

FREQUENTLY ASKED QUESTIONS

Bio-Rad SARS-CoV-2 Droplet Digital PCR (ddPCR[™]) Test

QUESTION	ANSWER
What is your test's name?	Bio-Rad SARS-CoV-2 ddPCR [™] Test
What does your test measure/detect?	The test is a triplex assay that detects two regions of the SARS-CoV-2 N gene (N1 & N2) and the human Rpp30 gene, which is used as an internal control.
What technology does your test use?	Bio-Rad ddPCR
What differentiates your test platform from other technologies?	Recent studies have shown that ddPCR-based testing is more sensitive than qPCR, specifically in the reduction of false negative results. ^{1,2}
When will your test be available?	The test was made available on April 6, 2020.
What is your testing turnaround time?	If the specimen is received in the lab prior to 2:30 PM MT, test results should be available in 24-48 hours.
What are your laboratory certifications?	The Biodesix Boulder, Colorado laboratory is a CLIA/CAP accredited, ISO 13485 certified and NYS CLEP approved high-complexity clinical laboratory.
Is the test FDA emergency use authorized?	Yes, the Bio-Rad SARS-CoV-2 ddPCR test received EUA authorization on May 1, 2020. ³
What is the test performance?	The test demonstrates 100% accuracy with the CDC FDA EUA authorized molecular test. ³
What is your test capacity?	Biodesix's current test capacity is 2,400 tests per day. Biodesix plans to scale capacity as the need arises.
What is the list price of your test?	The test list price is \$100.

QUESTION	ANSWER
How will billing be performed?	Biodesix will bill the client for all third-party contracts for testing.
Do you provide sample collection kits?	Biodesix has the ability to provide sample collection kits upon request.
What sample types are you accepting for testing?	Biodesix will accept and process any respiratory samples including, nasopharyngeal (NP), BAL, saliva, sputum, at home nasal swabs, anterior nasal, mid-turbinate and oropharyngeal (OP).
What are your sample collection protocols?	Please follow the recommendations for sample collection outlined by the CDC. ⁴
What are your sample storage protocols?	Store samples at 2-8°C for up to 72 hours after collection. If a delay in shipping is expected, store samples at -70°C or below. ⁴
How are samples shipped to your laboratory?	Samples will be shipped to the Biodesix laboratory by courier or FedEx. Biodesix will work with your institution to coordinate a shipping schedule and pickup location.
What are your sample shipping requirements?	Please refer to the <i>Biodesix SARS-CoV-2 ddPCR Testing Specimen Collection, Packaging, and Shipping Requirements</i> document for more information.
Does your laboratory accept samples on the weekend?	Biodesix accepts samples 7 days per week from 8 AM to 4 PM.
What are the criteria for sample rejection?	Biodesix will make every effort to process each sample received, except in cases where the received sample is compromised (broken, leaking, low volume of transport media).
What are the potential test results?	<p><i>Positive:</i> at least one of the two regions within the SARS-CoV-2 N gene was detected.</p> <p><i>Negative:</i> neither of the two regions in the SARS-CoV-2 N gene was detected.</p> <p><i>Invalid:</i> neither of the two regions in the SARS-CoV-2 N gene were detected and the control gene was NOT detected.</p>
How will test results be reported?	Test results will be electronically delivered in a batch to the primary site contact with a description of the test performed and results provided.

References

1. Suo, T et al. ddPCR: a more sensitive and accurate tool for SARS-CoV-2 detection in low viral load specimens. medRxiv (preprint). <https://doi.org/10.1101/2020.02.29.20029439> 2. Dong, I et al. Highly accurate and sensitive diagnostic detection of SARS-CoV-2 by digital PCR. medRxiv (preprint). <https://doi.org/10.1101/2020.03.14.20036129> 3. Bio-Rad SARS COV-2 ddPCR Test FDA Emergency Use Authorization Instructions for Use (<https://www.fda.gov/media/137579/download>) 4. CDC. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19) <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>