Lab Dept: Microbiology & Molecular Diagnostics

Test Name: SARS-CoV-2 RNA DETECTION

General Information

Lab Order Codes:	COVC
Synonyms:	Severe Acute Respiratory Syndrome coronavirus-2, COVID-19, 2019 novel coronavirus, 2019-nCoV, Respiratory viruses, PCR for SARS-CoV-2, PCR for COVID-19
CPT Codes:	U0003 – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies 87635 – Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique
Test Includes:	Rapid detection SARS-CoV-2 in upper respiratory tract infections by Reverse Transcription Polymerase Chain Reaction (RT-PCR) paired with Real time PCR. **NOTE:** The Cepheid Xpert Xpress RT-PCR Assay was issued an Emergency Use Authorization (EUA) by the FDA. **NOTE:** The DiaSorin Molecular Simplexa COVID-19 Direct RT-PCR Assay was issued an Emergency Use Authorization (EUA) by the FDA on March 19, 2020.

Logistics

Lab Testing Sections:	Microbiology & Molecular Diagnostics
Phone Numbers:	MIN Lab: 612-813-5866 STP Lab: 651-220-6555
Test Availability:	Specimens accepted daily, 24 hours
Turnaround Time:	Cepheid: 1 hour from receipt in the lab (Minneapolis or St Paul) DiaSorin: ≤24 hours from receipt in Minneapolis lab
Special Instructions:	Requisition must state specific date/time of collection

Specimen

Specimen Type:

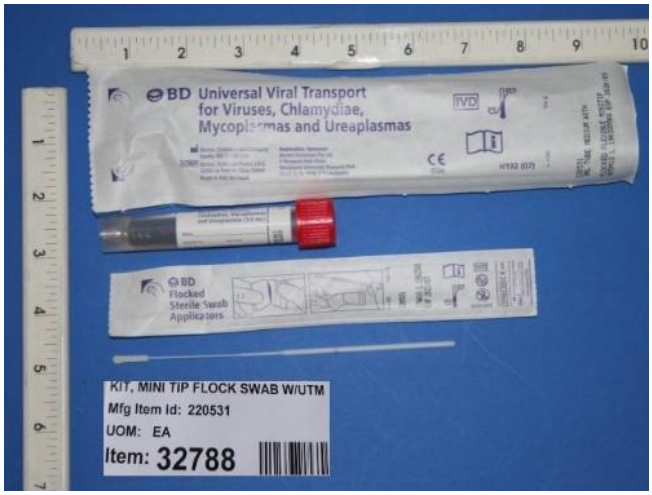
Preferred Sample:
Flocked Minitip Nasopharyngeal (NP) swab in Universal Transport Media (UTM)

Alternative Sample:
Flocked Regular Nasal swab in Universal Transport Media (UTM)

Container:

Flocked Flexible Minitip NP Swab in 3 mL Universal Transport Media (UTM)

CHC # 32788 Kit, Mini Tip Flock Swab w/UTM



Alternative Sample:

Flocked Regular Nasal Swab in 3 mL Universal Transport Media (UTM)

CHC number: 32720, Kit, Regular Flock w/UTM

Volume:

1 Flocked Flexible Minitip Nasopharyngeal (NP) swab in 3 mL UTM
OR
1 Flocked Regular Nasal swab in 3 mL UTM

Collection:

.

Nasopharyngeal swab:

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 score-line.
4. Gently insert the swab into the nostril until you touch the posterior nasopharynx. Rotate the swab several times.(See Figure 1)

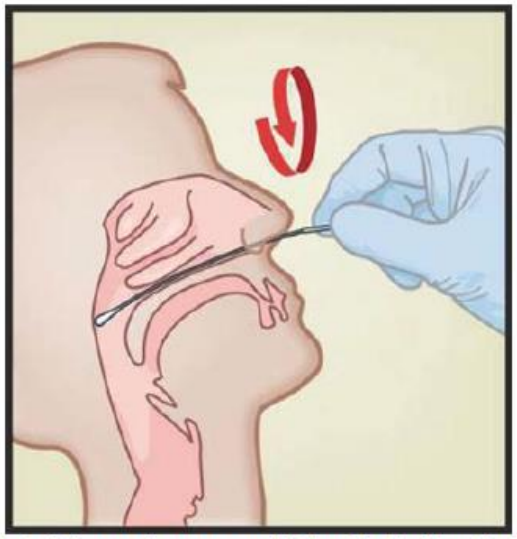


Figure 1. Nasopharyngeal Swab Collection

5. Remove 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 transport to the lab.

Nasal swab:

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 score-line.
4. Insert a nasal swab 1 to 1.5 cm 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

5. Repeat of 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.

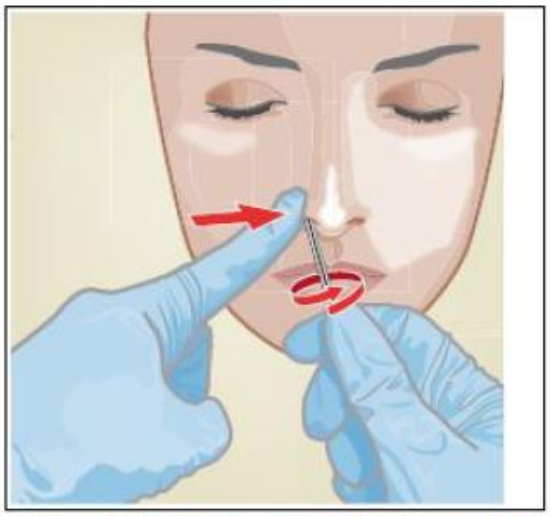


Figure 3. Nasal Swab Collection for Second Nostril

6. Remove 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 transport to the lab.

Storage/Transport

Transport to the laboratory immediately to maintain specimen integrity. Specimens can be stored refrigerated temperatures (2-8 °C) for 7 days.

Sample Rejection:

Samples collected with any other swab or collection device other than listed above; improperly labeled samples, leaking containers. If an unacceptable specimen is received, the patient's caregiver will be notified and another specimen will be requested before the specimen is discarded.

Interpretive

Reference Range: Negative

Alert Value Positive results will be phoned to the patient's Caregiver from perioperative services including CVOR. Positive results will not be phoned to inpatient units, ED or clinics.

Limitations: **Cepheid Xpert Xpress SARS-CoV-2 *plus* Assay**

● The Xpert Xpress SARS-CoV-2 *plus* Assay was issued an Emergency Use Authorization (EUA) by the FDA on March 20, 2020**.**
● Performance of the Xpert Xpress SARS-CoV-2 *plus* test has only been established in nasopharyngeal swab and anterior nasal swab specimens. Use of the Xpert Xpress SARS-CoV-2 *plus* test with other specimen types has not been assessed and performance characteristics are unknown.
● Performance of Xpert Xpress CoV-2 *plus* for asymptomatic screening population has only been established in anterior nasal swab specimens. Specimen types other than anterior nasal swab have not been assessed and performance characteristics are unknown.
● Nasopharyngeal swab and anterior nasal swabs samples collected in saline should not be frozen.
● The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with 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 or treated with COVID-19 therapies.
● Negative results do not preclude SARS-CoV-2 and should not be used as th4e sole basis for treatment or other patient management decisions.
● Results from the Xpert Xpress CoV-@ *plus* test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluation the patient.
● As with any molecular test, mutations within the target regions of Xpert Xpress CoV-2 *plus* could affect primer and/or probe binding and result in failure to detect the presence of virus.
● The test cannot rule out disease 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 collections, handling, and storage procedure; technical error or sample mix-up. Careful compliance with the instructions in this insert is necessary to avoid erroneous results.

● Viral nucleic acid may persist *in vivo*, independent of infectivity. Detection of analyte targets does not imply that the corresponding virus 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 organisms 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
● The effect of interfering substance has only been evaluated for those listed within the

labeling. Interference by substances other than these described can lead to erroneous results.
●The E gene targets by the Xpert Xpress CoV-2 *plus* test can detect in addition to SARS-CoV-2, other coronavirus species within the *Sarbecovirus* subgenus. .
● Cross-reactivity with respiratory tract organism other than those described herein can lead to erroneous results.

DiaSorin Molecular Simplexa COVID-19 Direct Assay

● For Emergency Use Authorization Only use only.
● For in vitro diagnostic use.
● For professional use only.
● Testing of nasal swabs even if collected by a healthcare provider is limited to patients with symptoms of COVID-19.
● Not for screening.
● False-negative results may occur if the viruses are present at a level that is below the analytical sensitivity of the assay or if the virus has genomic mutations, insertions, deletions, or rearrangements or if performed very early in the course of illness.
● As with other tests, false-positive results may occur. Repeat testing or testing with a different device may be indicated in some settings.
● This test is a qualitative test and does not provide the quantitative value of detected organisms present.

Methodology: Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) and Real-time PCR.

References:

Zou L, Ruan F, Huang M, et al. SARS-CoV-2 viral load in upper respiratory specimens of infected patients. 2020

Xu X-W, Wu X-X, Jiang X-G, et al. Clinical findings in a group of patients infected with the 2019 novel coronavirus (SARS-Cov-2) outside of Wuhan, China: retrospective case series. 2020;368

Lai C-C, Shih T-P, Ko W-C, Tang H-J, Hsueh P-RJIjoaa. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and corona virus disease-2019 (COVID-19): the epidemic and the challenges. 2020:105924.

Simplexa COVID-19 Direct Package Insert, REF: MOL4150, Rev. 05. In. Cypress, CA: DiaSorin Molecular

World Health Organization: Coronavirus. https://www.who.int/health-topics/coronavirus

Centers for Disease Control and Pevention: Coronavirus. https://www.cdc.gov/coronavirus/general-information.html

Cheng ZJ, Shan JJI. 2019 Novel coronavirus: where we are and what we know. 2020:1-9

Centers for Disease Control and Prevention: Coronavirus Disease 2019 (COVID-19)

US Department of Health and Human Services PHS/CDC/NIH. Biosafety in microbiology and biomendical laboratories. In. Washington DC: Government Printing Office, 2007

Wayne P. MM3-A2 Molecular diagnostic methods for infectious disease; approved guideline, 2nd ed. In. Clinical Laboratory Standards Institute, 2006

Simplexa COVID-19 Positive Control Pack Package Insert, REF: MOL4160, Rev. 01. In. Cypress, CA: DiaSorin Molecular

Xpert Xpress SARS-CoV-2/Flu/RSV Package Insert, 302-4421, Rev.C, January 2021, Sunnyvale CA: Cepheid

Influenza (Flu) Atlanta GA: Centers for Disease Control and Prevention; 2019 [Available from https://www.cdc.gov/flu/index.html]

Respiratory Synctial Virus Infection (RSV) Atlanta, GA: Centers for Disease Control and Preventiohn; 2018 [https://www.cdc.gov/rsv/index.html]
Xpert Epress SARS-CoV-2 Package Insert, 3023562, Rev D, August 2020. In. Sunnyvale, CA: Cepheid

Updates:

4/14/2020: Alert value update to include notification of patient's caregiver.
4/22/2020: Updated Limitations section.
5/1/2020: Updated CPT code
5/11/2020: Updated for testing on STP campus
7/14/2020: Added information for DiaSorin instrument testing.
11/11/2020: Updated collection methods, method info
1/7/2022: Updated to new *plus* test/assay.