

COVID-19: CUSTOMER GUIDE OUTLINE

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 COVID19 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

If your organization has the correct supplies to collect a sample intended for Exact Sciences Laboratories to process, please complete and submit the test requisition form for each sample.

Ordering supplies

To request collection supplies for samples you will send to Exact Sciences Laboratories per your agreement, please contact your dedicated Account Manager.

A completed test requisition form must be submitted for each sample.

SPECIMEN COLLECTION

Who collects specimen?

Specimens can only be collected at the healthcare organization where the patient was seen and from which the test is ordered.

How to collect specimen

Please review the Nasal Swab Collection Instructions.

A completed test requisition form must be submitted for each sample.

Can clients use own supplies for specimen collection?

Yes. Supplies to use:

- 1 tube of viral Transport Media (UTM) (universal transport media, Amies, or RNase free Normal saline is acceptable)
- 1 nasopharyngeal sterile swab (preferred) - oropharyngeal is acceptable if a nasopharyngeal swab is not possible

Acceptable alternative supplies: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2#troubleobtainingviraltransport>

Exact Sciences Laboratories cannot accept swabs with wooden handles, calcium-alginate swabs or cotton-tipped swabs.

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.

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.

Specimen type

Nasopharyngeal (NP) specimen is preferred. When collection of a nasopharyngeal swab is not possible, the following are acceptable alternatives:

- An oropharyngeal (OP) specimen collected by a healthcare professional, or
- A nasal mid-turbinate (NMT) swab collected by a healthcare professional or by onsite self-collection (using a flocked tapered swab), or
- An anterior nares specimen collected by a healthcare professional or by onsite self-collection (using a round foam swab).
- For nasal swab, a single polyester swab with a plastic shaft should be used to sample both nares.

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

TRANSPORTATION

Preparation requirements for specimen transportation:

- Ensure all steps have been completed per the Nasal Swab Collection Instructions (Healthcare Professional)
- Securely recap the collection tube
- Place tube in a bio-hazard bag with absorbent pad
- Refrigerate specimens if they will be received by ES Labs for testing within 72 hours of collection. Freeze specimens at $\leq -70^{\circ}\text{C}$ if specimens will not be received by ES Labs within 72 hours of collection.

To send specimens:

Samples should be couriered or shipped overnight to:

Exact Sciences Laboratories
650 Forward Drive
DOCK14
Madison, WI 53711

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.

RESULTS

How results are communicated

For all positive results, Exact Sciences Laboratories will place a call to the ordering provider at the phone number indicated on the test requisition form.

Exact Sciences Laboratories reports positive results 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](#)