

Xpert® Xpress SARS-CoV-2 (Cepheid EUA) Testing **at the NJMS Institute of Genomic Medicine**

Assay: Real time PCR assay to detect multiple regions targeted on the viral genome to provide rapid detection of SARS-CoV-2 using Cepheid's GeneXpert® DX system. The analytical limit of detection (LOD) for this assay is 250 copies/ml.

Patients: The FDA approved Xpert® SARS-CoV-2 test should be ordered for the detection of COVID-19.

Interpretation: A **Positive** result indicates that severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test result should always be considered in the context of patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.

A **Negative** result indicates that SARS-CoV-2 is not present in the patient's specimen. However, this result may be influenced by the stage of the infection and the quality of the specimen collected for testing.

Turnaround time: Same day and 24 hour turnaround services available.

CPT Code: 87635

Specimen type: Nasopharyngeal swabs or nasal swabs in viral transport media, universal transport media or saline.

Sample Type	Collection System	Vendor	Catalog Number	Acceptable Media
Nasopharyngeal Swab	Xpert Nasopharyngeal sample collection for viruses	Cepheid	SWABB/B-100	UTM, VTM, Saline
Nasal Swab	BD BBL Culture Swab EZII	BD	220145	UTM, VTM, Saline
Nasal Swab	Copan CLASSIQSwab	Copan Fisher	164KS01	UTM, VTM, Saline



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Email: diagnostics@njms.rutgers.edu

Storage and Shipping: Store at 4C until ready for transport. Ship at room temperature by courier, FedEx or other authorized shipper.

Reporting: Results can be reported by encrypted/secure email or electronic fax.

Contact us at: diagnostics@njms.rutgers.edu or 973-972-3170 for more information.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used)

The Institute of Genomic Medicine (IGM)

The Institute of Genomic Medicine (IGM) at Rutgers New Jersey Medical School has been the most comprehensive Clinical Genomics program in New Jersey, for over 20 years, committed to translational research and bringing personalized medicine into clinical practice. We provide a solid academic base for pathology residents, genetic counseling students and hold the only ABMGG Fellowship program for Laboratory Genetics and Genomics in New Jersey.

As a leading Academic Medical Center in NJ, Rutgers NJMS IGM has worked closely with neighboring hospitals, outreach centers and physician groups. The laboratory is CLIA certified and CAP accredited, with licenses to perform testing in many states. Our resources include diagnostic lab testing, clinical care, genetic counseling and outreach services for New Jersey hospitals as well as major initiatives in education, research and technology development. As Rutgers NJMS we are committed to ensuring that all researchers, clinicians and residents of New Jersey have access to our resources and services.