Influenza SARS-CoV-2 Multiplex Assay

ANALYTES TESTED: SARS-CoV-2, Influenza A, Influenza B

USE OF TEST: This assay is a real-time RT-PCR multiplexed test intended for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A virus and/or influenza B virus.

SPECIMEN COLLECTION AND SUBMISSION GUIDELINES:

Test Request Form MDHHS-5895
Specimen Submission Guidelines
Transport Temperature: 4°C with ice pack or frozen with dry ice.
DO NOT send at room temperature.
Patient Preparation: None

SPECIMEN TYPE:

Specimen Required: Nasopharyngeal swabs in viral transport medium, PBS or Amies; Nasal swabs in viral transport medium, PBS or Amies; OP swabs in viral transport medium, PBS or Amies; Nasal aspirates; Sputum; bronchoalveolar lavage.

Minimum Acceptable Volume: Swabs – Elute in viral transport medium (3mL preferred), PBS/Saline (3mL preferred), Amies Transport Media.

Container: Sterile Polypropylene tube with screw cap.
Shipping Unit: Unit 45

SPECIMEN REJECTION CRITERIA:

Critical Data Needed for Testing: Specimens lacking two unique patient identifiers (i.e, full name and date of birth, patient number or specimen number) will not be tested.
Specimens received unrefrigerated will not be tested.
Leaking specimens are unacceptable for testing and will be resulted as such.

TEST PERFORMED:

Methodology: real time RT-PCR
Turn Around Time: up to 1 week
Where/When Performed: Lansing, Weekly

RESULT INTERPRETATION:

Reference Range: SARS-CoV-2 RNA Not Detected
Influenza A RNA Not Detected
Influenza B RNA Not Detected

Reactive Result: **SARS-CoV-2 RNA Detected**.
Influenza A RNA Detected
Influenza B RNA Detected

FEES: None.

NOTES:

1. Specimens will be rejected if not in compliance with submission requirements.
2. Swabs with calcium alginate or cotton tips and wooden shafts are unacceptable.
3. Emergency Use Authorization (EUA) is needed at this time as no FDA-approved tests that identify the presence of 2019 novel coronavirus in clinical specimens are available in the United States.
4. Positive results are indicative of active infection but do not rule out bacterial infection or co-infection with other viruses.
5. Negative Flu SC2 Multiplex Assay results do not preclude SARS-CoV-2, influenza A and/or influenza B and should not be used for the sole basis for diagnosis, treatment or other patient management decision.
6. Negative results in asymptomatic individuals cannot be used as definitive evidence that an individual has not been exposed to SARS-CoV-2 or influenza viruses and has not been infected with any of these viruses.
7. Specimens received leaking will be reported as “Not Tested”.

ALIASES: FluVID, SARS-CoV-2, 2019 Novel Coronavirus, Flu A, Flu B