FREQUENTLY ASKED QUESTIONS

Platelia Sars-Cov-2 Total Ab Test

QUESTION	ANSWER
What is your test's name?	Bio-Rad Platelia SARS-CoV-2 Total Ab Test
What does your test measure/detect?	The Platelia SARS-CoV-2 Total Ab test detects total antibody as indicative of an adaptive immune response to SARS-CoV-2 infection in individuals suspected of SARS-CoV-2 infection. The Platelia SARS-CoV-2 Total Ab assay detects the presence of IgM, IgA, and/or IgG antibodies but does not identify each separately.[1]
What testing methodology is used?	The Platelia SARS-CoV-2 Total Ab test uses a recombinant SARS nucleocapsid protein in a one-step antigen capture format, Enzyme-Linked Immunosorbent Assay (ELISA), intended for the qualitative detection of total antibodies (including IgM/IgA/IgG) to SARS-CoV-2 in human serum and plasma EDTA.[1]
What is the tests intended use?	The Platelia SARS-CoV-2 Total Ab assay is intended for use eight days after the onset of symptoms as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The test should not be used to diagnose acute SARS-CoV-2 infection.[1]
Is the test FDA emergency use authorized?	Yes, the Bio-Rad Platelia SARS-CoV-2 Total Ab test received EUA authorization on April 29, 2020.[1]
What is the test performance?	Clinical evaluation demonstrated specificity greater than 99 percent and diagnostic sensitivity of 98 percent eight days after the onset of symptoms. Cross-reactivity testing demonstrated specificity of 100 percent with no reactivity against other interfering specimens including non-CoV-2 coronaviruses.[1]
What is your testing turnaround time?	The Platelia SARS-CoV-2 Total Ab test results will be available within 24 to 48 hours from receipt at the Biodesix laboratory.
What are your laboratory certifications?	The Biodesix De Soto, Kansas laboratory is a high-complexity CLIA certified, COLA accredited and NYS CLEP approved clinical laboratory.
What is your test capacity?	Biodesix's current test capacity is 14,000 tests per day. Biodesix plans to scale capacity as the need arises.
When will the test be available?	The Platelia SARS-CoV-2 Total Ab test will be available in early June.
What is the price of your test?	The price, which has been set by Medicare, is $42.13 per test
Is the test covered by insurance?	Yes, the Medicare rate is $42.13. For patients who have had COVID-19 or are suspected of having had COVID-19, the Federal Government requires that patients not have any copay, coinsurance, or deductible for the testing.

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How will billing be performed?	Biodesix is able to bill the healthcare provider, except as required by State or Federal regulations, or the patient's insurance for COVID-19 testing.
What specimen types are you accepting?	Biodesix will accept whole blood, serum and plasma EDTA specimen for testing with the Platelia SARS-CoV-2 Total Ab test.[1]
Do you provide specimen collection kits?	Yes, Biodesix provides kits to collect forty-eight whole blood specimens per shipment in EDTA tubes for testing the Platelia SARS-CoV-2 Total Ab test. Biodesix will also accept whole blood, serum, or plasma specimens collected according to the FDA EUA Instructions for Use.[1] For questions regarding specimen collection or shipment, please contact customer care at 866-432-5930, or email covidtesting@biodesix.com.
What are your specimen collection protocols?	For whole blood collection in EDTA tubes, please refer to the specific instructions in the blood tube package insert provided in the specimen collection kit. Serum or plasma specimens should be collected according to the FDA EUA Instructions for Use.[1]
How are samples shipped to your laboratory?	Specimens should be shipped to the Biodesix laboratory the same day as collection. Whole blood specimens should be shipped overnight at ambient temperature or within 24 to 72 hours on a cold pack. If specimens or cannot be shipped within 72 hours, serum or plasma should be isolated from the specimens, frozen and shipped on dry ice.
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 (e.g., broken, leaking).
Does your laboratory accept samples on the weekend?	Biodesix accepts samples 7 days per week from 8 AM to 4 PM.
What are the potential test results?	The Platelia SARS-CoV-2 Total Ab test has three potential test results: positive, negative, and equivocal. Please reference the FDA EUA Instructions for Use & Healthcare Provider Fact Sheet for more information on interpretation of results.[1,2]
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.
What are the limitations of this testing procedure?	1. Clinical diagnosis of COVID-19 should not be established based on a single test result. Follow-up and supplemental testing as well as other clinical and laboratory data should be considered. 2. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. 3. The detection of anti-SARS-CoV-2 antibodies is dependent on the presence of the analyte in the specimen. A negative or non-reactive result can occur if the quantity of antibodies for the SARSCoV-2 virus present in the specimen is below the detection limit of the assay. During the acute infection phase and/or for immunosuppressed patients, anti-SARS-CoV-2 antibodies might not be detectable. Thus, a negative result does not preclude or rule out COVID-19 infection. 4. The results obtained with this test should only be interpreted in conjunction with clinical findings, and the results from other laboratory tests and evaluations. 5. Performance characteristics of Platelia SARS-CoV-2 Total Ab have not been evaluated with specimens of serum or plasma originating from newborns or pediatric patients. 6. Platelia SARS-CoV-2 Total Ab assay can detect total antibodies specific to SARS-CoV-1 and to SARS-CoV-2, and cross-reaction is possible with MERS-CoV. 7. This test should not be used for screening of donated blood.[1]

References
1. Platelia SARS-CoV-2 Total Ab Test FDA EUA Instructions For Use (https://www.fda.gov/media/137493/download)
2. Platelia SARS-CoV-2 Total Ab Test FDA EUA Healthcare Provider Fact Sheet (https://www.fda.gov/media/137492/download)