Lab Dept: Microbiology & Molecular Diagnostics

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

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 Multiplex Reverse Transcription Polymerase Chain Reaction Matrix-Assisted Laser Desorption Ionization – Time of Flight (RT-PCR/MALDI-TOF). **NOTE:** The performance characteristics of the Agena Bioscience SARS-CoV-2 Assay have been determined by Children's MN Laboratory. The test has not been cleared or approved by the FDA

Logistics

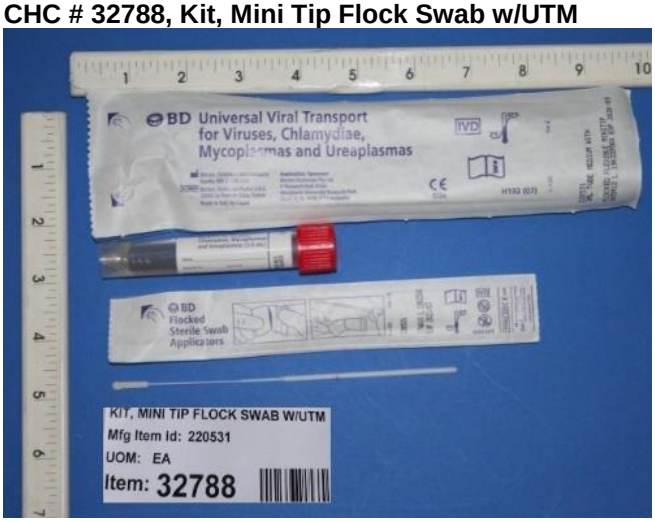
Lab Testing Sections:	Molecular Diagnostics
Phone Numbers:	MIN Lab: 612-813-7103
Test Availability:	Daily, 24 hours
Turnaround Time:	48 – 96 hours from receipt in Minneapolis lab
Special Instructions:	Requisition must state specific date/time of collection

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)

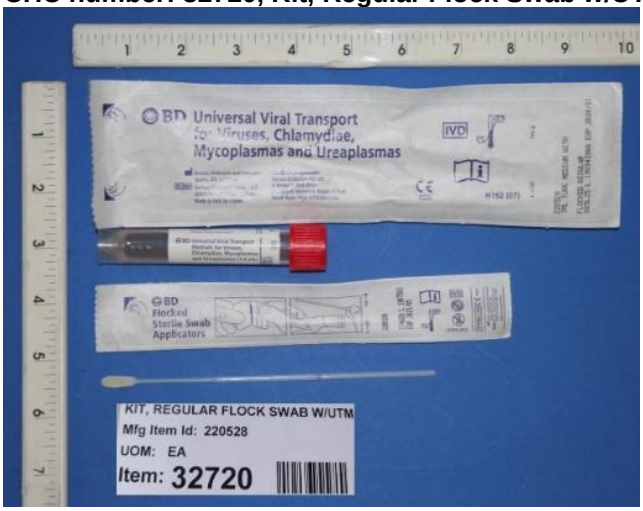
Container: Flocked Flexible Minitip NP Swab in 3 mL Universal Transport Media (UTM)

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).

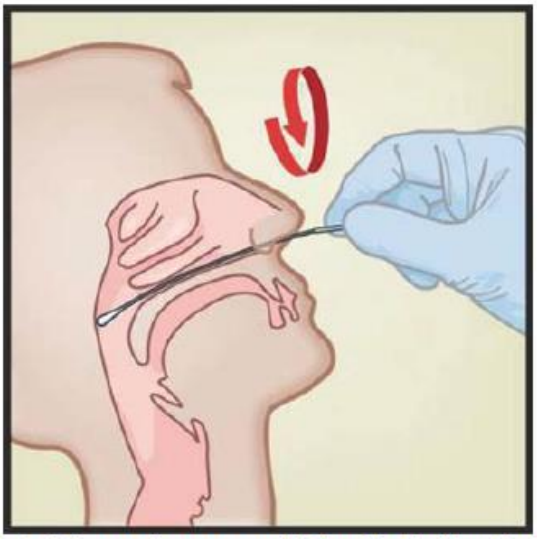


Figure 1. Nasopharyngeal Swab Collection

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 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 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.

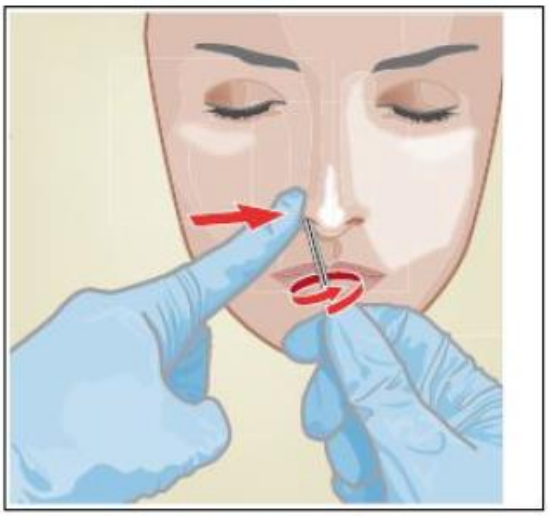


Figure 3. Nasal Swab Collection for Second Nostril

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.

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

Performance Specifications:

Nasal Samples – arbitrated results
Results (95% CI):
Positive Percent Agreement: 100% (81.47% - 100.00%)
Negative Percent Agreement: 100% (84.56% - 100.00%)
Overall Percent agreement: 100% (91.19% - 100.00%)

NP Samples – arbitrated results
Results (95% CI):
Positive Percent Agreement: 100% (82.35% - 100.00%)
Negative Percent Agreement: 95.24% (76.18% - 99.88%)
Overall Percent agreement: 97.50% (86.84% - 99.94%)

Nasal and NP Samples – overall arbitrated results
Results (95% CI):
Positive Percent Agreement: 100% (90.51% - 100.00%)
Negative Percent Agreement: 97.67% (87.71% - 99.94%)
Overall Percent agreement: 98.75% (93.23% - 99.97%)

Limit of Detection (upper respiratory matrix): 0.02 TCID50/mL

Limitations:

● The performance characteristics of the MassArray SARS-CoV-2 panel have been evaluated by Children's MN Laboratory.
● This assay may not be able to differentiate newly emerging SARS-CoV-2 subtypes.
● Analyte targets (viral sequences) 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.|
● All results from this and other tests must be considered in conjunction with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
● Samples must be collected, transported, and stored using appropriate procedures and conditions. Improper collection, transport, or storage of samples may hinder the ability of the assay to detect the target sequences.

● The performance of the SARS-CoV-2 Panel was established using nasopharyngeal swabs (NP) and Nasal (NA, Anterior Nares) samples.
● This test is a qualitative test and does not provide the quantitative value of detected organisms present.

● There is a risk of false positive values resulting from:

a. Cross-contamination by target organisms, their nucleic acids or amplified product, or from non-specific signals in the assay.
b. Cross-contamination during sample handling or preparation.
c. Cross-contamination between patient samples.
d. Sample mix up.
e. RNA contamination during product handling.

● There is a risk of false negative values due to:

a. The presence of sequence variants in the pathogen targets of the assay, procedural errors, amplification inhibitors in samples, or inadequate numbers of organisms for amplification.
b. Improper sample collection.
c. Sample mix up.
d. Degradation of the SARS-CoV-2 RNA during shipping/storage.
e. Sample collection does not collect SARS-CoV-2 RNA.
f. The presence of RT-PCR inhibitors.
g. Mutation in the SARS-CoV-2 virus.

● This test cannot rule out infections caused by other viral or bacterial pathogens not present on this panel.
● The impacts of vaccine, chemotherapeutic or immunosuppressant drugs have not been evaluated.
● Negative results do not preclude infection with SARS-CoV-2 virus, and should not be the sole basis of a patient management decision.
● This panel has been evaluated for use with human sample material only.
● The performance of this test has not been evaluated for monitoring treatment of infection.
● Upon completion of an In silico cross-reactivity analysis, it was determined that four assay components (N1 x2, N2, and ORF1ab) exhibited >80% homology to SARS-coronavirus. However, the risk of non-specific PCR amplification of SARS-coronavirus is low.

Methodology: Multiplex Reverse Transcription Polymerase Chain Reaction Matrix-Assisted Laser Desorption Ionization – Time of Flight (RT-PCR/MALDI-TOF)

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-RJIjoaa (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 YJJocm (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

Multiplex RT-PCR/MALDI-TOF (2020) test intended for the qualitative detection of nucleic acid from SARS-CoV-2, IFU-CUS-001 R02. In. San Diego, CA: Agena Bioscience