exosomedx™
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The ExoDx molecular test for COVID-19

At Exosome Diagnostics, we are doing our part and stepping up to support our community and keep our patients, physicians, and community safe by offering a test for detection of the coronavirus. **We're in this together.**

The Exo COVID-19 molecular diagnostic test is available to test individuals for COVID-19. The test uses RT-qPCR to detect the presence of SARS-CoV-2, the virus that causes COVID-19. Exosome Diagnostics processes test samples in our CLIA-certified, CAP-accredited laboratory in Waltham, Massachusetts.

Quick facts about the ExoDx molecular test:

- CLIA-validated RT-qPCR detection of SARS-CoV-2 with 100% specificity and 98% sensitivity
- Limit of detection at ≤0.85 copies/µl for self-collected nasal swab (anterior nares)
- Turnaround time is 36 to 72 hours from time of sample receipt
- Ambient shipping
- MD/NP/PA signature is required for ordering
- Covered by Medicare and mandatory reimbursement by health plans under the CARES Act (The Families First Coronavirus Response Act: https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf

How to order the ExoDx COVID-19 molecular test

Our ordering process is easy – simply request kits from our Client Service team by calling **844.396.7663**, **Option 3**, then **Option 2**. Kits are shipped overnight via FedEx. Everything needed to collect and return samples is included right in the kit.

Questions? Contact us at 844.396.7663 Monday – Friday, 8:30 am – 5:00 pm ET.

To avoid delays, please ensure the following information is provided:

- Sample collection date
- Name and DOB on bar code label attached to sample
- Billing information
- Phone number and home address
- Ethnicity/sex

This test has been authorized by FDA under an Emergency Use Authorization (EUA). This test has not been FDA cleared or approved. This test has been validated by Exosome Diagnostics in accordance with the FDA's Guidance Document (Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease during the Public Health Emergency) issued. This test is only authorized for the duration of time the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection of SARS-CoV-2 virus and/or diagnosis of COVID-19 infection under section 564(b)(1) of the Act, 21 U.S.C. 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Exosome Diagnostics is certified under the Clinical Laboratory Improvement Amendments (CLIA) Act of 1988 as qualified to perform high-complexity clinical testing. CLIA number: 22D2093470

Exosome Diagnostics, Inc. | 266 Second Ave., Suite 200, Waltham, MA 02451
844-EXOSOME (844-396-7663) | **tests@exosomedx.com** | **exosomedx.com** | CLIA #: 22D2093470 | EXOMAF-158

Frequently Asked Questions

Is this a diagnostic test or an antibody test?

This is a diagnostic test for the detection of SARS-CoV-2:

- A diagnostic viral test tells you if you currently have an infection with SARS-CoV-2, the virus that causes COVID-19.
- An antibody test tells you if you previously had an infection with SARS-CoV-2, the virus that causes COVID-19. his type of test is also called a serological test.

What does it mean if I have a positive result?

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

What does it mean if I have a negative test result?

A negative test result means that the virus that causes COVID-19 was not found in your sample. For COVID-19, a negative test result for a sample collected while a person has symptoms usually means that COVID-19 did not cause your recent illness. However, it is possible for this test to give a negative result that is incorrect (false negative) in some people with COVID-19. This means that you could possibly still have COVID-19 even though the test is negative.

This may be due to the fact that there is not enough detectable virus in your system or if the sample was collected incorrectly.

If this is the case, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you. It is important that you work with your healthcare provider to help you understand the next steps you should take.

How long is the test good for?

The results of the test reflects that moment in time. You may test negative on one day and become exposed the next day. It is up to you and your physician how often you should be tested. There are guidelines for various settings.

Is this test FDA-approved?

Exosome Diagnostics is running the CDC assay which has been granted Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration for detection of SARS-CoV-2 virus.

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What is the limit of detection of the test?

The limit of detection (LoD) was defined as the lowest viral copy number that would be detected at least 19 times out of 20 replicates. The LoD of the assay was found to be ≤0.85 copies per microliter sample.

Can the medical professional stand 6 feet away while an individual is collecting the sample in the office?

The nasal swab sample can be self-collected in the presence of healthcare professional while maintaining physical distancing. We also recommend PPE per your standard office protocol.

How far does the nasal swab need to be inserted in the nose?

The swab should be inserted such that the flocked tip is able to meet gentle resistance, approximately ½ inch on the inside of the nostril. Do not force the swab any further into the nose. See Instructions for Use (IFU) for visual graphic representation.

What ICD-10 code should I use for this test?

Exosome Diagnostics cannot recommend a specific code to use. Below are listed the most common ICD-10 codes related to Covid-19 testing, and these can be located on the Test Requisition Form. This is not an all-inclusive list. The physician will need to determine why the test is being ordered and choose the appropriate DX code:

U07.1	2019-n Cov acute respiratory disease
Z03.818	Encounter for observation for suspected exposure to other biological agents ruled out
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases
Z11.59	Encounter for screening for other viral disease
R05	Cough
R06.02	Shortness of breath
R50.9	Fever unspecified