



# Respiratory Infection Specimen Collection for testing on the GeneXpert

This document outlines the intended use and specimen collection procedures for Respiratory Infection Point-of-Care (POC) testing on the GeneXpert device, under the First Nations Molecular Point-of-Care Testing Program, in accordance with the Cepheid® Xpert® Xpress CoV-2/Flu/RSV *plus* Instructions for Use.

## **Intended Use<sup>1</sup>**

The Cepheid® Xpert® Xpress CoV-2/Flu/RSV *plus* test is a rapid, multiplexed real-time RT-PCR test intended for the simultaneous 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 suspected of respiratory viral infection, consistent with COVID-19, by their healthcare provider. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2, influenza, and RSV can be similar.

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. The SARS-CoV-2, influenza A, influenza B and RSV RNA is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results are indicative of active infection, 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.

Testing with the Xpert Xpress CoV-2/Flu/RSV *plus* test is intended for use by trained operators who are proficient in performing tests using GeneXpert Dx, as part of the First Nations Molecular POC Testing Program.

## **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.

All respiratory samples for testing on the GeneXpert must be collected using collection materials provided by the First Nations Molecular POC Testing Program:

- Copan eNAT – 2mL Nucleic Acid Preservation Medium
- Specimen Collection swab

Once transferred to the Copan eNAT, all patient samples can be stored at room temperature (<25°C) or between 2-8°C for 28 days.

<sup>1</sup> Xpert® Xpress CoV-2/Flu/RSV *plus* Instructions for Use, 302-8927, Rev.C, October 2023



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The following instructions and images for both Nasopharyngeal and Nasal swab collection are taken from the Cepheid® **Xpert® Xpress CoV-2/Flu/RSV plus Instructions for Use** (302-8927, Rev. C, October 2023).

### **Nasopharyngeal Swab Collection Procedure**<sup>1</sup>

1. Insert the swab into either nostril, passing it into the posterior nasopharynx (see Figure 1).



Figure 1. Nasopharyngeal Swab Collection

2. Rotate swab by firmly brushing against the nasopharynx several times.
3. Remove and place the swab into the tube containing 2mL of Copan eNAT
4. Break swab at the indicated break line and cap the specimen collection tube tightly.

### **Nasal Swab Collection Procedure**<sup>1</sup>

1. Insert a nasal swab 1 to 1.5cm into a nostril. Rotate the swab against the inside of the nostril for 3 seconds while applying pressure with a finger to the outside of the nostril (see Figure 2).



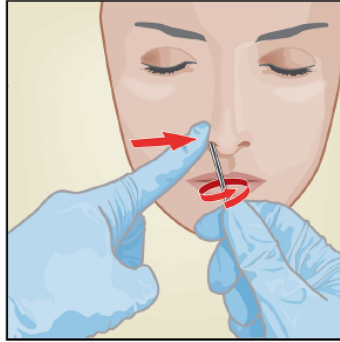
Figure 2. Nasal Swab Collection for First Nostril

<sup>1</sup> Xpert® Xpress CoV-2/Flu/RSV plus Instructions for Use, 302-8927, Rev.C, October 2023



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2. Repeat on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). To avoid specimen contamination, do not touch the swab tip to anything other than the inside of the nostril.



**Figure 3. Nasal Swab Collection for Second Nostril**

3. Remove and place the swab into the tube containing the 2mL of Copan eNAT. Break swab at the indicated break line and cap the specimen collection tube tightly.

<sup>1</sup> Xpert® Xpress CoV-2/Flu/RSV *plus* Instructions for Use, 302-8927, Rev.C, October 2023