package that contains the swab and transport medium tube. Set the tube aside before collecting the specimen.



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.

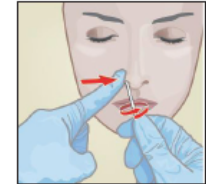


4 Rotate swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.

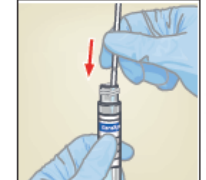


Do not insert the swabs more than 1-1.5 cm.

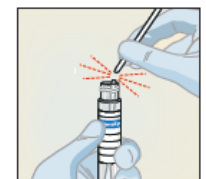
5 Repeat Step 4 on the other nostril with the same swab. To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.



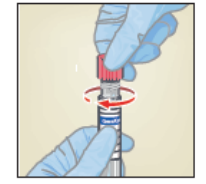
6 Remove the cap from the tube. Insert the swab into the transport medium.



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

© 2020 Cepheid In Vitro Diagnostic Use **IVD**

In Vitro Diagnostic Use **CE IVD**

301-9057, Rev. B April 2020

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Specimen Collection: Nasal Wash/Aspirate

Nasal wash/aspirate specimens can be collected following the user institution standard procedure. Also, refer to the WHO guidelines for the collection of human nasal wash/aspirate specimens.

1. Using a transfer pipette, transfer 600 μ L of the undiluted nasal wash/aspirate specimen into the tube containing 3mL of viral transport medium or 3mL of saline.
2. Cap the tube.

 https://www.who.int/influenza/human_animal_interface/virology_laboratories_and_vaccines/guidelines_collection_h5n1_humans/en/

Specimen Transport and Storage

Sample Type

Transport and Storage Conditions

Viral Transport Medium or saline containing:

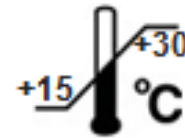
Nasopharyngeal swab

OR

Nasal swab

OR

Nasal wash/aspirate specimens



Up to 8 hours



Up to 7 days

Cartridge Preparation

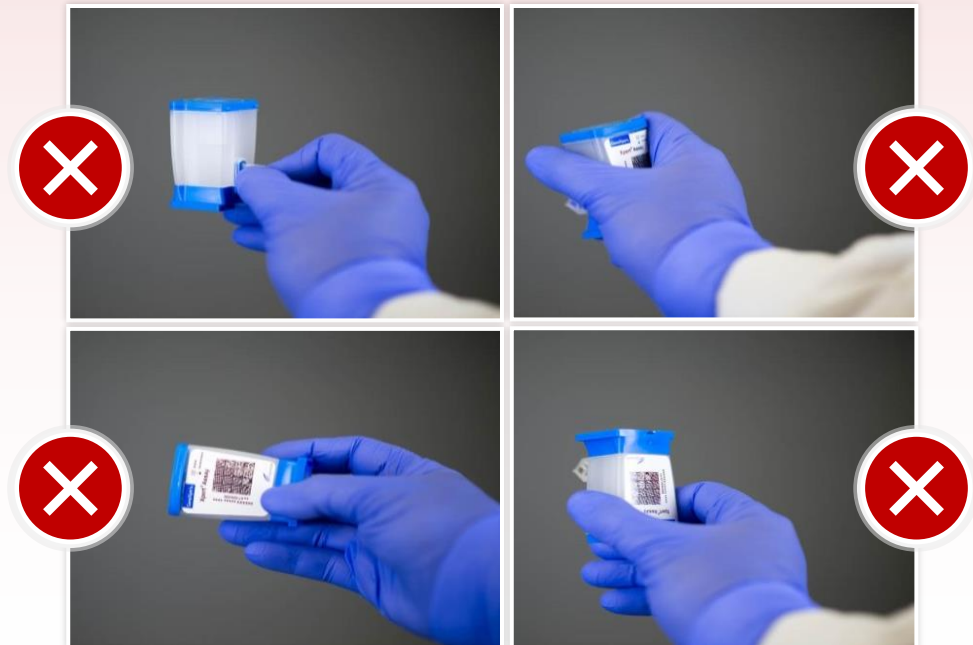
Proper Cartridge Handling Techniques

Correct



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

Incorrect



Xpert® Xpress SARS-CoV-2 Cartridge Preparation

Xpert® Cartridge Preparation

- Xpert Xpress SARS-CoV-2
- Xpert Xpress SARS-CoV-2/Flu/RSV
- Xpert Xpress CoV-2/Flu/RSV 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.

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In Vitro Diagnostic Use.

In vitro medical diagnostic device. May not be available in all countries.

302-3816, Rev. B September 2021

Sample Qualification—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 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

1



Take one Xpert® cartridge for each sample.

2



Rapidly invert the tube 5 times.

3



Open the cartridge lid.

4



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

5



Close the cartridge lid.

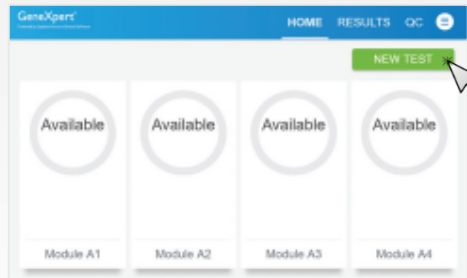
6



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

Run a Test

Start the Test Within 30 Minutes



1 New Test



2 Scan barcode: Patient ID
(if applicable)
Then **CONFIRM**



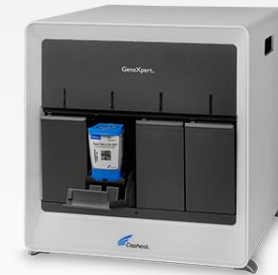
3 Scan barcode: Sample ID
(if applicable)
Then **CONFIRM**



4 Scan the cartridge
Then **CONFIRM**



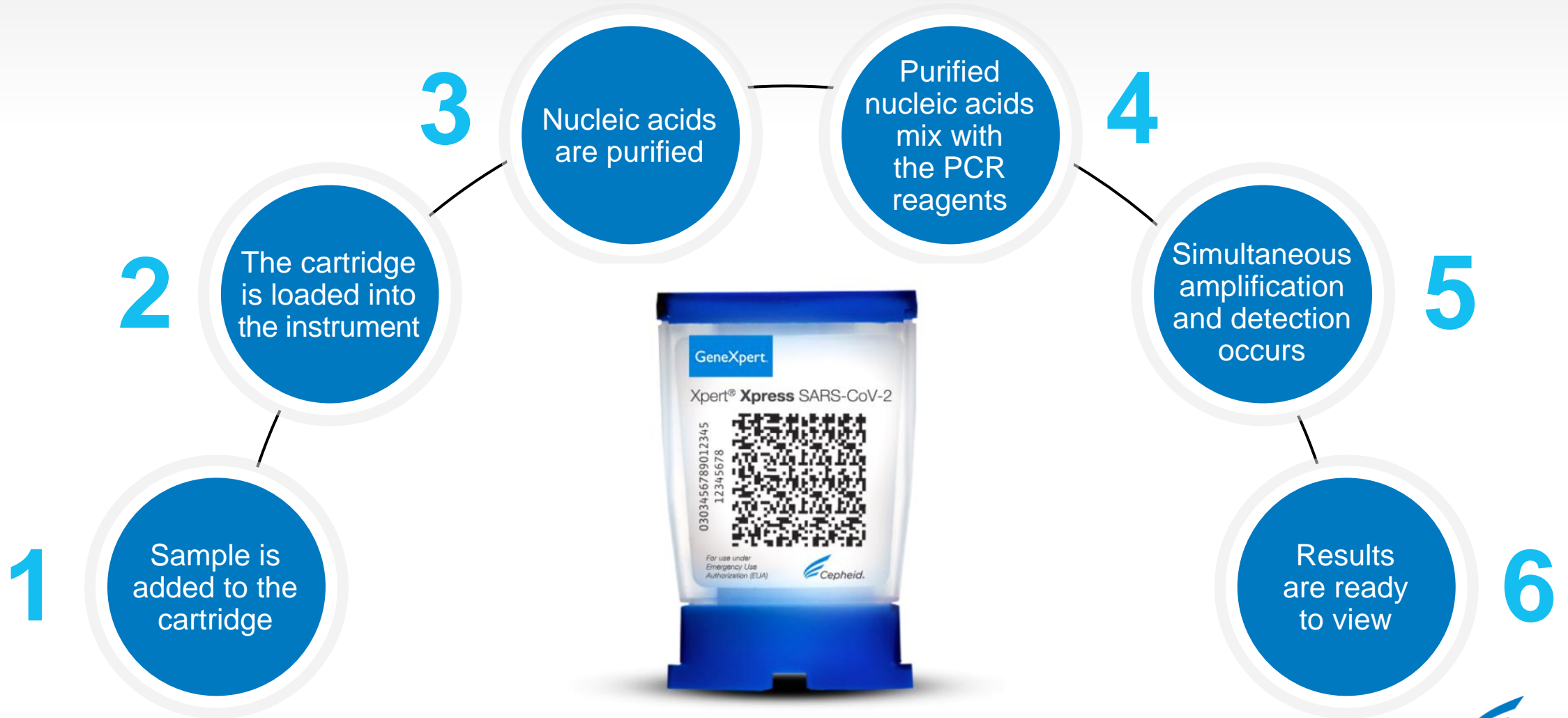
5 Prepare the cartridge (video)
Start the test within **30 minutes** after
adding the sample to the cartridge



6 Load the cartridge into module
7 Close the module door

For complete details on how to run a test, refer to the Instructions For Use and the GeneXpert® System with Touchscreen Operator Manual.

Automated Xpert[®] Xpress SARS-CoV-2 Protocol



Quality Controls

Refer to the Instructions For Use for complete details

Assay Control Strategy

CONTROL

Xpert® Xpress SARS-CoV-2 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*
 1. Sample Processing Control (SPC)
 2. Probe Check Controls (PCC)



*Refer to 301-4868 GeneXpert® Quality Control Features for All Cepheid Xpert® 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
 - Probe integrity
 - PCR tube filling
 - Dye stability
-

Sample Processing Controls (SPC)

- Non-infectious spore in each cartridge
 - Verifies adequate sample processing
 - Verifies lysis and detects PCR inhibition
 - Should be positive in a negative sample
 - Can be positive or negative in a positive sample

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 (300µl) of the external control sample into the large opening (Sample Chamber) in the cartridge.

4

Close the 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

Refer to the Instructions For Use for complete details

Early Assay Termination

- The **Xpress SARS-CoV-2 test** includes an Early Assay Termination (EAT) function that will provide earlier time to result 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.

Results Summary

Result Displayed	N2	E	SPC
SARS-CoV-2 POSITIVE	+	+	+/-
SARS-CoV-2 PRESUMPTIVE POS	-	+	+/-
SARS-CoV-2 NEGATIVE	-	-	+
INVALID	-	-	-
ERROR	NO RESULT	NO RESULT	NO RESULT
NO RESULT	NO RESULT	NO RESULT	NO RESULT

SARS-CoV-2 POSITIVE

Result

SARS-CoV-2 POSITIF

◀ BACK HOME RESULTS QC ADMIN

Test Completed

Module B2

Result: SARS-CoV-2 POSITIF

Sample ID: BCC38BFA5CE90094CD584D847

Patient ID:

Test Type: Specimen

Assay Name: Xpert Xpress SARS-CoV-2

User: cepheid

Start Date & Time: 06/05/20 16:04:46

Test Disclaimer: For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US).

REPORT

Test Report

Patient ID:

Sample ID: BCC38BFA5CE90094CD584D847

Test Type: Specimen

Assay Information

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

Test Result: SARS-CoV-2 POSITIF

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	40.9	47	POS	PASS
N2	38.8	174	POS	PASS
SPC	27.8	342	NA	PASS

The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are detected.

- The SARS-CoV-2 signal for the N2 nucleic acid target or signals for both nucleic acid targets (N2 and E) have a Ct within the valid range and endpoint above the minimum setting
- SPC: NA; SPC is ignored because coronavirus target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 PRESUMPTIVE POS

Result

SARS-CoV-2 PRESUMPTIVE POS

◀ BACK HOME RESULTS QC ADMIN

Test Completed

Module L2

Result: SARS-CoV-2 PRESUMPTIVE POS

Sample ID: 1010603573A

Patient ID:

Test Type: Specimen

Assay Name: Xpert Xpress SARS-CoV-2

User: Nwe Tun

Start Date & Time: 04/15/20 23:32:21

Test Disclaimer: For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (EUA).

REPORT

Test Report

Patient ID:

Sample ID*: 1010603573A

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
E	39.2	144	POS	PASS
N2	0.0	-6	NEG	PASS
SPC	28.0	451	NA	PASS

The 2019 novel coronavirus (SARS-CoV-2) nucleic acids may be present.

- Sample should be retested. For samples with a repeated Presumptive Positive result, additional confirmatory testing may be conducted, if it is necessary to differentiate between SARS-CoV-2 and SARS-CoV-1 or other Sarbecovirus currently unknown to infect humans, for epidemiological purposes or clinical management.
- The SARS-CoV-2 signal for only the E nucleic acid target has a Ct within the valid range and endpoint above the minimum setting
- SPC: NA; SPC is ignored because a target amplification has occurred.
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 NEGATIVE

Result

SARS-CoV-2 NEGATIVE

◀ BACK HOME RESULTS QC ADMIN

Test Completed

Module D4

Result
SARS-CoV-2 NEGATIVE

REPORT

Sample ID	Flu A-Flu B
Patient ID	
Test Type	Specimen
Assay Name	Xpert Xpress_SARS-CoV-2
User	JoAnn Kop
Start Date & Time	11/18/20 09:03:26
Test Disclaimer	For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US).

Test Report

Patient ID:
Sample ID: Flu A-Flu B
Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
Xpert Xpress_SARS-CoV-2	4	In Vitro Diagnostic

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2 0.0		2	NEG	PASS
SPC	28.3	184	PASS	PASS

The 2019 novel coronavirus (SARS-CoV-2) target nucleic acids are not detected.

- The SARS-CoV-2 signals for two nucleic acid targets (N2 and E) 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

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

NO RESULT - REPEAT TEST

← BACK HOME RESULTS QC ADMIN

Test Completed

REPORT

Module D4

Result
NO RESULT - REPEAT TEST

Sample ID: Test 01

Patient ID:

Test Type: Specimen

Assay Name: Xpert Xpress_SARS-CoV-2_Flu_RSV

User: Jun Zhang

Start Date & Time: 11/19/20 17:46:01

Test Disclaimer: For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US).

Test Report

Patient ID:

Sample ID: Test 01

Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
Xpert Xpress_SARS-CoV-2_Flu_RSV	4	In Vitro Diagnostic

Test Result: NO RESULT - REPEAT TEST

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	1	INVALID	PASS
Flu A 1	0.0	0	INVALID	PASS
Flu A 2	0.0	2	INVALID	PASS
Flu B	0.0	-4	INVALID	PASS
RSV	0.0	-2	INVALID	PASS
SPC	0.0	1	FAIL	PASS

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

- SPC: FAIL;
- SARS-CoV-2, Flu A , Flu B, RSV 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

NO RESULT - REPEAT TEST

← BACK HOME RESULTS QC ADMIN

Test Failed

UPLOAD REPORT

Module A1 Result Uploaded: No

NO RESULT - REPEAT TEST

Sample ID 220155923501

Patient ID

Test Type Specimen

Assay Name Xpress SARS-CoV-2_Flu_RSV plus

User Admin1

Start Date & Time 01/25/22 08:30:40

Test Disclaimer For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US). Test Methodology: RT-PCR

Presence or absence of the target RNAs cannot be determined.

- SARS-CoV-2: NO RESULT
- Flu A: NO RESULT
- Flu B: NO RESULT
- RSV: 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.

Test Report

Patient ID:

Sample ID*: 220155923501

Test Type: Specimen

Assay Information

Assay Name	Assay Version	Assay Type
Xpress SARS-CoV-2_Flu_RSV plus		In Vitro Diagnostic

Test Result: **NO RESULT-REPEAT TEST**

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	0	NO RESULT	PASS
Flu A 1	0.0	0	NO RESULT	PASS
FluA2	0.0	0	NO RESULT	PASS
Flu B	0.0	0	NO RESULT	FAIL
RSV	0.0	0	NO RESULT	PASS
SPC	0.0	0	NO RESULT	PASS

Solution

- Repeat the test with a new cartridge

INSTRUMENT ERROR

Test Failed

Module A2

Result: INSTRUMENT ERROR

Uploaded: No

Sample ID: L21120601953

Patient ID:

Test Type: Specimen

Assay Name: Xpress SARS-CoV-2_Flu_RSV plus

User:

Start Date & Time: 12/06/21 11:43:16

Test Disclaimer: For In Vitro Diagnostic Use Only. For use under the Emergency Use Authorization (US). Test Methodology: RT-PCR

Presence or absence of the target RNAs cannot be determined.

- An INSTRUMENT ERROR indicates that insufficient data was collected. For example, the operator stopped a test that was in progress.

Test Report

Patient ID:

Sample ID*: 21120601953

Test Type: Specimen

Assay Information

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

Test Result: INSTRUMENT ERROR

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	0	NO RESULT	NA
Flu A 1	0.0	0	NO RESULT	NA
Flu A 2	0.0	0	NO RESULT	NA
Flu B	0.0	0	NO RESULT	NA
RSV	0.0	0	NO RESULT	NA
SPC	0.0	0	NO RESULT	NA

Possible causes

An INSTRUMENT ERROR indicates that insufficient data was collected

- Test was stopped with stop test button; Electrical failure

Solution

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

Reasons to Repeat the Test

- A **“SARS-CoV-2 PRESUMPTIVE POS”** 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.
- A **“NO RESULT - REPEAT TEST”** result indicates that the control SPC failed. The sample was not properly processed, PCR is inhibited, or the sample was not properly collected.
- A **“NO RESULT - REPEAT TEST”** 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.
- An **“INSTRUMENT ERROR”** 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.
- If only one viral target is positive but coinfection with multiple targets is suspected, the sample should be re-tested with another FDA cleared, approved, or authorized test, if coinfection would change clinical management.

Technical Assistance

Before contacting Cepheid Technical Support, collect the following GeneXpert® information:

Product name	X
Lot number	X
Serial number of the System	X
Software version and, if applicable, Computer Service Tag number	X
Error messages (if any)	X

Log your case online using the following link:

<http://www.cepheid.com/us/support>

→ Create a Support Case



Thank You

www.cepheid.com

