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**Lab Dept:** Microbiology & Molecular Diagnostics

**Test Name:** SARS-COV2 RNA DETECTION (2-4 DAY TAT)

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***General Information***

**Lab Order Codes:** COVID

**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:** 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:** Detection of SARS-CoV-2 RNA in upper respiratory tract samples by Reverse Transcription Polymerase Chain Reaction. (RT-PCR) paired with Real time PCR.

**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.

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***Logistics***

**Lab Testing Sections:** Molecular Diagnostics

**Phone Numbers:** MIN Lab: 612-813-7103

**Test Availability:** Daily, 24 hours

**Turnaround Time:** 48 – 96 hours from receipt in Minneapolis lab

**Special Instructions:** Requisition must state specific date/time of collection

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***Specimen***

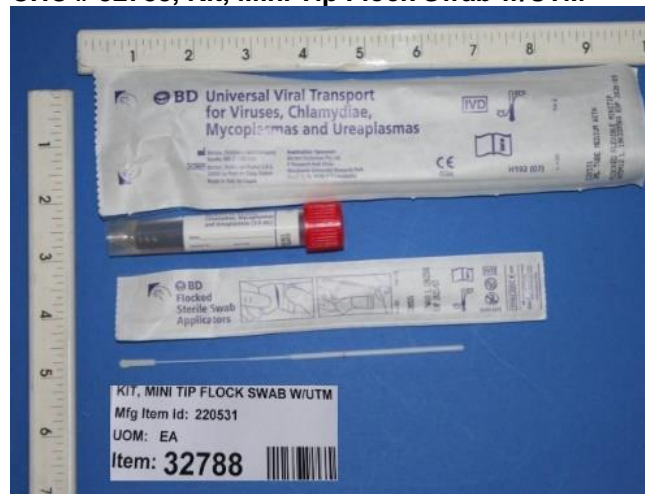
**Specimen Type:** **Preferred Sample:**  
Flocked Minitip Nasopharyngeal (NP) swab in Universal Transport Media (UTM)

**Alternate 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**



**Alternate Sample:**

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

**CHC number: 32720, Kit, Regular Flock Swab 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 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 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 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 on the other nostril with the same swab, using external pressure on the outside of the other nostril (see Figure 3). The 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 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 transport to the lab.

**Storage/Transport:**

Transport to the laboratory immediately to maintain specimen integrity. Specimens can be stored at 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.

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## ***Interpretive***

**Reference Range:** Negative

Positive results indicate the detection of SARS-CoV-2 RNA

Inconclusive results may suggest that the sample has a low level of SARS-CoV-2 RNA or a variant strain. Submission of a new specimen for testing is recommended.

Invalid results indicate that the presence or absence of SARS-CoV-2 RNA could not be determined after repeat testing in the laboratory, possibly due to RT-PCR inhibition. Submission of a new specimen for testing is recommended.

**Critical Values:** None

**Limitations:** **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 Transcription Polymerase Chain Reaction. (RT-PCR) paired with Real time PCR

**References:** Cheng ZJ, Shan JJI (2020:1-9) 2019 Novel coronavirus: where we are and what we know

Lai C-C, Shih T-P, Ko W-C, Tang H-J, Hsueh P-R, et al (2020:1059240) Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and corona virus disease-2019 (COVID-19): the epidemic and the challenges

Lieberman D, Lieberman D, Shimoni A, Keren-Naus A, Steinberg R, Shemer-Avni YJ (2009;47(11):3439-3443) Identification of respiratory viruses in adults: nasopharyngeal versus oropharyngeal sampling

Wandernoth P, Kriegsmann K, Groh-Mohanu C, et al (2020;12(8):849) Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) by Mass Spectrometry..

Wang D, Hu B, Hu C, et al (2020;323(11):1061-1069) Clinical characteristics of 138 hospitalized patients with 2019 novel coronavirus–infected pneumonia in Wuhan, China

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

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

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

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

**Updates:**

1/7/2022: Updated method/information for Diasorin Simplexa.