

COVID-19: HEALTHCARE PROVIDER TESTING GUIDE

TEST INFORMATION

The test is offered in the US only.

Test name and test code

Test names: SARS-CoV-2 (N gene detection)

Test code: COVID-19 [EXAS1002]

Testing methodology

Real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens. Two primary steps:

1. Extraction of viral RNA from patient specimens
2. One-step reverse transcription and PCR amplification with primer and probe sets that are specific to regions of the SARS-CoV-2 RNA genome.

Who can order the Exact Sciences test for COVID-19?

The test must be ordered by a physician or other authorized healthcare provider from an organization that has a fully executed client bill agreement with Exact Sciences Laboratories. The test is intended for use with patients who meet the current guidance for evaluation of COVID-19 infection.

Where is the Exact Sciences test for COVID-19 performed?

All testing is performed in Exact Sciences Laboratories' two labs in Madison, WI. These laboratories are certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing. CLIA numbers: 52D2072838 and 52D2162828

ORDERING

How to order the Exact Sciences test

A completed test requisition is required for every specimen submitted to Exact Sciences Laboratories. We encourage these requisitions to be submitted electronically. Please speak with your Account Managers for more information about ordering options.

Ordering supplies

Exact Sciences Laboratories can provide nasal collection supplies if needed. Please contact your dedicated Account Manager if you need specimen collection supplies.

SPECIMEN COLLECTION

Onsite Specimen Collection

Specimens collected at healthcare organizations can be collected by a trained healthcare provider directly following the institution's standard procedure. If using the nasal specimen collection supplies provided by Exact Sciences Laboratories, self-collection by the patient with oversight from a healthcare provider is also an option.

Specimen type

The following specimen types are acceptable:

- Nasopharyngeal (NP) specimen collected by a health care professional
- Oropharyngeal (OP) specimen collected by a healthcare professional
- Mid-turbinate specimen by onsite self-collection or healthcare professional (using a flocked tapered swab)
- Anterior nares (Nasal) specimen by onsite self-collection or healthcare professional (using a flocked swab, round foam swab, or spun fiber swab)

Please note that Exact Sciences Laboratories cannot accept specimens collected with wooden handles, calcium-alginate swabs, or cotton-tipped swabs.

Specimens should be collected into viral or universal transport media, Amies, or RNase free Normal saline.

SARS-CoV-2 (N gene detection)

Real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in respiratory specimens. Two primary steps:

- Extraction of total nucleic acids from specimen
- One-step reverse transcription & PCR amplification with real-time detection using primers and probes specific for the SARS-CoV-2 N gene and human RP gene.

SARS-CoV-2 Test from Exact Sciences

This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

*COVID-19 Test Home Collection Kit from Everlywell

This home collection kit has not been FDA cleared or approved. This home collection kit has been authorized by FDA under an EUA. This home collection kit has been authorized only for the home collection and maintenance of nasal swab specimens as an aid in detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This home collection kit in combination with the authorized test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

Collection Methods

- Specimens should be collected using methods recommended by the FDA and CDC
- If using Exact Sciences specimen collection supplies, instructions are provided in Nasal Swab Collection Instructions (Healthcare Professional) that accompany the supplies
- Securely cap specimen in the collection tube
- Label specimen with patient name, date of birth, date of collection, and time of collection—all elements required for testing
- Place tube in a bio-hazard bag with absorbent pad

Alternative collection method

The SARS-CoV-2 (N gene detection) Test may be used with the Everlywell COVID-19 Test Home Collection Kit to self-collect nasal swab specimens when determined to be appropriate by a healthcare provider.*

For more information about the Everlywell COVID-19 Test Home Collection Kit, please ask your Account Manager or the Exact Sciences Laboratories COVID-19 Response team at 844-870-8870. The Everlywell kit requires a different process for ordering, obtaining, distributing, collecting, and resulting the COVID-19 test.

SPECIMEN HANDLING AND DELIVERY

Handling requirements

- For specimens that will arrive at the lab for testing within 72 hours of collection, refrigerate specimen to 2-8°C or chill with ice packs in a cooler
- For specimens that will not arrive at the lab within 72 hours of collection, freeze specimen at $\leq -70^{\circ}\text{C}$ immediately after collection

Delivery address

Samples should be couriered or shipped overnight to:

Exact Sciences Laboratories
650 Forward Drive
Madison, WI 53711
(Hand deliveries should go to Dock 12 and ring the doorbell, semi truck deliveries should go to Dock 14)

Ship specimens overnight as UN 3373 Biological Substance, Category B, in accordance with the current edition of the International Air Transport Association (IATA) Dangerous Goods Regulation.

Preferred drop-off times are:

11:30 am - 12:00 pm, 2:30 - 3:00 pm and 8:30 - 9:00 pm
Laboratory Operating hours are Sunday-Saturday 24 hours

Please note: UPS/FedEx/others do NOT deliver on Sundays. We recommend shipping Monday-Thursday. For samples collected Friday and Saturday, please follow the preparation requirements for transportation in the section above.

TEST RESULTS

Ordering providers can receive results through an online portal, secure electronic interface, or fax.]

For all positive results, a call will be placed to the ordering provider at the phone number indicated on the test requisition form.

All positive results will be reported to state health departments in accordance with communicable disease reporting requirements.

BILLING

Billing process

All tests processed by Exact Sciences Laboratories will follow the billing terms outlined in the agreement between the organization ordering the test and Exact Sciences Laboratories.

EXACT SCIENCES LABORATORIES INFORMATION

Schedule for processing tests: Sunday – Saturday, variable times

Support contact information: If you have any questions regarding the Exact Sciences test for COVID-19, please reach out to our support team at: **844-870-8870**

COMMON DIAGNOSIS CODES ASSOCIATED WITH COVID-19:

This section is not intended to replace the medical judgment of the ordering provider. The ordering provider is responsible for patient diagnosis. Ordering providers should report the diagnosis code(s) that best describes the reason for performing the test.

- Z20.828 For cases where there is an actual exposure to someone who is confirmed or suspected (not ruled out) to have COVID-19, and the exposed individual either tests negative or the test results are unknown
- Z11.59 For asymptomatic individuals who are being screened for COVID-19 and have no known exposure to the virus, and the test results are either unknown or negative
- For patients presenting with any signs/symptoms associated with COVID-19 (such as fever, etc.) but a definitive diagnosis has not been established
 - R05 Cough
 - R06.02 Shortness of breath
 - R50.9 Fever, unspecified

ADDITIONAL RESOURCES ABOUT COVID-19:

[Coronavirus.gov](https://www.cdc.gov/coronavirus)

CDC RESOURCES:

[CDC Situation Summary](#)

[About Coronavirus](#)

[Information for Healthcare Professionals](#)

[Information for Laboratories](#)