Assay Training:
Xpert® Xpress SARS-CoV-2/Flu/RSV
For Use with GeneXpert® Dx or GeneXpert® Infinity Systems

For Use Under an Emergency Use Authorization (EUA) Only

Rx only

IVD In Vitro Diagnostic Medical Device

302-4571 Rev. C February 2021

Disclaimer

In the United States:

- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Training Agenda

- **Xpert® Xpress SARS-CoV-2/Flu/RSV**
  - Reagents
  - Specimen collection, storage, & handling
  - Kit storage and handling
  - Cartridge Preparation
  - Quality Controls
  - Results analysis
- **Discussion**

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Training Objectives

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

  Properly store and handle the Xpert® Xpress SARS-CoV-2/Flu/RSV kit

  Follow proper laboratory safety precautions

  Collect and store appropriate specimen(s)

  Prepare a cartridge and run the Xpert® Xpress SARS-CoV-2/Flu/RSV test

  Report the various software generated results

  Understand the Xpert® Xpress SARS-CoV-2/Flu/RSV control strategy

The Cepheid Solution

- Detection of SARS-CoV-2, FluA, FluB, RSV RNA
- On-board internal controls for each sample
  - Probe Check Control (PCC)
  - Sample Processing Control (SPC)
- Closed cartridge system minimizes risk of contamination
- EAT (Early Assay Termination for SARS-CoV-2 ADF only)
- On-demand results
- Random access

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Intended Use

- The Xpert Xpress SARS-CoV-2/Flu/RSV test is a rapid, multiplexed real-time RT-PCR test intended for the simultaneous qualitative detection and differentiation of SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV) viral RNA in either nasopharyngeal swab, nasal swab or nasal wash/ aspirate specimens collected from individuals suspected of respiratory viral infection consistent with COVID-19 by their healthcare provider.[1] Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar.

- Testing of nasopharyngeal swab, nasal swab, or nasal wash/aspirate specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV 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, that meet requirements to perform high or moderate complexity tests.

- Testing of nasopharyngeal or nasal swab specimens using the Xpert Xpress SARS-CoV-2/Flu/RSV test run on the GeneXpert Xpress System (Tablet and Hub Configurations) is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

[1] For this EUA, a healthcare provider includes, but is not limited to, physicians, nurses, pharmacists, technologists, laboratory directors, epidemiologists, or any other practitioners or allied health professionals.

Intended Use (continued)

Results are for the simultaneous detection and differentiation of SARS-CoV-2, influenza A virus, influenza B virus and RSV nucleic acids in clinical specimens and is not intended to detect influenza C virus. 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. Laboratories within the United States and its territories are required to report all SARS-CoV-2 results to the appropriate public health authorities.

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.

Testing with the Xpert Xpress SARS-CoV-2/Flu/RSV 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/Flu/RSV test is only for use under the Food and Drug Administration's Emergency Use Authorization.

Good Laboratory Practice Review

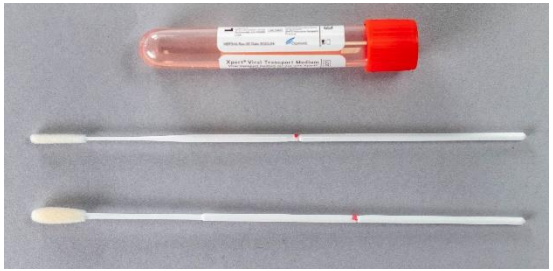
Personal Protective Equipment (PPE)	• Wear clean lab coats, safety glasses, and gloves • Change gloves between processing samples
Lab Bench area	• Clean work surfaces routinely with: ✓ 1:10 dilution of household bleach* ✓ 70% Ethanol Solution ** Final Active Chlorine concentration should be 0.5% regardless of the household bleach concentration in your country* • After cleaning, ensure work surfaces are dry
Specimens, Samples, and Kits Storage	• Store specimens and sample away from kit to prevent contamination
Equipment	• Use filtered pipette tips when recommended • Follow the manufacturer's requirements for calibration and maintenance of equipment

Specimen Collection, Storage and Handling

Specimen Collection

Specimen Type:
nasopharyngeal swab, nasal swab, or nasal wash/ aspirate specimens

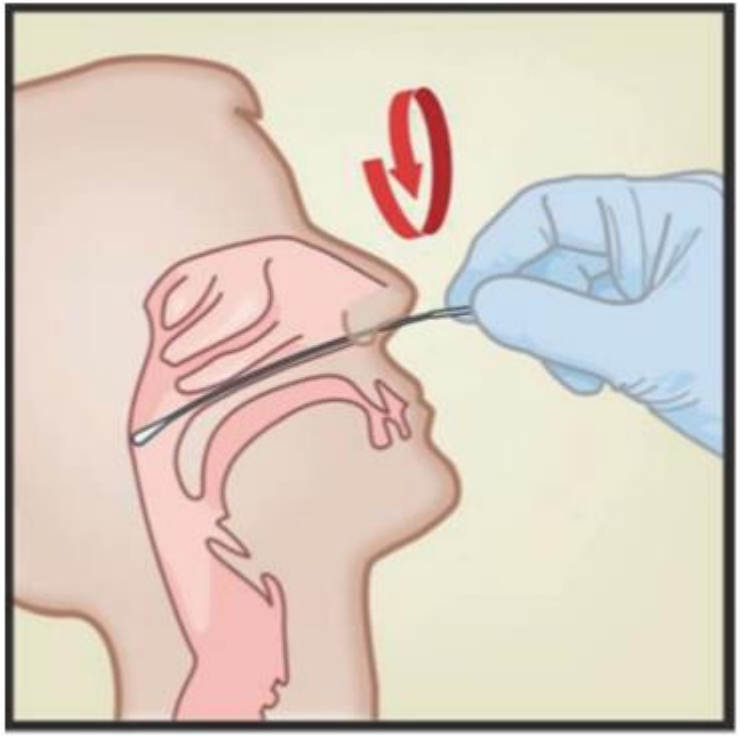
Place specimen into 3mL of viral transport medium or 3mL of saline



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

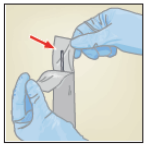


Specimen Collection- Nasopharyngeal Swab

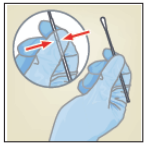
Nasopharyngeal Specimen Collection

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.

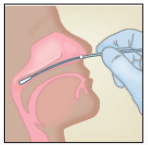


3. Hold the swab in your hand, pinching in the middle of the swab shaft on the scoreline.

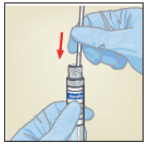


4. Gently insert the swab into the nostril until you touch the posterior nasopharynx.

   Rotate swab several times.

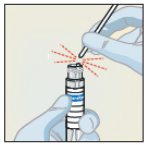


5. Remove the cap from the tube. Insert the swab into the transport medium.

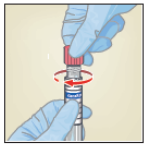


6. Break the swab shaft against the side of the tube at the scoreline.

   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, Xpert Xpress Flu/RSV, and Xpert Xpress SARS-CoV-2/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 up to 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

301-6052, Rev. F October 2020

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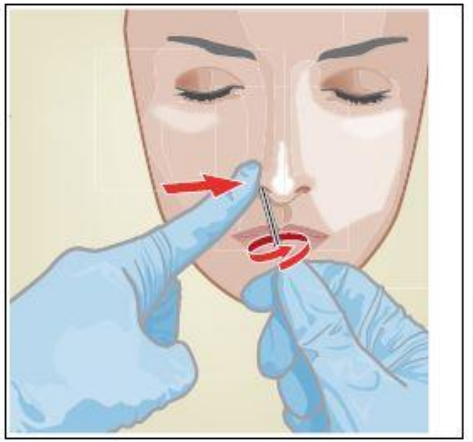
Specimen Collection- Nasal Swab

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.



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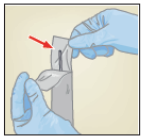
Specimen Collection- Nasal Swab

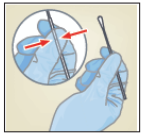
Nasal Swab Specimen Collection

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 <u>any</u> surface.



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



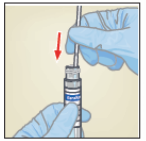
4. Rotate swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril.

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

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

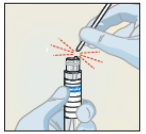
   To avoid specimen contamination, do not touch the swab tip to anything after collecting the specimen.

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

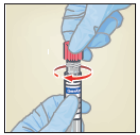


7. Break the swab shaft against the side of the tube at the scoreline.

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

301-9057, Rev. D October 2020

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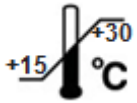
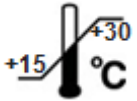
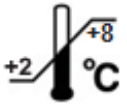
Specimen Collection- Nasal Wash/Aspirate

Transfer 600µL of the wash sample into the 3mL viral transport medium or 3mL of saline.

Specimen Transport and Storage

Sample type	Transport and Storage Conditions
3mL Viral Transport Medium containing nasopharyngeal swab, nasal swab, or nasal wash/aspirate	 ≤ 24 hours
3mL saline containing nasopharyngeal swab, nasal swab, or nasal wash/aspirate	 ≤ 48 hours
3mL Viral Transport Medium or 3mL saline containing nasopharyngeal swab, nasal swab, or nasal wash/aspirate	 ≤ 7 days

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Kit Storage and Handling

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Xpert® Xpress SARS-CoV-2/Flu/RSV 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

- XPCOV2/FLU/RSV-10

Materials Required but not Provided

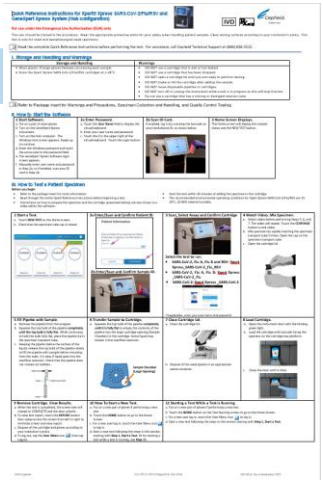
- 3mL viral transport media or 3mL saline
- Personal Protective Equipment (PPE)
- 1:10 dilution of bleach
- 70% ethanol or denatured ethanol

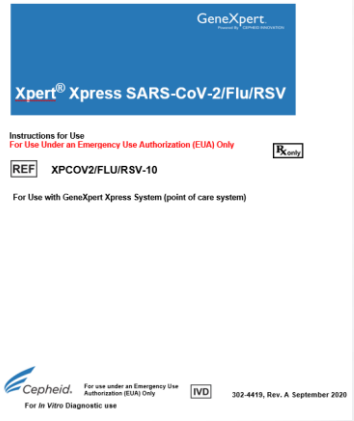
Optional

- Uninterruptible Power Supply/ Surge Protector
- Printer

Kit Components

	Xpert® Xpress SARS-CoV-2/Flu/RSV
Catalog Number	**XPCOV2/FLU/RSV-10**
Tests per kit	10
Flyer	Directions to locate the Instructions For Use and Quick Reference Instructions on www.cepheid.com www.cepheid.com/coronavirus-resources
Transfer pipettes	10-12
Storage	2-28˚C





The kit also includes 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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Xpert® Xpress SARS-CoV-2/Flu/RSV 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

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
  - 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

Correct

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

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Xpert® Xpress SARS-CoV-2/Flu/RSV

Cartridge Preparation

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® Cartridge Preparation

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

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.

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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. B September 2020

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Xpert® Xpress SARS-CoV-2/Flu/RSV

Cartridge Preparation

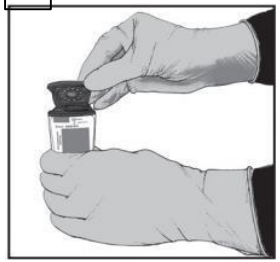
1

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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Run a Test- Start the test within 30 minutes

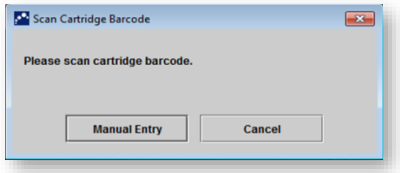
1 Create Test

GeneXpert

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

2 Scan barcode :

Cartridge/ Patient and/or Sample ID

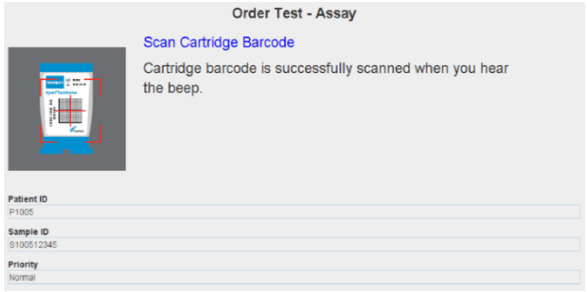


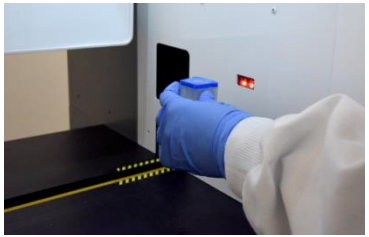
By default, do not click on **Manual Entry** or **Cancel**

3 Scan the cartridge

GeneXpert Infinity

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





For complete details on how to run a test, refer to the Instructions For Use and the GeneXpert® Dx or Xpertise™ Operator Manual.

Create a Test on GeneXpert Dx Software

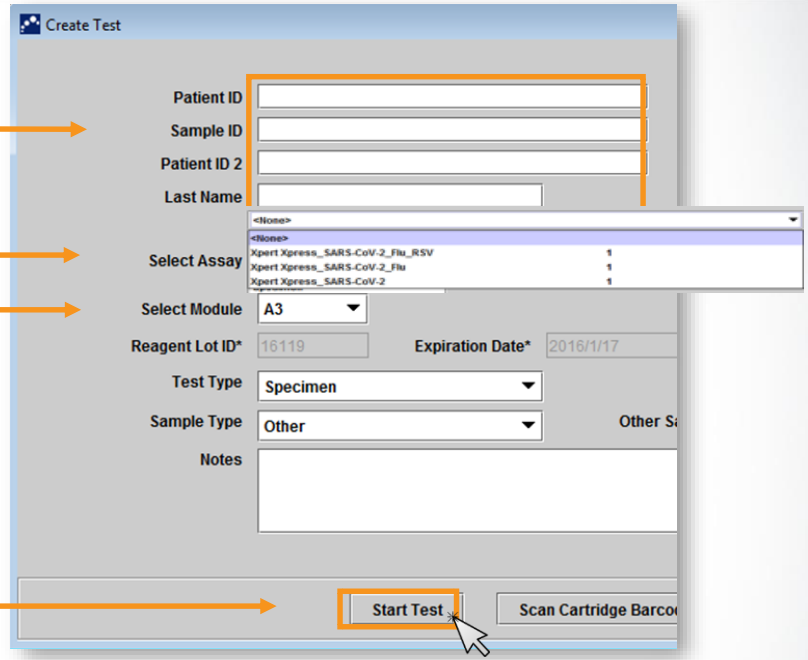
4 Complete the fields as required

5 Select the Assay Protocol

6 The module is selected automatically

7 Click on Start Test

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



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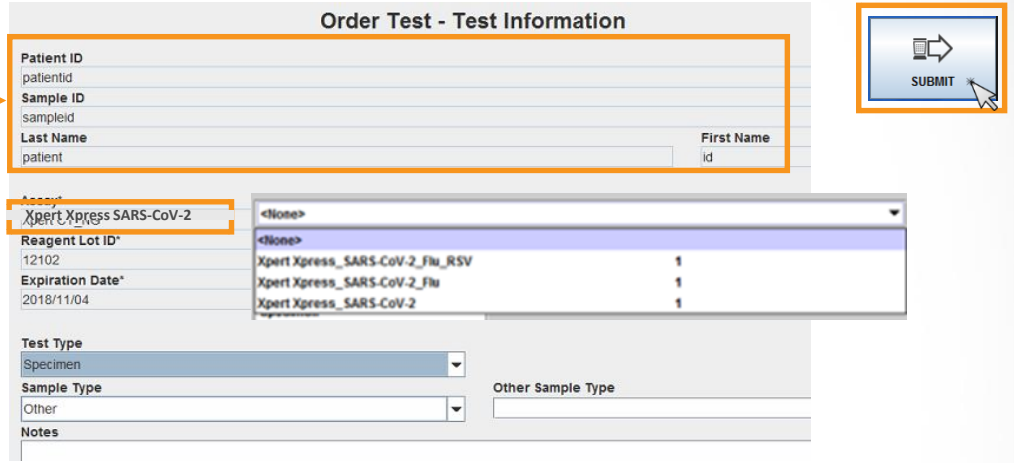
Create a Test on Xpertise Software

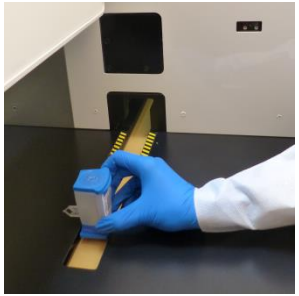
4 Complete the fields as required

5 Select the Assay Protocol

6 Click on SUBMIT

7 Place the cartridge onto the conveyor belt





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Automated Xpert® Protocol

1. Sample is added to the cartridge
2. The cartridge is loaded into the system
3. Nucleic acids are purified
4. Purified nucleic acids mix with the 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 Controls

Refer to the Instructions For Use for complete details

Xpert® Xpress SARS-CoV-2/Flu/RSV Cartridge Controls

- **Xpert® Xpress SARS-CoV-2/Flu/RSV 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 Xpert Assays

Xpert® Xpress SARS-CoV-2/Flu/RSV Cartridge 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
  - Verifies lysis and detects PCR inhibition
  - Must be positive in a negative sample to be a valid test
  - Can be positive or negative in a positive sample

External Control Testing Frequency

- External controls should be used in accordance with local, state, and federal accrediting organizations as applicable.

- Due to the COVID-19 pandemic and the resulting shortage of external control material, Cepheid recommends that all laboratories perform external QC with each new lot and shipment of reagents, at a minimum, while running the Xpert Xpress SARS-CoV-2/Flu/RSV test under Emergency Use Authorization (EUA).

Commercially Available External Controls

Zeptometrix	Description	Configuration	Storage
NATFRC-6C	Positive Control	6 x 0.5mL	2-8˚C or -20˚C
NATCV9-6C	Negative Control	6 x 0.5mL	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 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.

Result Interpretation

Refer to the Instructions For Use for complete details

Assay Targets

- SARS-CoV-2
- Flu A1
- Flu A2
- Flu B
- RSV
- SPC

Early Assay Termination

- The Xpert® Xpress SARS-CoV-2 test mode includes an Early Assay Termination (EAT) function which will provide earlier time to results in high titer specimens if the signal from the SARS-CoV-2 target 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 amplification curve may not be seen and its 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

For use under an Emergency Use Authorization (EUA) only

Results Summary SARS-CoV-2 and Flu ADF

Result displayed	SARS-CoV-2	Flu A1	Flu A2	Flu B	SPC
Influenza A POSITIVE	-	+	+/-	-	+/-
Influenza A POSITIVE	-	+/-	+	-	+/-
Influenza B POSITIVE	-	-	-	+	+/-
SARS-CoV-2 POSITIVE	+	-	-	-	+/-
SARS-CoV-2, Flu A, Flu B, 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

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

Result displayed	SARS- -CoV-2	Flu A1	Flu A2	Flu B	RSV	SPC
Influenza A POSITIVE	-	+	+/-	-	-	+/-
Influenza A POSITIVE	-	+/-	+	-	-	+/-
Influenza B POSITIVE	-	-	-	+	-	+/-
RSV POSITIVE	-	-	-	-	+	+/-
SARS-CoV-2 POSITIVE	+	-	-	-	-	+/-
SARS-CoV-2, Flu A, Flu B, 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

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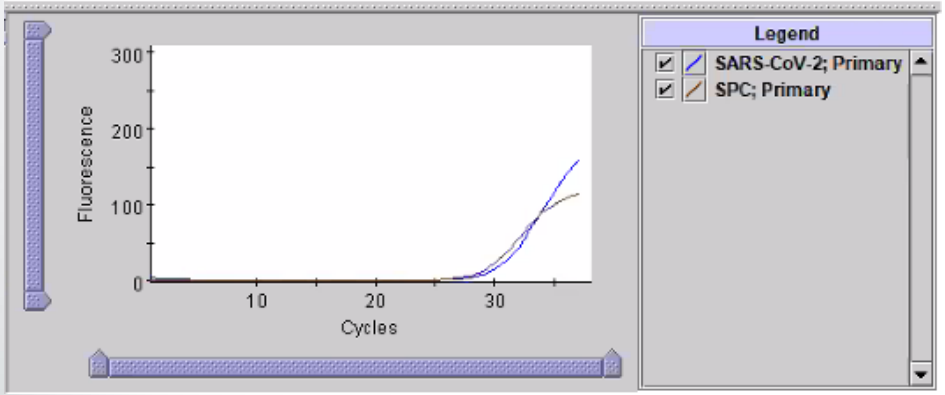
SARS-CoV-2 POSITIVE

Test Result	SARS-CoV-2 POSITIVE

Test Result | Analyte Result | Detail | Errors | History | Messages | Support

Analyte Name	Ct	EndPt	Interpretation Result	Reason	Analyte Result	Probe Check Result
SARS-CoV-2	30.9	57	POS		POS	PASS
SPC	30.2	14	PASS		NA	PASS



- SARS-CoV2-RNA detected
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

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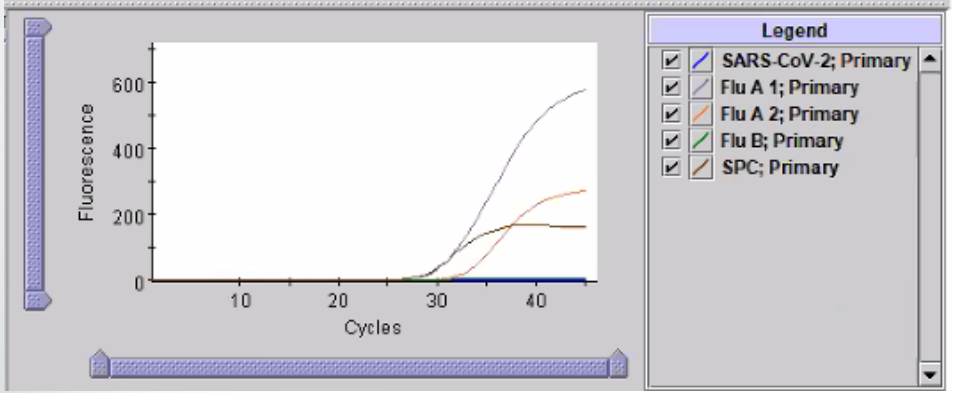
SARS CoV2 Negative, Influenza A Positive, Influenza B Negative

Test Result	SARS-CoV-2 NEGATIVE; Flu A POSITIVE; Flu B NEGATIVE

Test Result | Analyte Result | Detail | Errors | History | Messages | Support

Analyte Name	Ct	EndPt	Interpretation Result	Reason	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	2	NEG	No Ct	NEG	PASS
Flu A 1	30.3	576	POS		POS	PASS
Flu A 2	34.1	272	POS		POS	PASS
Flu B	0.0	7	NEG	No Ct	NEG	PASS
SPC	29.2	164	PASS		NA	PASS



- SARS-CoV-2 RNA not detected
  Flu A target RNA detected;
  Flu B target RNA not detected;
- SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

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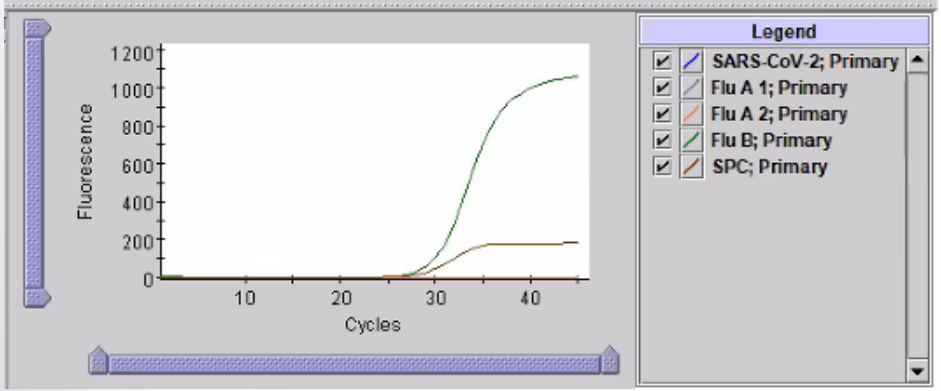
SARS CoV2 Negative, Influenza A Negative, Influenza B Positive

Test Result	SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B POSITIVE

Test Result | Analyte Result | Detail | Errors | History | Messages | Support

Analyte Name	Ct	EndPt	Interpretation Result	Reason	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	-6	NEG	No Ct	NEG	PASS
Flu A 1	0.0	-2	NEG	No Ct	NEG	PASS
Flu A 2	0.0	-1	NEG	No Ct	NEG	PASS
Flu B	28.5	1059	POS		POS	PASS
SPC	29.0	181	PASS		NA	PASS



- SARS-CoV-2 RNA not detected
  Flu A target RNA not detected;
  Flu B target RNA detected;
- SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

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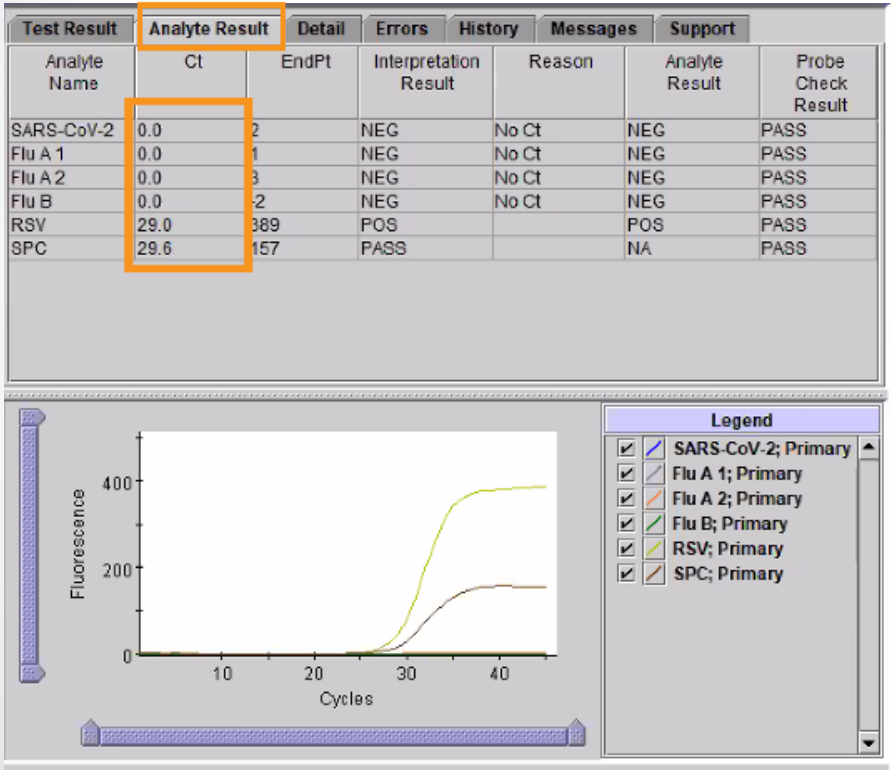
SARS CoV2 Negative, Influenza A Negative, Influenza B Negative, RSV Positive

Test Result	SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B NEGATIVE; RSV POSITIVE



- SARS-CoV-2 RNA not detected
  Flu A target RNA not detected
  Flu B target RNA not detected
  RSV target RNA detected
- SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

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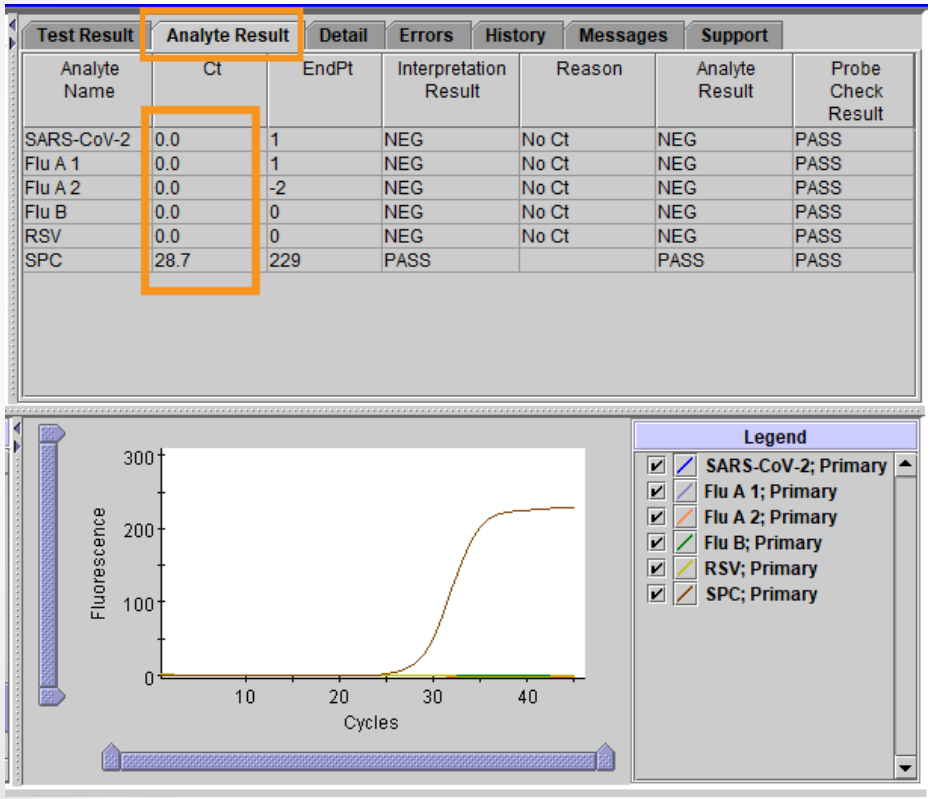
SARS CoV2 Negative, Influenza A Negative, Influenza B Negative, RSV Negative

Test Result	SARS-CoV-2 NEGATIVE; Flu A NEGATIVE; Flu B NEGATIVE; RSV NEGATIVE



- SARS-CoV-2 RNA not detected
  Flu A target RNA not detected
  Flu B target RNA not detected
  RSV target RNA not detected
- SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting
- Probe Check: PASS; all probe check results pass

Limitations

- Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV has only been established in nasopharyngeal swab specimens. Use of the Xpert Xpress SARS-CoV-2/Flu/RSV test with other specimen types has not been assessed and performance characteristics are unknown.
- Nasal swabs (self-collected under supervision of, or collected by, a healthcare provider) are considered acceptable specimen types for use with the Xpert Xpress SARS-CoV-2/Flu/RSV test but performance with these specimen types has not been established.
- As with any molecular test, mutations within the target regions of the Xpert Xpress SARS-CoV-2/Flu/RSV test could affect primer and/or probe binding resulting in failure to detect the presence of virus or the virus being detected less predictably.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.
- The performance of this test was validated using the procedures provided in this package insert only. Modifications to these procedures may alter the performance of the test.
- 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.

Limitations (continued)

- False negative results may occur if virus is present at levels below the analytical limit of detection.
- Negative results do not preclude SARS-CoV-2, influenza or RSV infection and should not be used as the sole basis for treatment or other patient management decisions.
- Results from the Xpert Xpress SARS-CoV-2/Flu/RSV test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
- Viral nucleic acid may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious or are the causative agents for clinical symptoms.
- This test has been evaluated for use with human specimen material only.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- This test has not been evaluated for monitoring treatment of infection.
- This test has not been evaluated for screening of blood or blood products for the presence of SARS-CoV-2, influenza or RSV.
- The effect of interfering substances has only been evaluated for those listed within the labeling. Interference by substances other than those described can lead to erroneous results.
- Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, influenza, or RSV was present at 1X LoD levels.

Limitations (continued)

- Cross-reactivity with respiratory tract organisms other than those described herein can lead to erroneous results.
- Recent patient exposure to FluMist® or other live attenuated influenza vaccines may cause inaccurate positive results.
- As the Xpert Xpress SARS-CoV-2/Flu/RSV test does not differentiate between the N2 and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV-1 may cause a false positive result. None of these other coronaviruses is known to currently circulate in the human population.
- This test is not intended to differentiate RSV subgroups, influenza A subtypes or influenza B lineages. If differentiation of specific RSV or influenza subtypes and strains is needed, additional testing, in consultation with state or local public health departments, is required.
- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Limitations (continued)

- Specimen transport media that contain guanidine thiocyanate (GTC) may interfere with the test causing false negative results.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

Troubleshooting

Factors That Negatively Affect Results

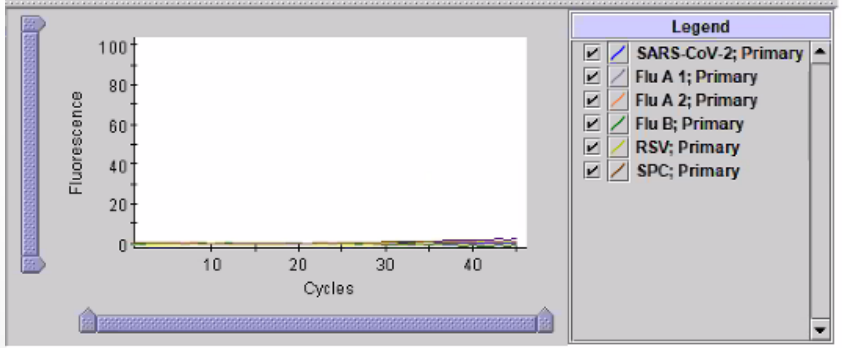
- Improper specimen collection
  - The performance of this assay with other specimen types or samples has not been evaluated
- Inadequate numbers of organisms are present in the specimen.
- Improper transport or storage of collected specimen
  - Storage and transport conditions are specimen specific
  - 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

INVALID Result

Test Result	INVALID

Test Result | Analyte Result | Detail | Errors | History | Messages | Support

Analyte Name	Ct	EndPt	Interpretation Result	Reason	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	1	NEG	No Ct	INVALID	PASS
Flu A 1	0.0	0	NEG	No Ct	INVALID	PASS
Flu A 2	0.0	1	NEG	No Ct	INVALID	PASS
Flu B	0.0	-1	NEG	No Ct	INVALID	PASS
RSV	0.0	0	NEG	No Ct	INVALID	PASS
SPC	0.0	3	FAIL	No Ct	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

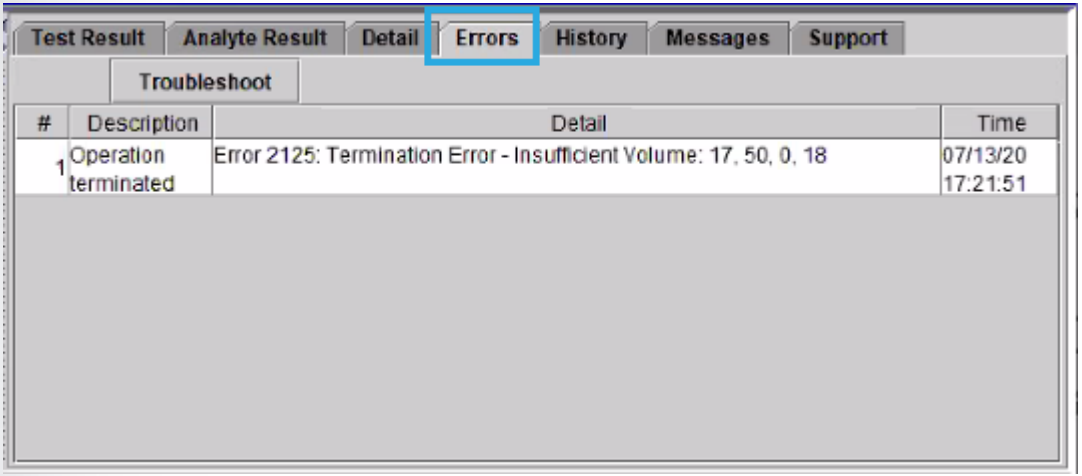
- Improper sample collection or preparation
- Presence of interfering substances in the sample

Solution

- Repeat the test with a new cartridge

ERROR Result

Test Result	ERROR



Presence or absence of the target RNAs cannot be determined.

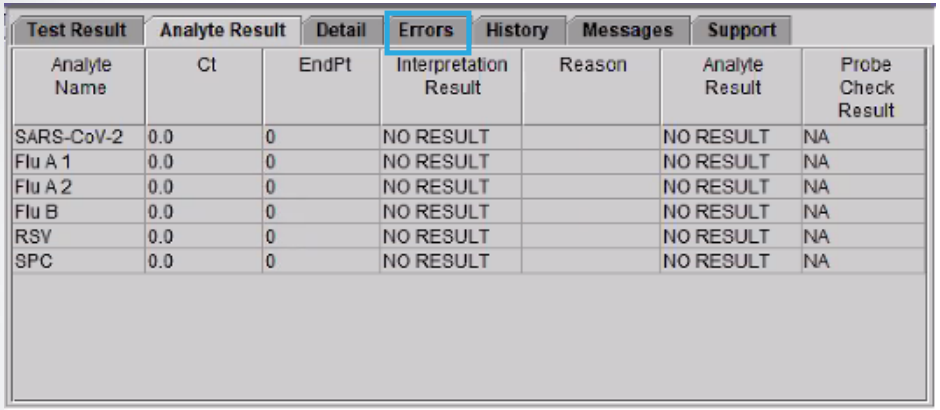
- SARS-CoV-2: NO RESULT
- Flu A: NO RESULT
- Flu B: NO RESULT
- RSV: NO RESULT
- SPC: NO RESULT
- Probe Check: FAIL; all or one of the probe check results fail

If the probe check passes, the error is caused by the maximum pressure limit exceeding the acceptable range or by a system component failure.

Solution

- Repeat the test with a new cartridge.

NO RESULT



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

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

A NO RESULT 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

- 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

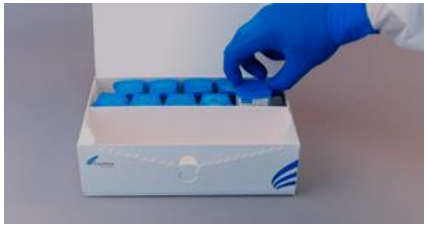
Follow your institution's safety guidelines for disposal of cartridges

2

Obtain the residual specimen, 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

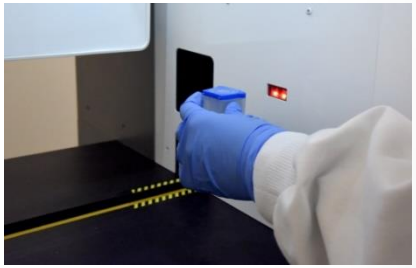


Obtain a new cartridge

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 case online using the following link ***http://www.cepheid.com/us/support*** **:**

Create a Support Case


Thank You.
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