Frequently Asked Question about the Mount Sinai SARS-CoV-2 Assay

What do I need to know about Authorization of The Mount Sinai SARS-CoV-2 Assay?

- The Mount Sinai SARS-CoV-2 assay is authorized for use with saliva specimens, including individuals without symptoms.
- The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA).

What are the advantages of The Mount Sinai SARS-CoV-2 Assay?

- Easily accessible, non-invasive collection technique for Saliva.
- Allows self-collection, suitable for at-home sampling.
- It is highly sensitive and accurate PCR-based test with a multi-target viral RNA detection approach.
- Follows an automated workflow with a turnaround time of less than 24 hours.

How well does the The Mount Sinai SARS-CoV-2 Assay perform?

- Has been extensively validated exhibiting comparable or better performance against other commercially available testing platforms.
- **The Mount Sinai SARS-CoV-2 Assay using saliva has 100% agreement with positives and negatives compared with a common testing platform using Nasopharyngeal Swabs**
- It detects very low copies of the virus.
  - The FDA SARS-CoV-2 Reference Panel Results lists the detection assay used by our laboratory as the most sensitive RT-PCR based testing. (Limit of detection of 7.14 to 27.24 copies/mL).
- Allows specific detection of SARS-CoV-2 ORF1ab and N genes. This ensures robust results by building redundancy in the event of mutations.

*Please see the entire FDA EUA Summary at [https://www.fda.gov/media/151764/download](https://www.fda.gov/media/151764/download)*
What does it mean if the specimen tests positive for the virus that causes COVID-19?

- A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be contagious.
- The Mount Sinai SARS-CoV-2 Assay has been designed to minimize the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%.

What does it mean if the specimen tests negative for the virus that causes COVID-19?

A negative test result for this test means that SARS-CoV-2 RNA was not present in the specimen above the limit of detection.

However, a negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions. It is possible to test a person too early or too late during COVID-19 infection to make an accurate diagnosis via the Mount Sinai SARS-CoV-2 Assay. In addition, asymptomatic people infected with COVID-19 may not shed enough virus to reach the limit of detection of the test, giving a false negative result.

What happens to my saliva sample after testing is completed?

- Follows sample retention and escort policies as per New York State, College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA) guidelines.
- The specimens are only undergo testing related to SARS-CoV-2 diagnosis. The specimens are destroyed according NYS, CAP, and CLIA guidelines.