Assay Training: Xpert® Xpress CoV-2/Flu/RSV *plus*

For use with GeneXpert® Dx or GeneXpert Infinity Systems
Catalog Number (XP3COV2/FLU/RSV-10)
For CE-IVD Only

IVD In Vitro Diagnostic Medical Device

303-3297 Rev. A June 2024

Training Agenda

Xpert® Xpress CoV-2/Flu/RSV plus

1. Intended Use
2. Kit Contents, Storage and Handling
3. Specimen Collection, Storage and Transport
4. Cartridge Preparation
5. Quality Controls
6. Results Interpretation
7. Troubleshooting

Intended Use

- The Xpert® Xpress CoV-2/Flu/RSV *plus* test, performed on the GeneXpert® Instrument Systems, is a multiplexed real-time RT-PCR test intended for use in the simultaneous, *in vitro* qualitative detection and differentiation of RNA from SARS-CoV-2, influenza A, influenza B, and/or respiratory syncytial virus (RSV) in either nasopharyngeal swab or anterior nasal swab specimens collected from individuals with signs and/or symptoms of respiratory viral infection.
- SARS-CoV-2, influenza, A, influenza B and RSV RNA identified by this test are generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of the identified virus, but do not rule out bacterial infection or co-infection with other pathogens not detected by the test.
- Clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. The agent detected may not be the definite cause of disease.
- Negative results do not preclude SARS-CoV-2, influenza A virus, influenza B virus and/or RSV 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/or epidemiological information.

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

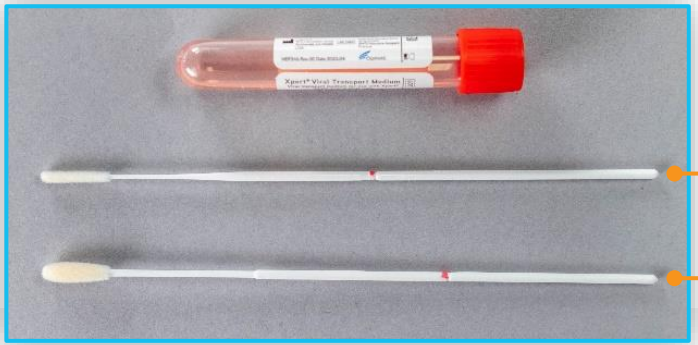
*Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country.

Specimen Collection, Storage and Handling

Specimen Collection

Specimen Type: Nasopharyngeal swab or anterior nasal swab

- Place specimen into 3mL of viral transport medium, 3mL of saline, or 2mL of eNAT™



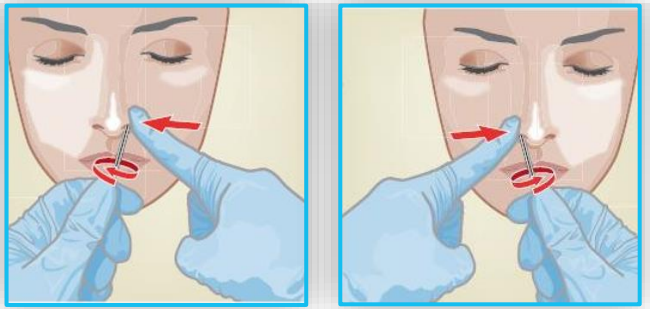
Refer to the WHO Laboratory Biosafety Guidance Related to the Coronovirus Disease 2019 (COVID-19):

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

Specimen Collection: Nasopharyngeal Swab

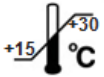
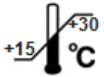
1. Insert the swab into either nostril, passing it into the posterior nasopharynx.
2. Rotate swab by firmly brushing against the nasopharynx several times.
3. Remove and place the swab into the tube containing 3mL of viral transport medium, 3mL of Saline, or 2mL of eNAT™ .
4. Break swab at the indicated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

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 using external pressure on the outside of the other nostril.
4. Remove and place the swab into tube containing 3mL of viral transport medium, 3mL of Saline, or 2mL of eNAT™ the transport tube.
5. Break swab at the indicated break line.
6. Cap the specimen collection tube tightly.

Specimen Transport and Storage

Sample Type	Transport and Storage Conditions	
Transport tube containing nasopharyngeal swab, nasal swab		≤ 48 hours
Viral transport medium / Saline		≤ 7 days
Transport tube containing nasopharyngeal swab, nasal swab		≤ 48 hours
eNAT™		≤ 6 days

Nasopharyngeal, anterior nasal swab samples collected into saline should NOT BE FROZEN.

Kit Storage and Handling

10

Xpert® Xpress CoV-2/Flu/RSV *plus*

Kit Components

Catalog Number	**XP3COV2/FLU/RSV-10 & XP3COV2FLURSV–GB10**
Tests per Kit	10
Flyer	Instructions to locate (and import) the ADF and documentation such as the Product Insert on www.cepheid.com
Disposable 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.

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.

Cartridge Preparation

Proper Cartridge Handling Techniques

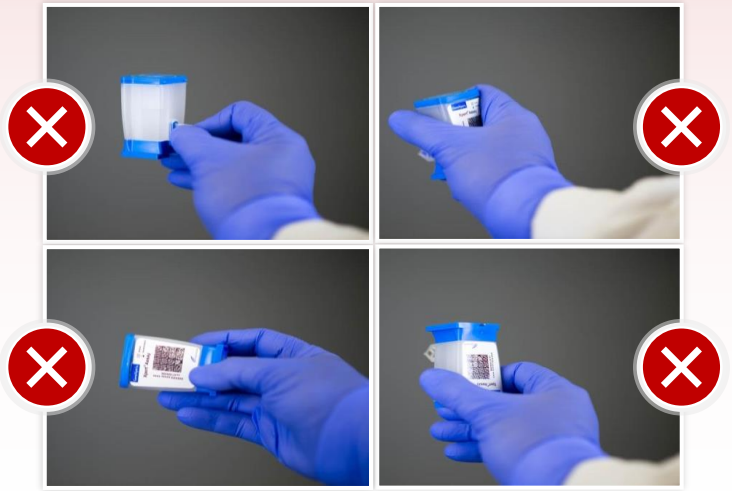
Correct

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 CoV-2/Flu/RSV *plus*

Cartridge Preparation

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***

**** Available for both CE-IVD & UKCA - IVD**

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

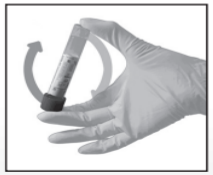
For a copy of the SDS, visit www.cepheid.com or www.cepheidinternational.com

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.

UK CA CE IVD

CE-IVD. *In Vitro* Diagnostic Medical Device. May not be available in all countries. Not available in the United States.

302-3816, Rev. D March 2024

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

Cepheid.

Xpert® Xpress CoV-2/Flu/RSV *plus*

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 of the sample to the cartridge.

5

Close the cartridge lid.

6

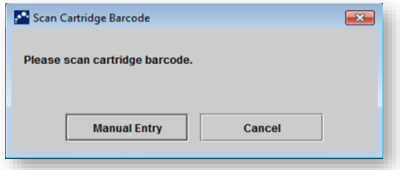
Start the test within the timeframe specified in the Instructions For Use.

Run a Test on GeneXpert® Dx

1 Create a test.

Start the test within 1 hour 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.

For complete details on how to run a test, refer to the Package Insert and the GeneXpert Dx or Xpertise Operator Manual.

Quality Controls

Xpert® Xpress CoV-2/Flu/RSV *plus* Cartridge Controls

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

*Refer to 301-4868 GeneXpert® Quality Control Features for All Cepheid Xpert® Assays

Result Interpretation

Results Summary SARS-CoV-2, Flu, and RSV ADF

Result Displayed	SARS-CoV-2	Flu A1	Flu A2	Flu B	RSV	SPC
SARS-CoV-2 POSITIVE	+	-	-	-	-	+/-
Flu A POSITIVE	-	+	+/-	-	-	+/-
Flu A POSITIVE	-	+/-	+	-	-	+/-
Flu B POSITIVE	-	-	-	+	-	+/-
RSV POSITIVE	-	-	-	-	+	+/-
SARS-CoV-2 NEGATIVE Flu A NEGATIVE Flu B NEGATIVE RSV NEGATIVE	-	-	-	-	-	+
INVALID	-	-	-	-		-
ERROR	NO RESULT	NO RESULT	NO RESULT	NO RESULT	NO RESULT	NO RESULT
No Result	NO RESULT	NO RESULT	NO RESULT	NO RESULT	NO RESULT	NO RESULT

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.

- 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.

Retest Procedure

1

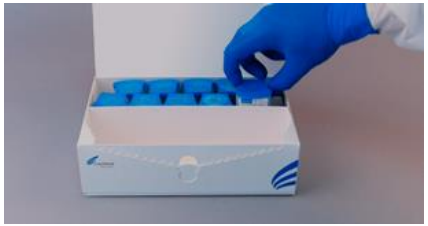
Discard used cartridge. Follow your institution's safety guidelines for disposal of cartridges.

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

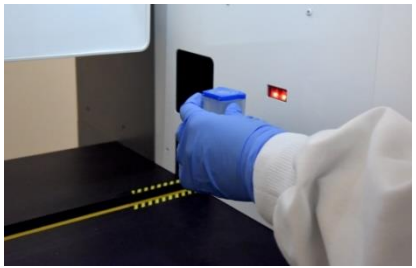


Obtain a new cartridge.

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 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