

Test Performed By

Northwest Genomics Center University of Washington School of Medicine Genome Sciences Box 355065 3720 15th Ave NE Seattle, WA 98195-5065

NWGC SARS-CoV-2 (COVID-19) Qual PCR Lab Report

Participant Name John Doe
Participant Date of Birth 2020-01-01
Specimen Identifier CCCCCCC
Date Sample Submitted 2020-03-14
Date Sample Tested 2020-03-25

Specimen Type Midnasal, self-collected

Result of SARS-CoV-2 (COVID-19) Qual PCR

Unable to be tested

Please Note:

- The type of sample and testing used in this project is conducted as part of a public health surveillance program in partnership with King County and other agencies. The testing you have received is not a substitute for receiving personal medical care by a healthcare provider.
- **Specimen Chain of Custody:** The specimen tested was self-collected, self-labeled, and submitted to SCAN by mail or delivery service. It was not collected, labeled, and transported by a licensed healthcare professional. This may impact test results and false negative results cannot be excluded. Follow-up clinical testing may be warranted.
- **Specimen collection device:** The mid-turbinate swab is not an FDA/CDC Emergency Use Authorization (EUA) approved specimen type. Therefore, not detected/negative results may not exclude SARS-CoV-2 infection.
- "Positive" results may be verified by the Washington State Department of Health. This result should be discussed with your healthcare provider if you have questions.
- If your test says "Not detected" it means that SARS-CoV-2 was not detected in our laboratory.

No test is perfect and there is a small chance that you do have the SARS-CoV-2 virus that causes COVID-19 with a negative test. This test does not use the standard way of collecting specimens by a health care provider, and the sample was sent by mail or delivery service, not collected and transported in a healthcare setting. Regardless of your test result, it's best to stay home when you feel sick, and avoid contact with other people. If you have other health problems or are very sick or are worried about your illness, you should contact your healthcare provider. If your symptoms persist, you should discuss getting another test for COVID-19 with your health care provider.

• If your test says "Inconclusive" it means that our laboratory test results for the SARS-CoV-2 target are not certain.

No test is perfect and there is a chance that an inconclusive result could mean that you do have the SARS-CoV-2 virus that causes COVID-19. This test does not use the standard way of collecting specimens by a health care provider, and the sample was sent by mail or delivery service, not collected and transported in a healthcare setting. Regardless of your test result, it's best to stay home when you feel sick, and avoid contact with other people. If you have other health problems or are very sick or are worried about your illness, you should contact your healthcare provider. If your symptoms persist, you should discuss getting another test for COVID-19 with your health care provider.



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• If your test says "Unable to be tested" it means that there was either not enough of the specimen or there was an error in the test process.

Since testing was unable to be performed, there is a chance that you do have the SARS-CoV-2 virus that causes COVID-19. This test does not use the standard way of collecting specimens by a health care provider, and the sample was sent by mail or delivery service, not collected and transported in a healthcare setting. Regardless of your test result, it's best to stay home when you feel sick, and avoid contact with other people. If you have other health problems or are very sick or are worried about your illness, you should contact your healthcare provider. If your symptoms persist, you should discuss getting another test for COVID-19 with your health care provider.

- Positive tests (shown as "DETECTED" or "Virus Detected") will be reported to the appropriate state and county Health Department by the testing facility. You DO NOT need to report these results yourself. Public Health may follow up with you if your test is positive for novel coronavirus to ask you about your illness and people you may have come in contact with.
- You can print out or email these test results to your health care provider.

Methodology of SARS-CoV-2 (COVID-19) Qual PCR:

This assay is designed to detect SARS-CoV-2 using reverse-transcription PCR. This assay relies on amplification of the viral genome segments Orf1B and S with an internal human RNaseP amplification control. This test was developed and its performance characteristics determined by the University of Washington's Northwest Genomics Center. This laboratory developed test is validated and has been submitted to the US Food and Drug Administration for Emergency Use Authorization. The FDA's independent review of the test validation is pending. This laboratory is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high complexity clinical laboratory testing.

For further provider information, please see these links provided by the Washington State Department of Health:

- Patients with confirmed or suspected COVID-19¹
- Patients who were exposed to a confirmed COVID-19 case²
- Unexposed patients with COVID-19 symptoms³

Additional resources are available at the Washington State Department of Health and CDC websites:

- https://www.doh.wa.gov
- https://www.cdc.gov/coronavirus/2019-ncov/index.html

¹https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/COVIDcasepositive.pdf

²https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/COVIDexposed.pdf

³https://www.doh.wa.gov/Portals/1/Documents/1600/coronavirus/COVIDconcerned.pdf