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

For use with GeneXpert® Systems with Touchscreen
Catalog Number (XP3COV2/FLU/RSV-10 & XP3COV2FLURSV–GB10)
For CE-IVD & UKCA-IVD Only

IVD In Vitro Diagnostic Medical Device

302-8254 Rev. B April 2024

Training Agenda

Xpert® Xpress CoV-2/Flu/RSV plus

1. Overview
2. Kit Storage and Handling
3. Specimen Collection, Transport and Storage
4. Cartridge Preparation
5. Quality Controls
6. Results Interpretation
7. 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** CoV-2/Flu/RSV ***plus*** kit
- Follow proper laboratory safety precautions
- Collect and store appropriate specimen(s)
- Prepare a cartridge and run the Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** test
- Report the various software generated results
- Understand the Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** control strategy

Overview

The Cepheid Solution

Detection of SARS-CoV-2, Flu A, Flu B, 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

Intended Use

- The Xpert® **Xpress** CoV-2/Flu/RSV ***plus*** test, performed on GeneXpert® system with Touchscreen Running Cepheid OS (A touchscreen configuration within the GeneXpert ® Instrument System family), 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 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.

Intended User / Environment

- The Xpert® Xpress CoV-2/Flu/RSV plus test is intended to be performed by trained users in both laboratory and near patient testing settings.

Xpert® Xpress CoV-2/Flu/RSV *plus* Requirements

GeneXpert® Systems

- GeneXpert system with Touchscreen Running Cepheid OS

Test Kits

- Catalog Number (XP3COV2/FLU/RSV-10) & (XP3COV2FLURSV–GB10)

Sample Type

- Nasopharyngeal swab
- Anterior nasal swab

Materials required but not provided

- Personal Protective Equipment (PPE)
- 10% Bleach / Sodium Hypochlorite
- 70% ethanol or denatured ethanol
- Nylon flocked swab (Copan P/N 502CS01, 503CS01) or equivalent
- Viral transport medium, 3 mL (Copan P/N 330C) or equivalent
- 0.85-0.9% (w/v) saline, 3 mL
- Nasopharyngeal Sample Collection Kit for Viruses (Cepheid P/N SWAB/B-100, Copan P/N 305C) or equivalent
- Nasal Sample Collection Kit for Viruses (Cepheid P/N SWAB/F-100, Copan P/N 346C) or equivalent

Materials Available but Not Provided

- External controls in the form of inactivated virus(es) available from ZeptoMetrix : Catalog #NATFRC-6C (NATtrol Flu/RSV/SARS-CoV-2) & (#NATCV9-6C (NATrol Coxsackievirus A9)
- eNAT™ Molecular Collection and Preservation Medium, Copan Catalog #6U073S01 & # 6U074S01

Other Materials

- Uninterruptible Power Supply /Surge Protector
- Cepheid OS
- Printer If a printer is required, contact Cepheid Technical Support to arrange for the purchase of a recommended printer.

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.

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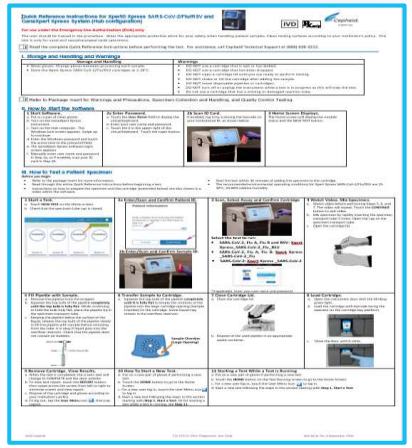
Kit Storage and Handling

Xpert® Xpress CoV-2/Flu/RSV *plus*

Kit Components

Catalog Numbers	**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



The kit also includes printed copies of the Quick Reference Instructions, which should **ONLY** be used with the GeneXpert® Xpress System.
Not included in the XP3COV2FLURSV–GB10 kit.

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

Warnings and Precautions

General

- For *in vitro* diagnostic use.
- Positive results are indicative of presence of Flu A, Flu B, RSV, or SARS-CoV-2 RNA.
- Treat all biological specimens, including used cartridges, as if capable of transmitting infectious agents. Because it is often impossible to know which might be infectious, all biological specimens should be handled using standard precautions. Guidelines for specimen handling are available from the U.S. Centers for Disease Control and Prevention[9] and the Clinical and Laboratory Standards Institute.[10]
- Follow safety procedures set by your institution for working with chemicals and handling biological specimens.
- Refer to Copan eNAT™ Package Insert for safety and handling information.

9. Centers for Disease Control and Prevention. Biosafety in Microbiological and Biomedical laboratories (refer to latest edition). http://www.cdc.gov/biosafety/publications/

10.Clinical and Laboratory Standards Institute. Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline. Document M29 (refer to latest edition).

Warnings and Precautions

General continued

- Avoid direct contact between guanidine thiocyanate and sodium hypochlorite (bleach) or other highly reactive reagents such as acids and bases. These mixtures could release noxious gas
- Biological specimens, transfer devices, and used cartridges should be considered capable of transmitting infectious agents requiring 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 disposal. If country 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.

Warnings and Precautions

Specimens

- Maintain proper storage conditions during specimen transport to ensure the integrity of the specimen (see Section: Specimen Collection, Transport, and Storage).
- Specimen stability under shipping conditions other than those recommended has not been evaluated.

Warnings and Precautions

Assay /Reagent

- DO NOT :
- Open the Xpert® Xpress CoV-2/Flu/RSV plus cartridge lid except when adding specimen
- Use cartridge that has been dropped after removing it from the packaging
- Shake the cartridge. Shaking or dropping the cartridge after opening lid may yield non-determinate results
- Place the sample ID label on the cartridge lid or on the barcode label of the cartridge
- Use a cartridge that has a damaged barcode label
- Use a cartridge that has a damaged reaction tube
- Use reagents beyond their expiry date
- Use a cartridge if it appears wet or if the lid seal appears to have been broken

Warnings and Precautions

Assay /Reagent continued

- Each single-use Xpert® Xpress CoV-2/Flu/RSV *plus* cartridge is used to process one test. Do not reuse processed cartridges.
- Each single-use disposable pipette is used to transfer one specimen. Do not resuse disposable pipettes
- Wear clean lab coats and gloves. Change gloves between the handling of each specimen.
- In the event of a spill of specimens or controls, wear gloves and absorb the spill with paper towels. Then, thoroughly clean the contaminated area with a 10% freshly prepared household chlorine bleach. Allow a minimum of two minutes of contact time. Ensure the work area is dry before using 70% denatured ethanol to remove bleach residue. Allow surface to dry completely before proceeding. Or, follow your institution's standard procedures for a contamination or spill event. For equipment, follow the manufacturer's recommendations for decontamination of equipment.

Specimen Collection, Transport and Storage

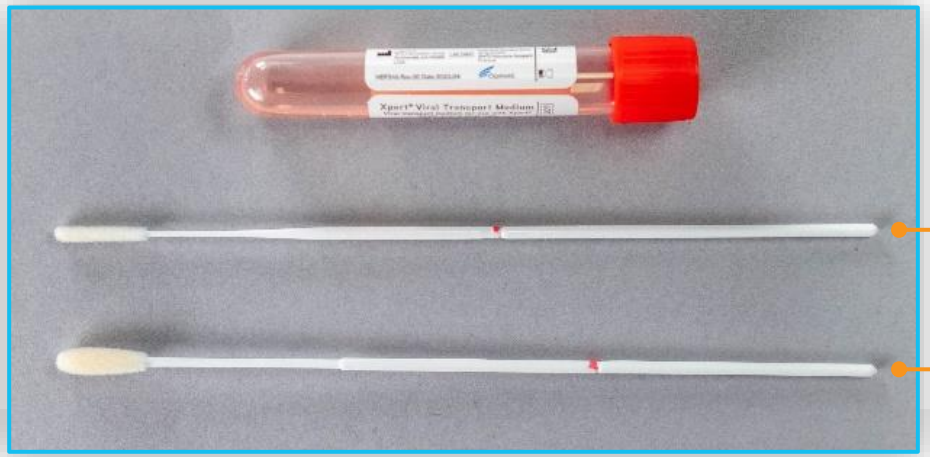
Specimen Collection, Transport and Storage

- Proper specimen collection, storage and transport are critical to the performance of this test.
- Inadequate specimen collection, improper specimen handling and/or transport may yield a false result.

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.

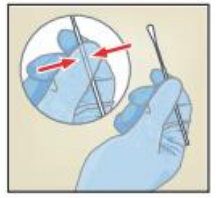
Specimen Collection: Nasopharyngeal Swab

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.

301-6052, Rev. H September 2021

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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 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.

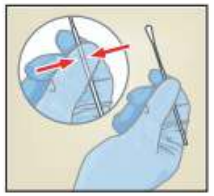
Specimen Collection: Nasal Swab

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.

301-9057, Rev. F September 2021

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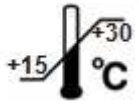
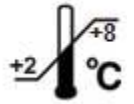
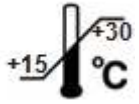
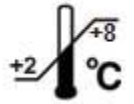
Specimen Transport and Storage

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.

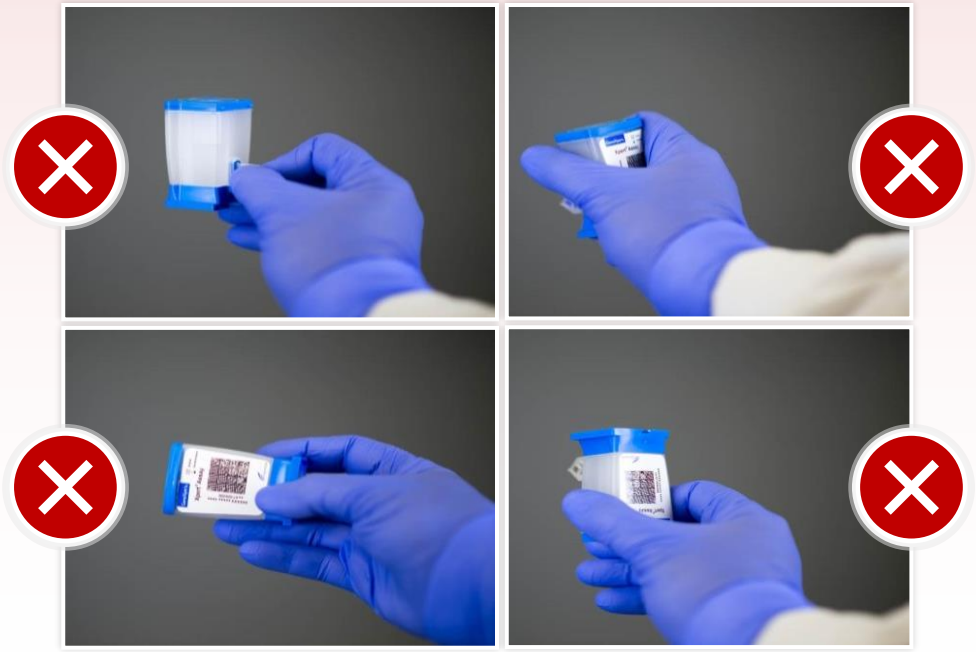
Cartridge Preparation

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

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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.

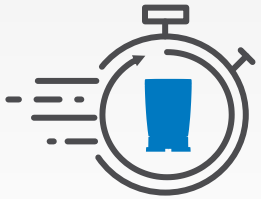
4

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.

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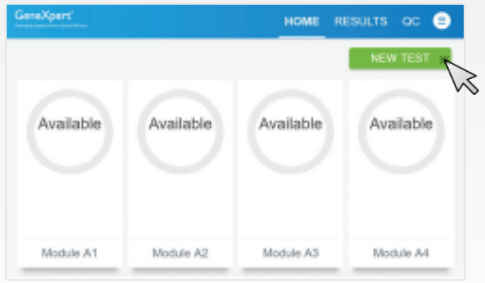
Run a Test

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

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Automated Xpert® Xpress CoV-2/Flu/RSV *plus*

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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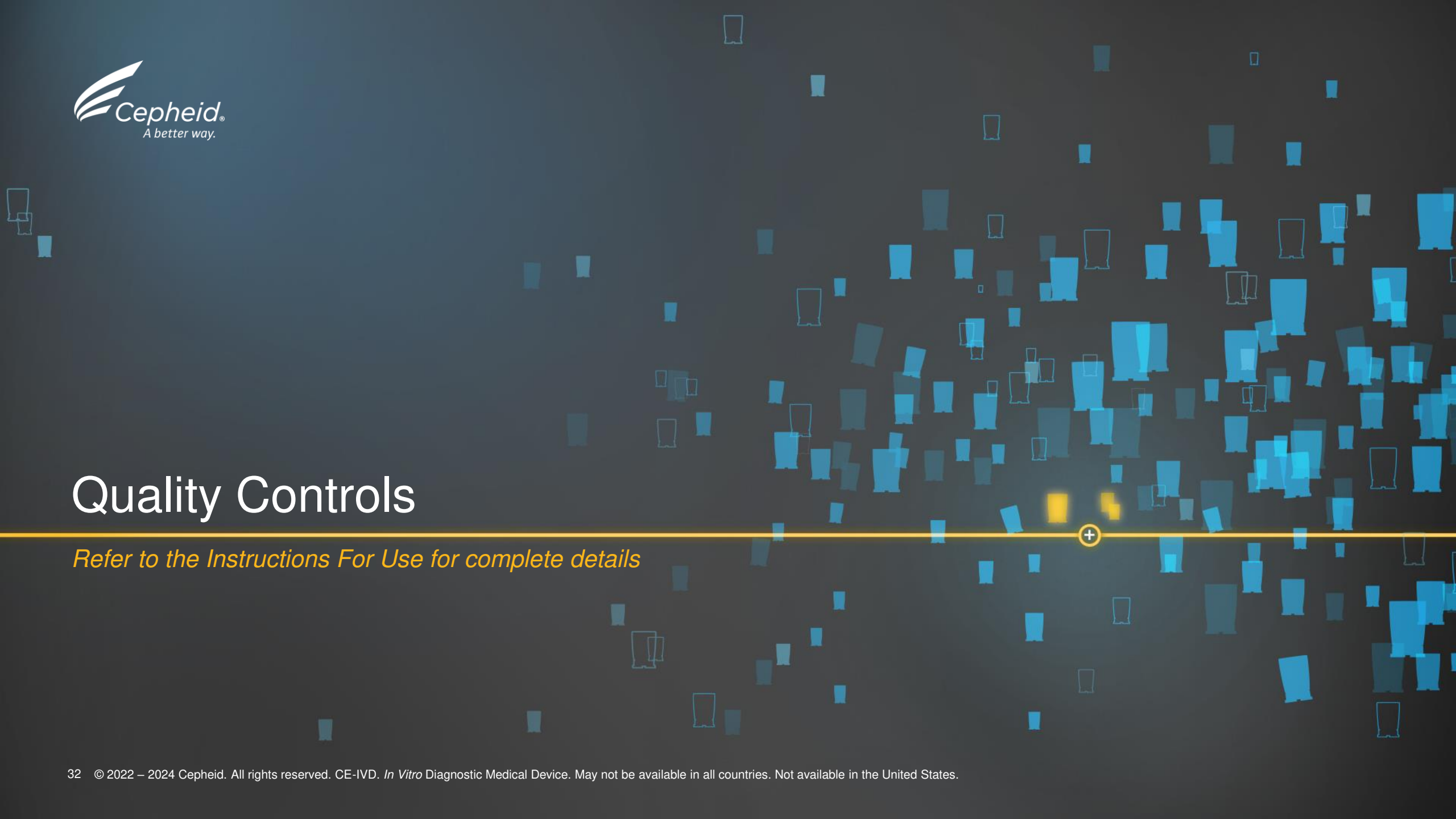
Waste Disposal

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



Quality Controls

Refer to the Instructions For Use for complete details

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

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

Assay Targets

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

Early Assay Termination

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

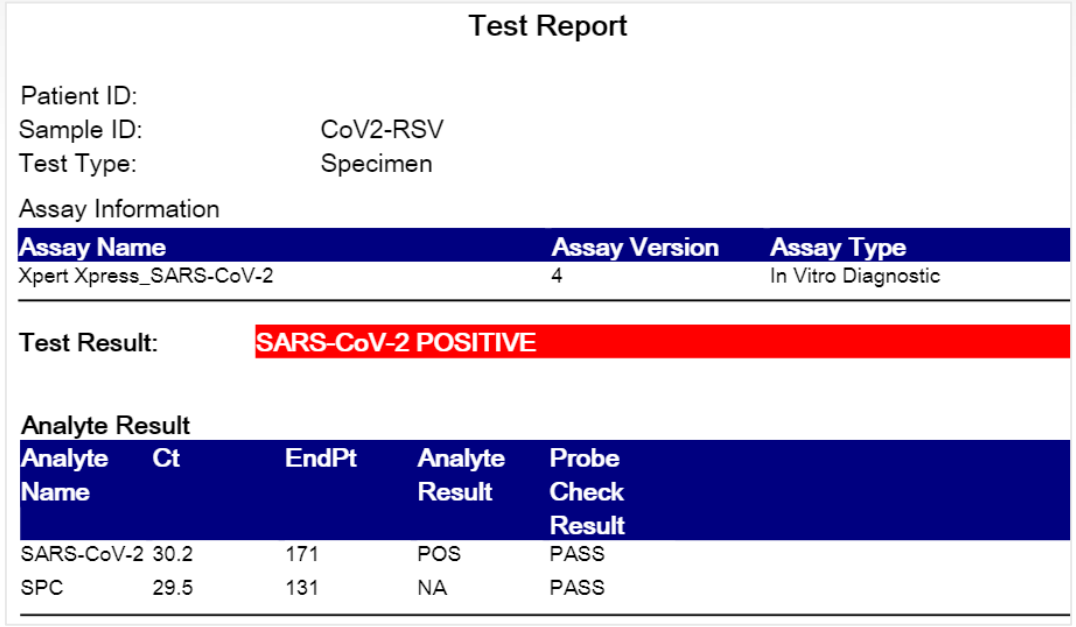
Results Summary: Xpress SARS-CoV-2 ADF

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 POS

Result

SARS-CoV-2 POSITIVE



Test Report

Patient ID:
Sample ID: CoV2-RSV
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 POSITIVE

Analyte Result

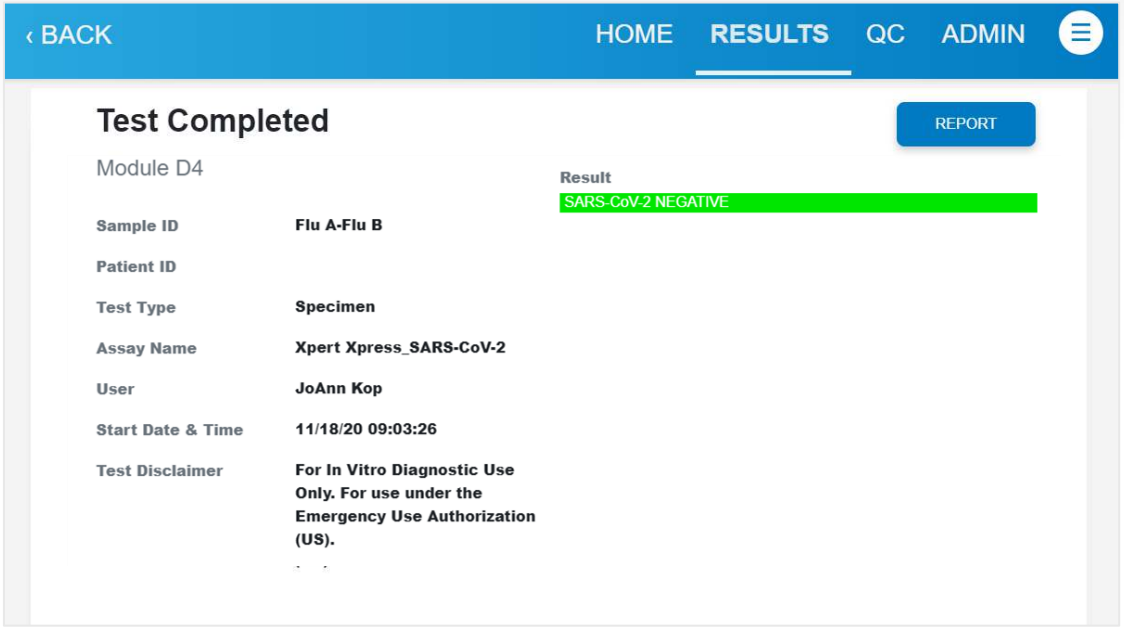
Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	30.2	171	POS	PASS
SPC	29.5	131	NA	PASS

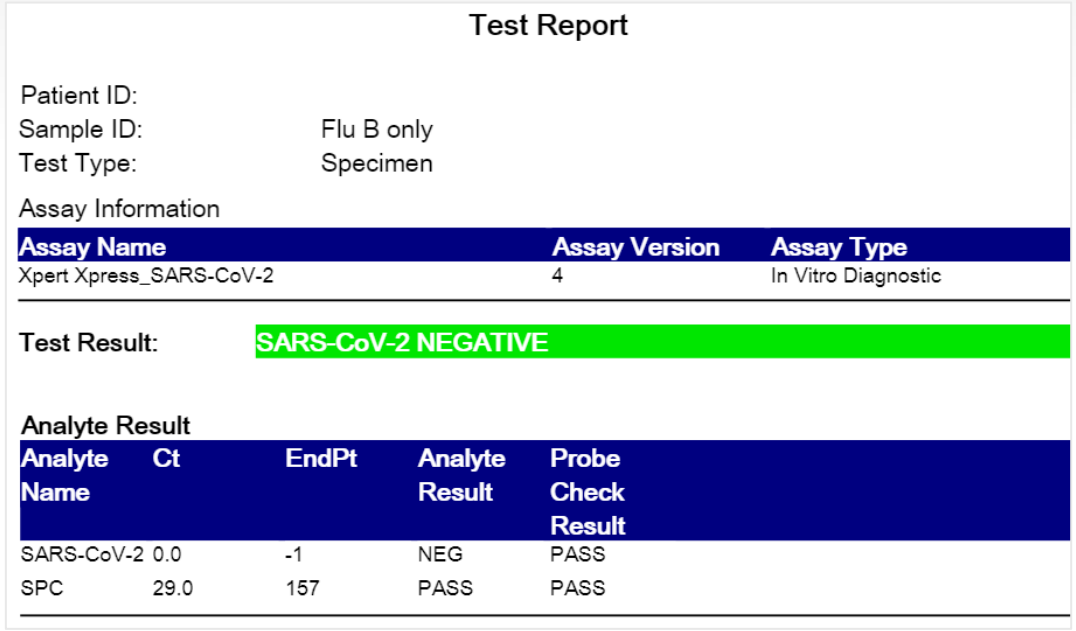
- SARS-CoV-2 target RNA is detected
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 NEG

Result

SARS-CoV-2 NEGATIVE





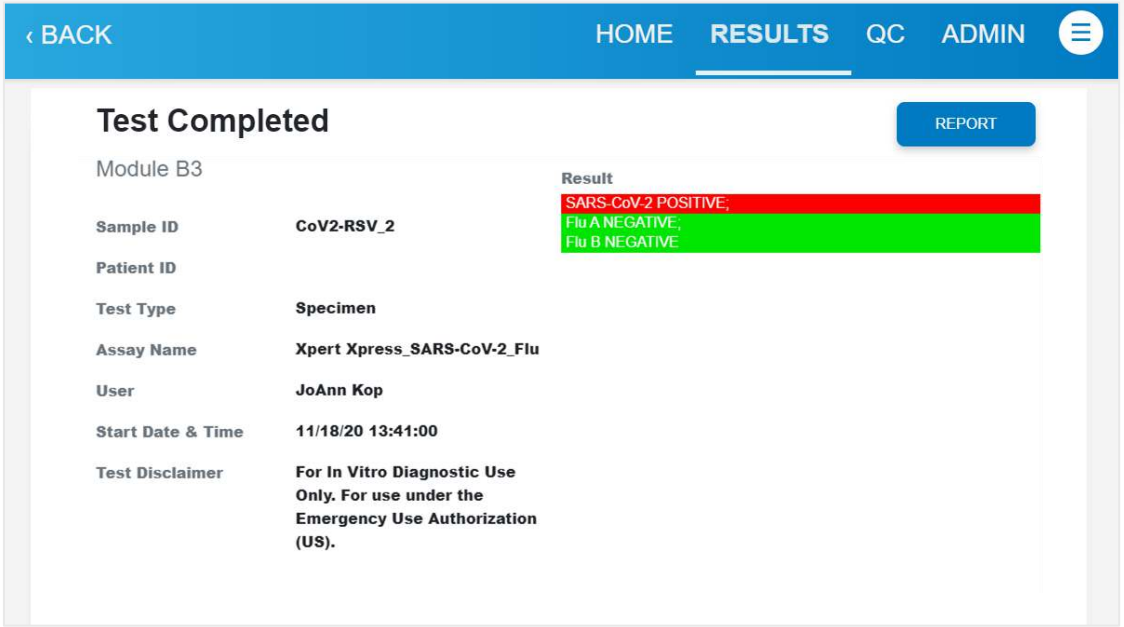
- SARS-CoV-2 target RNA is not detected
- SPC: PASS; SPC has a Ct within the valid range and endpoint above the minimum setting
- Probe Check: PASS; all probe check results pass

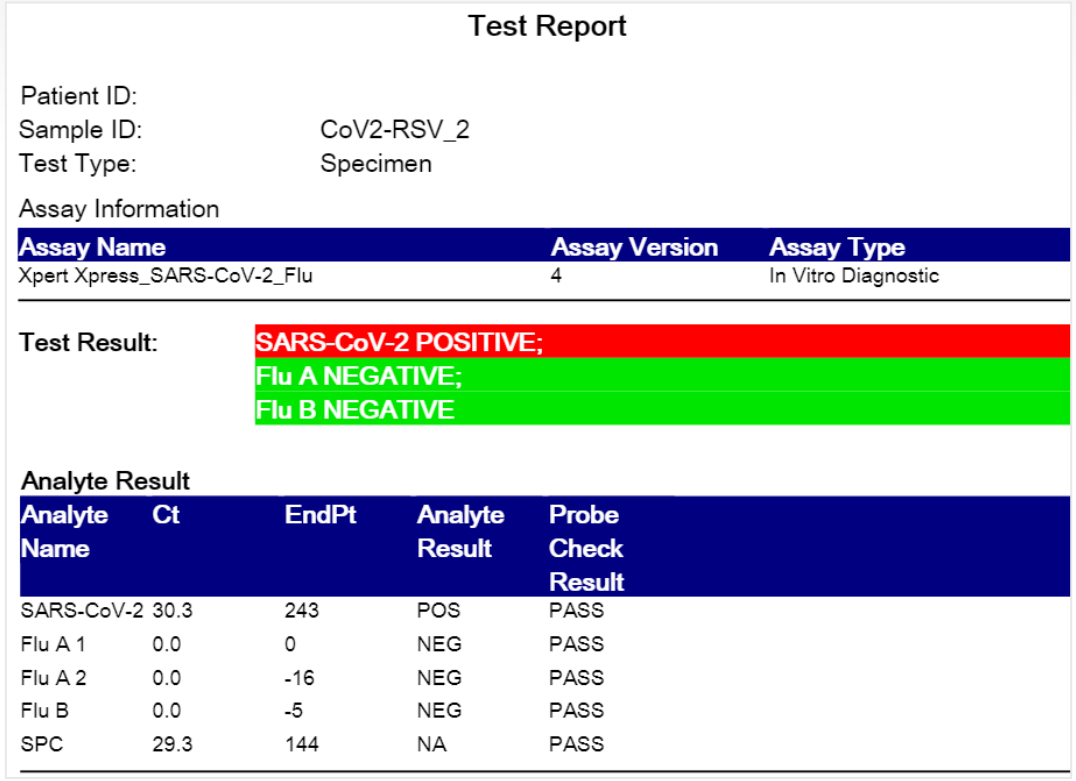
Results Summary: Xpress SARS-CoV-2 and Flu ADF

Result Displayed	SARS-CoV-2	Flu A1	Flu A2	Flu B	SPC
Flu A POSITIVE	–	+	+/–	–	+/–
Flu A POSITIVE	–	+/–	+	–	+/–
Flu B POSITIVE	–	–	–	+	+/–
SARS-CoV-2 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

SARS-CoV-2 POS, FLU A/B NEG

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

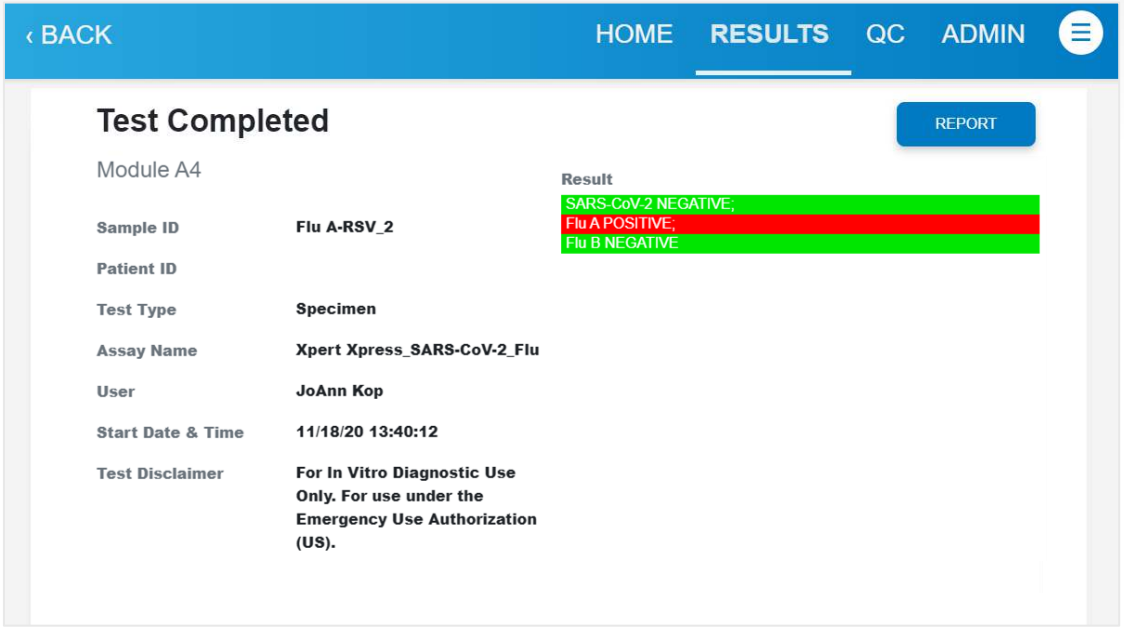


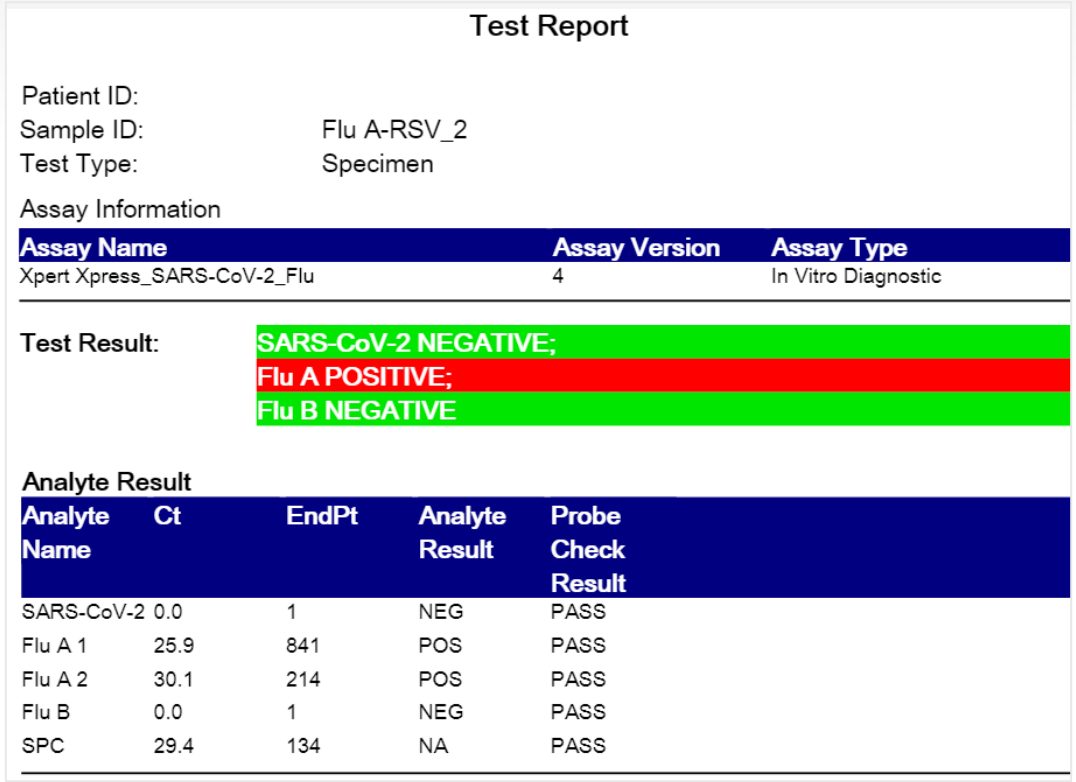


- SARS-CoV-2 target RNA is detected
- Flu A targets RNA are not detected
- Flu B target RNA is not detected
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2 NEG, FLU A POS, FLU B NEG

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



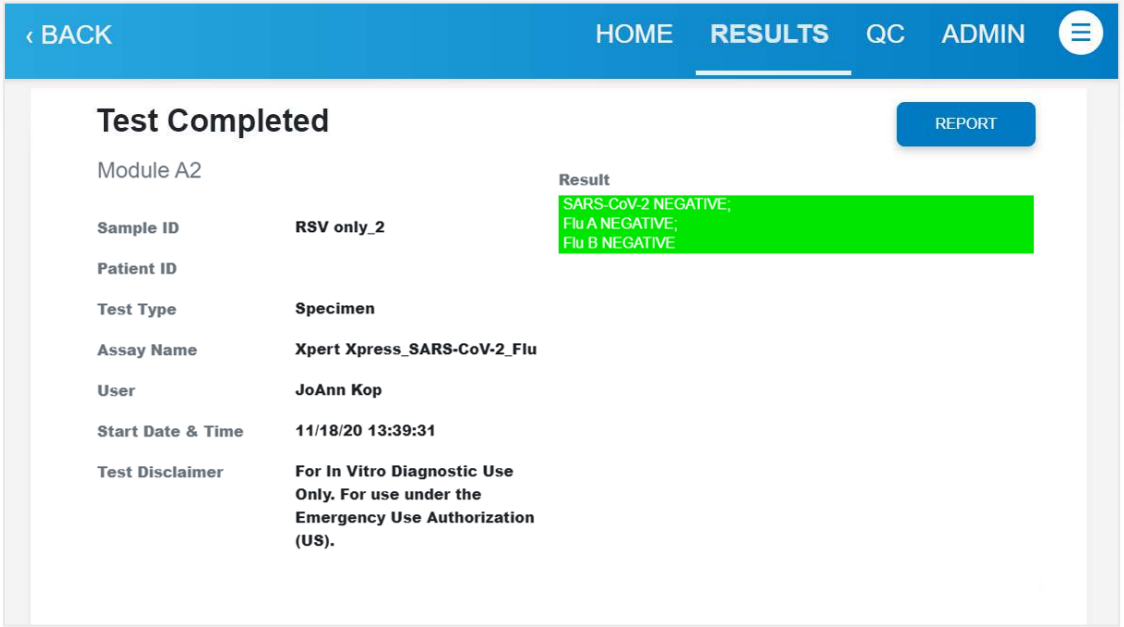


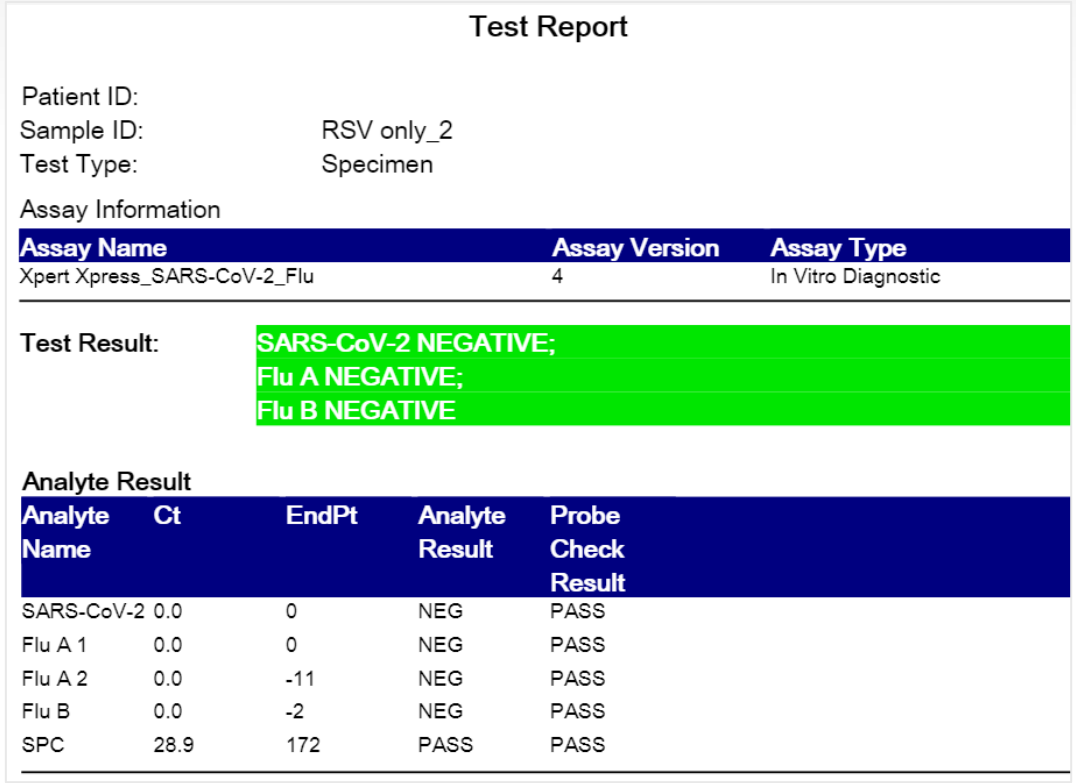
- SARS-CoV-2 target RNA is not detected
- Flu A target RNA is detected
- Flu B target RNA is not detected
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2, FLU A, FLU B NEG

Result

SARS-CoV-2 NEGATIVE;
Flu A NEGATIVE;
Flu B NEGATIVE





Test Report

Patient ID:
Sample ID: RSV only_2
Test Type: Specimen

Assay Information

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

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	0	NEG	PASS
Flu A 1	0.0	0	NEG	PASS
Flu A 2	0.0	-11	NEG	PASS
Flu B	0.0	-2	NEG	PASS
SPC	28.9	172	PASS	PASS

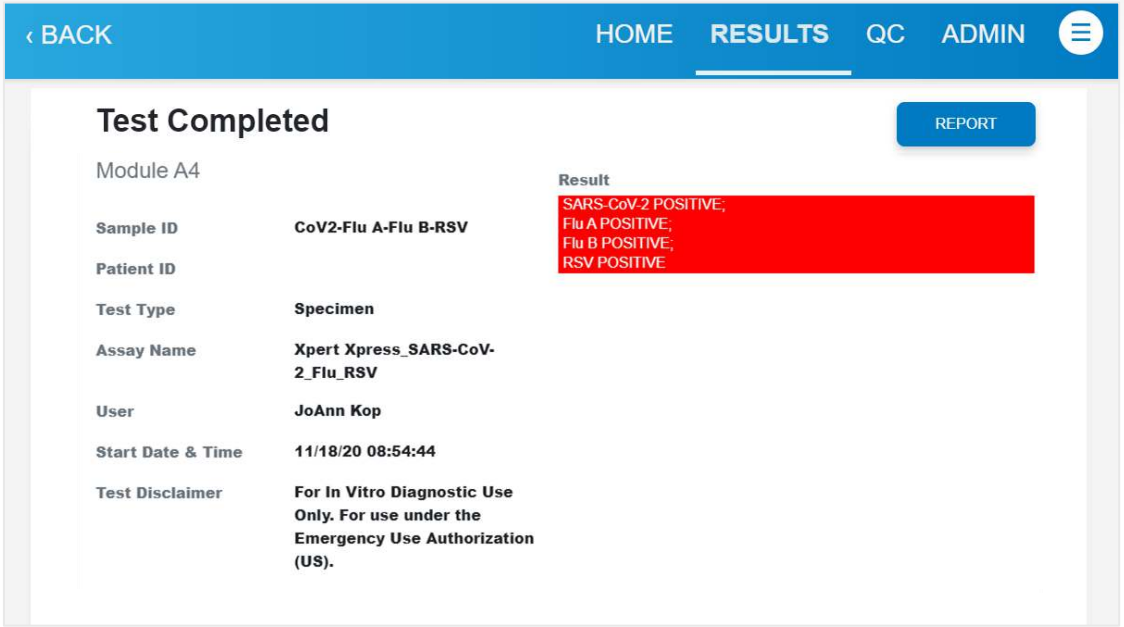
- SARS-CoV-2 target RNA is not detected
- Flu A target RNA is not detected
- Flu B target RNA is not detected
- SPC: PASS; SPC has a CT within the valid range and endpoint above the minimum setting
- Probe Check: PASS; all probe check results pass

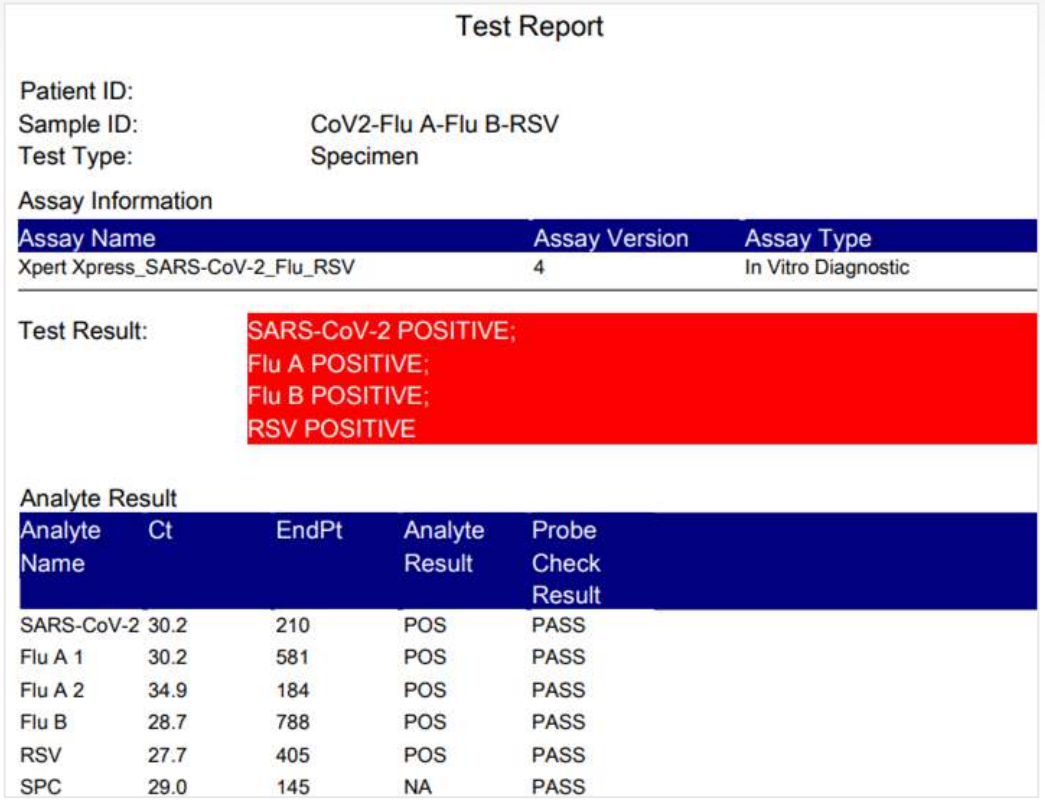
Results Summary: Xpress SARS-CoV-2, Flu, RSV ADF

Result Displayed	SARS-CoV-2	Flu A1	Flu A2	Flu B	RSV	SPC
Flu A POSITIVE	–	+	+/–	–	–	+/–
Flu A POSITIVE	–	+/–	+	–	–	+/–
Flu B POSITIVE	–	–	–	+	–	+/–
RSV POSITIVE	–	–	–	–	+	+/–
SARS-CoV-2 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

SARS-CoV-2, FLU A, FLU B, RSV POSITIVE

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



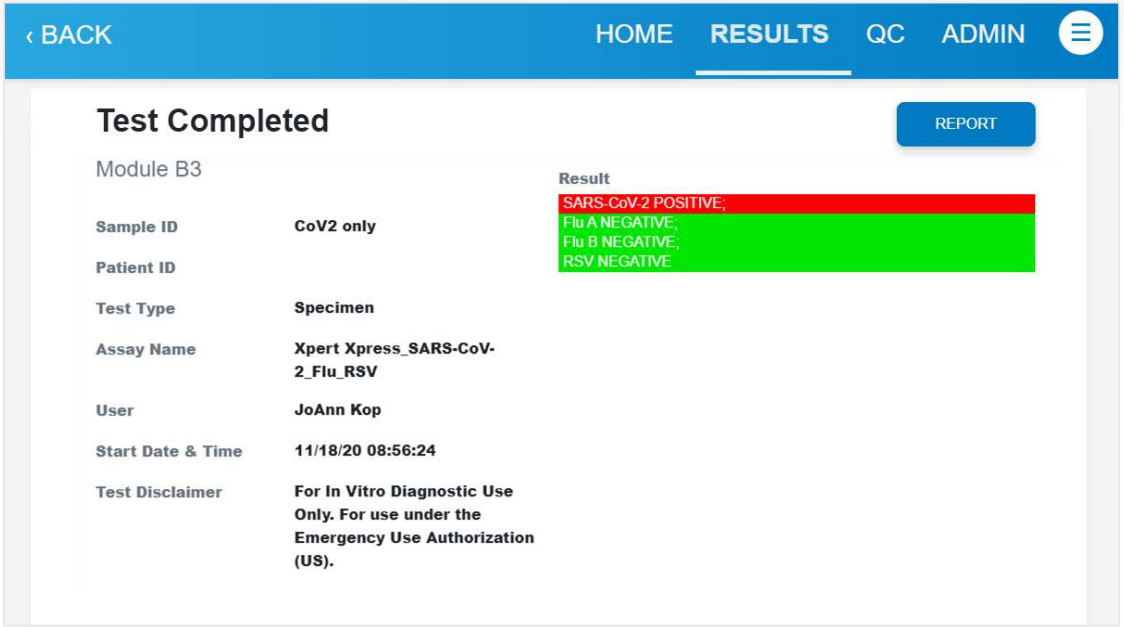


- SARS-CoV-2 target RNA is detected
- Flu A target RNA is detected
- Flu B target RNA is detected
- RSV target RNA is detected

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

SARS-CoV-2 POS, FLU A, FLU B, RSV NEG

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



Test Report

Patient ID:
Sample ID: CoV2 only
Test Type: Specimen

Assay Information

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

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	30.5	241	POS	PASS
Flu A 1	0.0	1	NEG	PASS
Flu A 2	0.0	-1	NEG	PASS
Flu B	0.0	1	NEG	PASS
RSV	0.0	0	NEG	PASS
SPC	28.8	170	NA	PASS

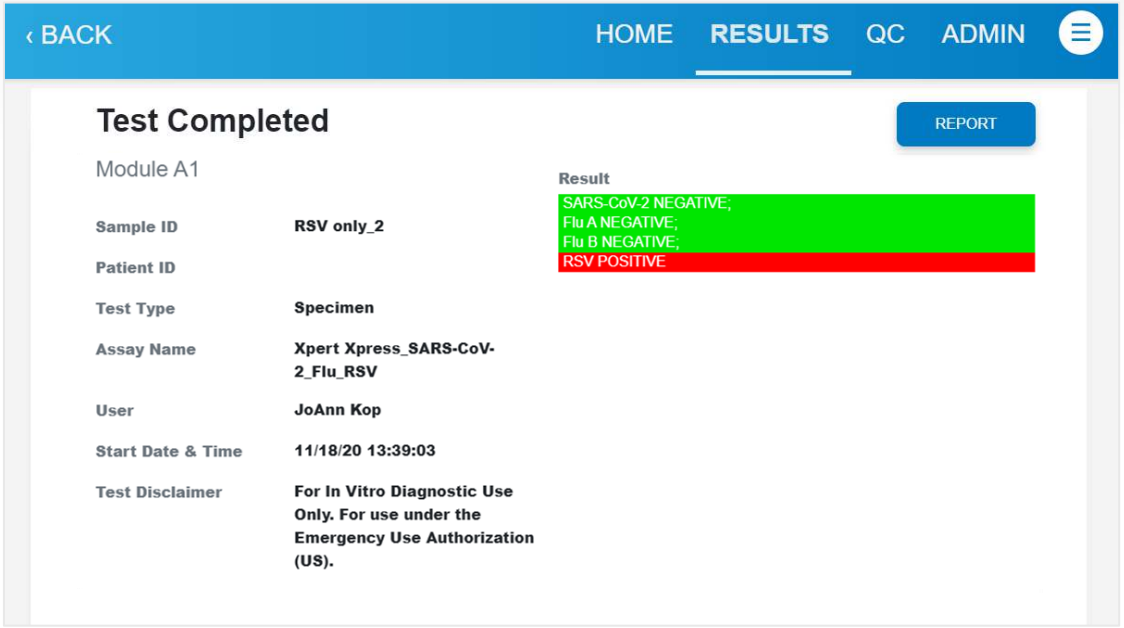
- SARS-CoV-2 target RNA is detected
- Flu A target RNA is not detected
- Flu B target RNA is not detected
- RSV target RNA is not detected

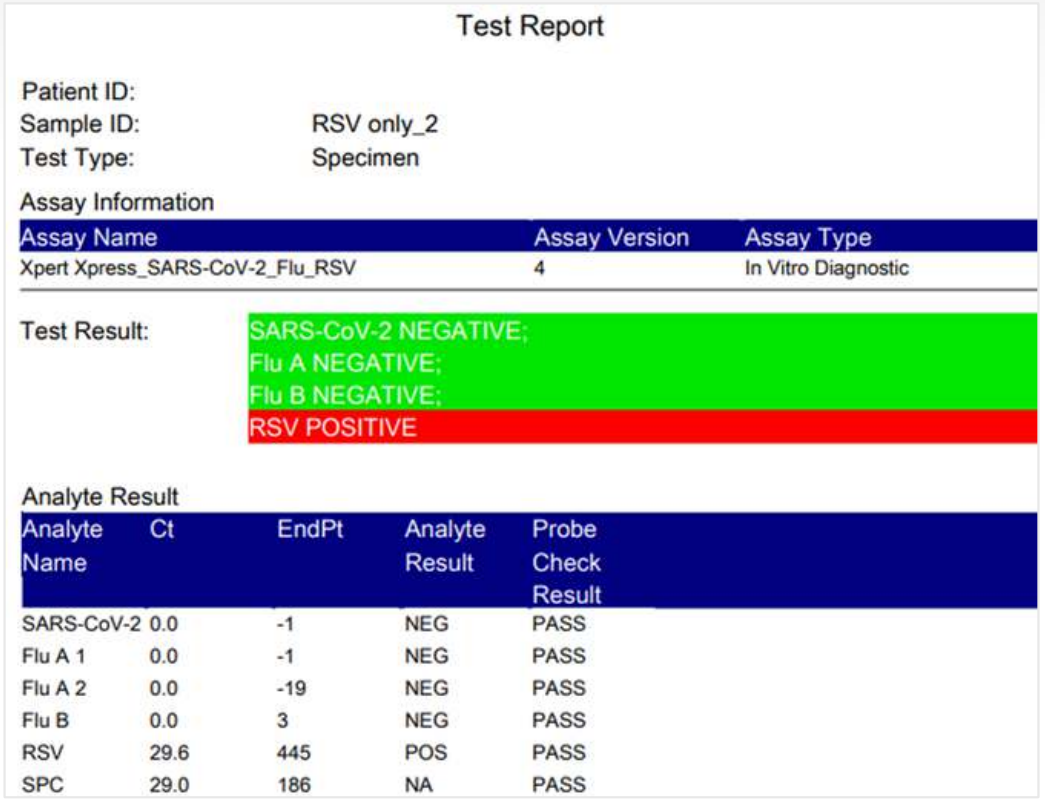
- SPC: NA; SPC is ignored because target amplification occurred
- Probe Check: PASS; all probe check results pass

SARS-CoV-2, FLU A, FLU B NEG, RSV POS

Result

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





Test Report

Patient ID:
Sample ID: RSV only_2
Test Type: Specimen

Assay Information

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

Test Result:

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

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
SARS-CoV-2	0.0	-1	NEG	PASS
Flu A 1	0.0	-1	NEG	PASS
Flu A 2	0.0	-19	NEG	PASS
Flu B	0.0	3	NEG	PASS
RSV	29.6	445	POS	PASS
SPC	29.0	186	NA	PASS

- SARS-CoV-2 target RNA is not detected
- Flu A target RNA is not detected
- Flu B target RNA is not detected
- RSV target RNA is detected

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

Limitations

- Performance of the Xpert® Xpress CoV-2/Flu/RSV *plus* test has only been established in nasopharyngeal and anterior nasal swab specimens. Use of the Xpert® Xpress CoV-2/Flu/RSV *plus* test with other specimen types has not been assessed and performance characteristics are unknown.
- The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established in all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- The performance of this device has not been assessed in a population vaccinated against COVID-19.

Limitations *(Continued)*

- As with any molecular test, mutations within the target regions of the Xpert® Xpress CoV-2/Flu/RSV *plus* 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 CoV-2/Flu/RSV *plus* 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 infectivity. 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 patients without signs and symptoms of respiratory tract infection.

Limitations *(Continued)*

- 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 of influenza B or RSV A at low concentrations (~3X LoD) when influenza A concentration is >1.7e5 RNA copies/mL or 1.7e6 RNA copies/mL, respectively. In addition, there is potential for competitive interference of influenza B at low concentration (~3X LoD) when SARS-CoV-2 concentration is >1e5 RNA copies/mL.
- 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.

Limitations *(Continued)*

- Zicam at 15% (w/v) may interfere with the detection of low levels of influenza B and RSV A.
- As the Xpert® Xpress CoV-2/Flu/RSV *plus* test does not differentiate between the N2, RdRP and E gene targets, the presence of other coronaviruses in the B lineage, *Betacoronavirus* genus, including SARS-CoV 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.
- Performance has not been established with media containing guanidine thiocyanate (GTC) other than eNAT™.

Troubleshooting

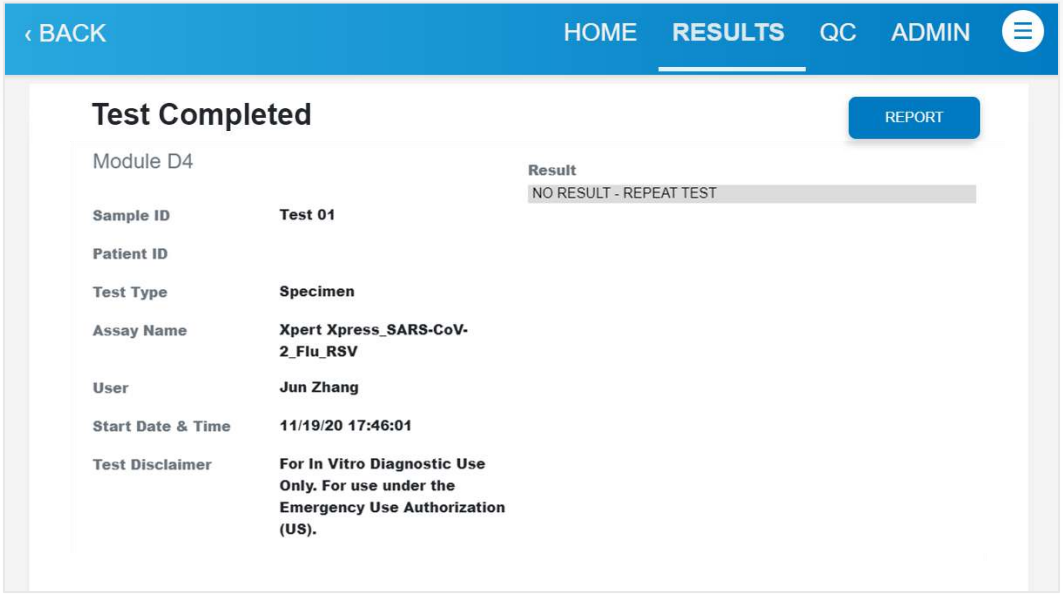
Factors That Negatively Affect Results

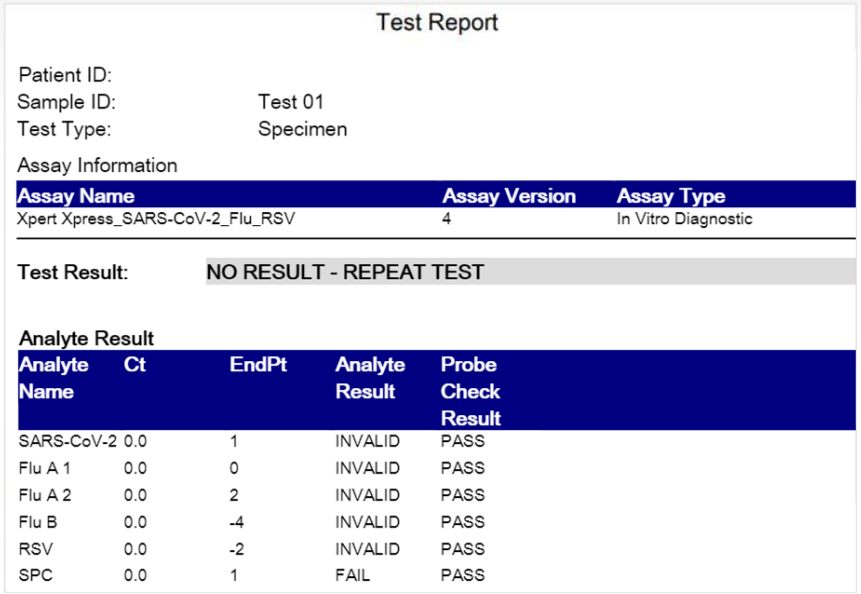
- Improper specimen collection
  - The performance of this assay with other specimen types or samples has not been evaluated
- Inadequate numbers of organisms are present in the specimen
- Improper transport or storage of collected specimen
  - Storage and transport conditions are specimen specific
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

- A “NO RESULT ” result indicates that insufficient data was collected e.g cartridge failed integrity test, the other operator stopped a test that was in progress, or a power failure occurred.
- An “ERROR” result could be due to and not limited to :Probe Check Control failure, system component failure, no sample added, or the maximum pressure limits were exceeded.
- 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.

NO RESULT - REPEAT TEST





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

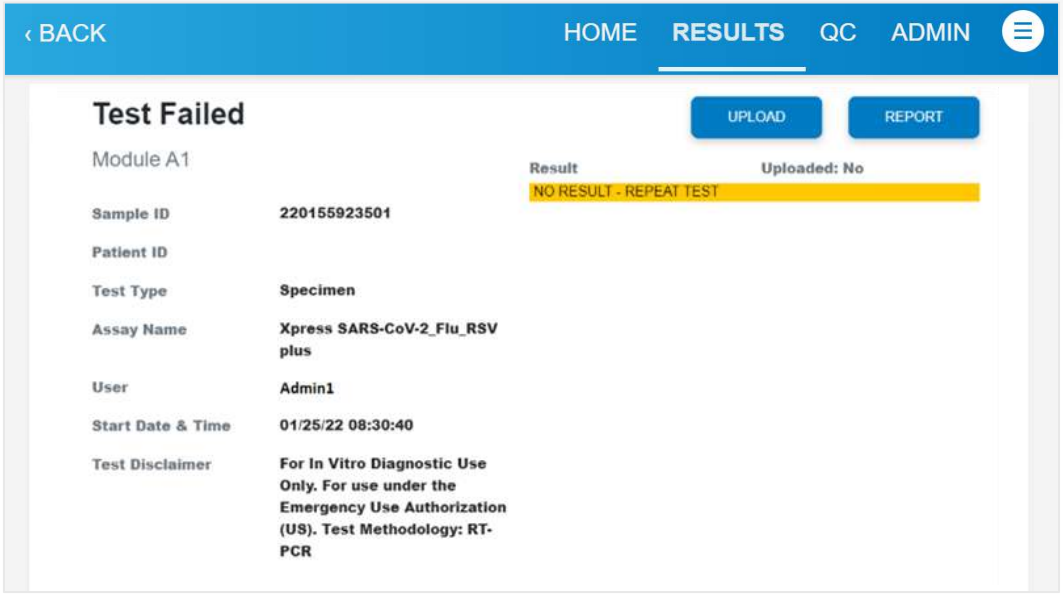
Possible causes

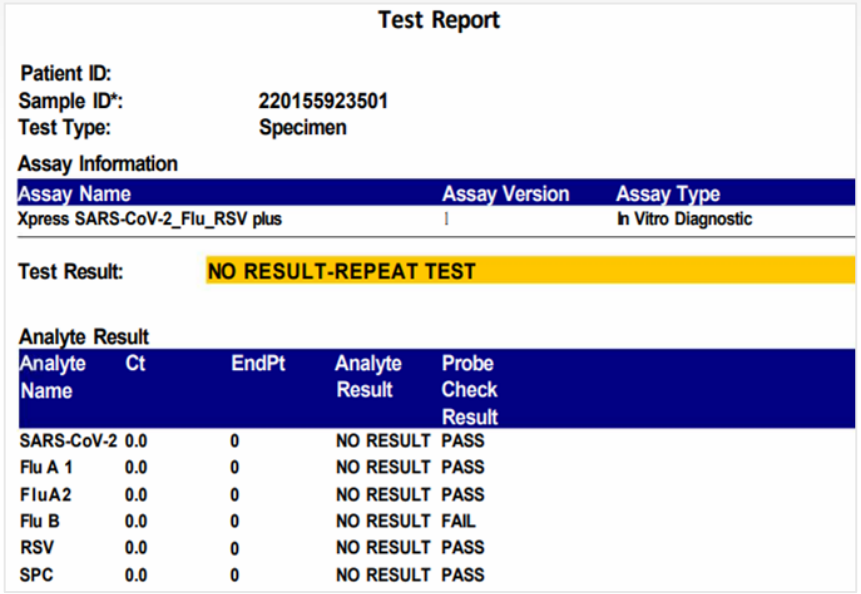
- Improper sample collection of preparation
- Presence of interfering substances in the sample

Solution

- Repeat the test with a new cartridge

NO RESULT - REPEAT TEST





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	1	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

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

Retest Procedure

1

Discard used cartridge.

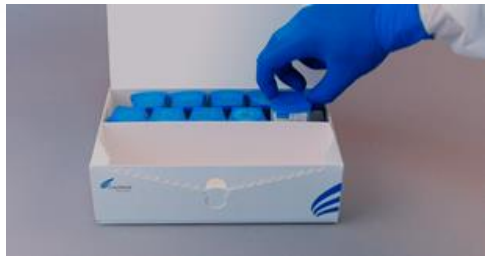
Follow your institution's safety guidelines for disposal of cartridges.

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 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.

Cepheid

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

Cepheid
A better way.