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:

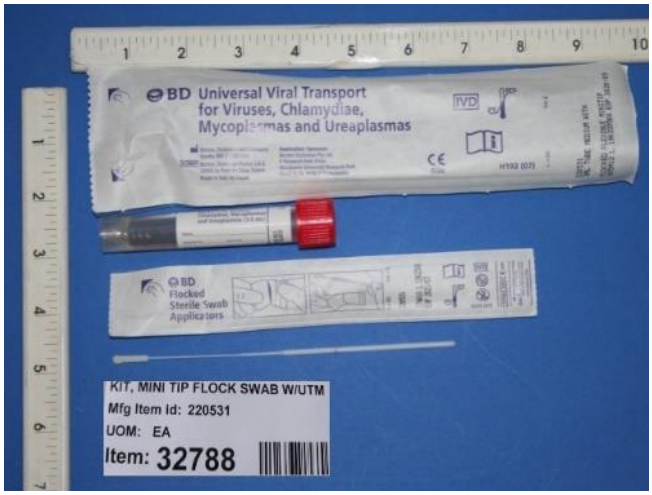
Preferred Sample:
Flocked Minitip Nasopharyngeal (NP) swab in Universal Transport Media (UTM)

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:

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

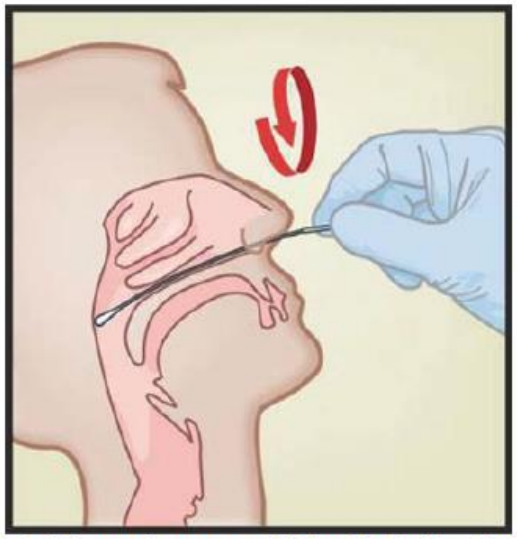

Figure 1. Nasopharyngeal Swab Collection

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 scoreline.
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.

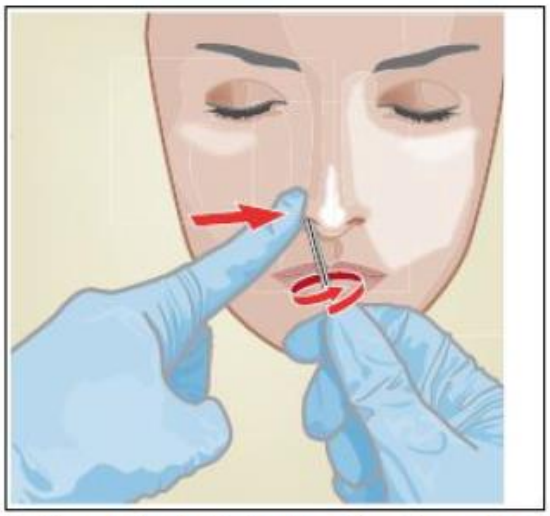

Figure 3. Nasal Swab Collection for Second Nostril

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.

Limitations:

Cepheid Xpert Xpress SARS-CoV-2 Assay

● The Xpert Xpress SARS-CoV-2 Assay was issued an Emergency Use Authorization (EUA) by the FDA on March 20, 2020**.**
● Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test 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.
● Oropharyngeal, nasal swabs and mid-turbinate 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 test but performance with these specimen types has not been established by the manufacturer.
● The effect of interfering substances has not been evaluated for this test. Because of assay similarities, refer to the Xpert Xpress Flu/RSV Assay package insert for a list substances tested. 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.
● A false negative result may occur if a specimen is improperly collected, transported or handled. False negative results may also occur if inadequate numbers of organisms are present in the specimen.
● As with any molecular test, mutations within the target regions of Xpert Xpress SARS-CoV-2 could affect primer and/or probe binding resulting in failure to detect the presence of virus.
● A presumptive positive result may indicate SARS-2-CoV-2 viral nucleic acids are present near the Limit of Detection or a cross-reaction with Human (SARS-CoV-1) or Bat SARS-coronavirus.
● This test cannot rule out diseases caused by other bacterial or viral pathogens
● 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 detection of nucleic acid from SARS-CoV-2, 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 Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner

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

● Performance of the Xpert Xpress SARS-CoV-2/Flu/RSV test 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.
● 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 listed in the instructions foruse can lead to erroneous results.
● Results from analytical studies with contrived co-infected samples showed potential for competitive interference when SARS-CoV-2, Flu or RSV was present at 1X LoD levels.
● 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.
● The performance of this device has not been assessed in a population vaccinated against COVID-19.
● 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.

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:

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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