COVID-19 TESTING

COVID-19 Test Offerings For Vaccine Development & Clinical Trial Monitoring

Biodesix is supporting the global effort to combat COVID-19 by expanding our diagnostic offerings to include three COVID-19 diagnostic tests, one molecular and two serology tests. As a trusted partner to several biopharmaceutical companies, we strive to assist our partners with laboratory developed tests for COVID-19 clinical trials for vaccine and therapeutic development. Our COVID-19 approach can be tailored to your company's research efforts with the option to order both serology and/or molecular testing. We can support your clinical trials with accurate, comprehensive, and actionable COVID-19 testing data.

	BIO-RAD SARS-COV-2 DDPCR TEST*	PLATELIA SARS-COV-2 TOTAL AB ASSAY*	SARS-COV-2 MULTI-PLEX ANTIGEN ASSAY**
TYPE	Molecular	Serology	Serology
PLATFORM/ TECHNOLOGY	Droplet Digital PCR (ddPCR)	One-step antigen capture enzyme-linked immunosorbent assay (ELISA)	Luminex immunobead
METHOD	Detects two regions of the SARS-CoV-2 N gene (N1 & N2) and the human Rpp30 gene	Nucleocaspid (N) glycoproteins	Spike (S), nucleocapsid (N), membrane (M), and envelope (E) glycoproteins
ANTIBODIES	N/A	Total immunoglobulins (IgA/ IgM/IgG) of the nucleocapsid glycoprotein	Evaluates IgG, IgM or IgA individually and/or total IgG for the indicated antigens
SAMPLE TYPE	Nasopharyngeal, anterior nasal and mid-turbinate nasal swab	Whole blood, plasma, serum	Venous serum or plasma, capillary blood on a dried blood card
APPLICATION	Detects active SARS-CoV-2 infection	Screening for previous infection	Screening for previous infection, monitor neutralizing antibodies/ immune response for clinical trials
TEST PERFORMANCE	100% concordance with the CDC assay[1] symptomatic individuals	97.5% sensitivity 99.6% specificity >8 days post symptom onset	100% sensitivity 98.1% specificity ≥12 days post symptom onset
FDA EUA AUTHORIZATION	Yes on May 1, 2020	Yes on April 29, 2020	No – for Research Use Only (RUO)

*Commercialized in collaboration with Bio-Rad Laboratories
** For research use only in collaboration with Rush University Medical Center

Please contact **bizdev@biodesix.com** for more information

MOLECULAR TEST

Bio-Rad SARS-CoV-2 ddPCR Test

The Bio-Rad SARS-CoV-2 ddPCR test is a molecular/diagnostic test that detects active COVID-19 infection and has demonstrated 100% concordance with the CDC EUA-FDA authorized assay[2]. The EUA-FDA authorized test detects two regions of the SARS-CoV-2 N gene (N1 & N2), and the human Rpp30 gene (as an internal sample control) using ddPCR[1]. In general, ddPCR is 500-1000x more sensitive than qRT-PCR[3]. For SARS-CoV-2 detection, ddPCR has proven to be more accurate in specimens with low viral loads, thus reducing false negative results[3].

Benefits of this test:

- Rapid turnaround time
- Works well with low viral load specimens
- Most sensitive technology platform on the market
- Extensive clinical validation
- Very low cross reactivity

SEROLOGY TESTS

Platelia SARS-CoV-2 Total Ab Test

The Platelia SARS-CoV-2 Total Ab Test is a serology/antibody test that detects the presence of the total immunoglobulins (IgM, IgG, and IgA) to SARS-CoV-2. This EUA-FDA authorized assay uses a recombinant SARS nucleocapsid glycoprotein in a one-step antigen capture ELISA platform to assess whether individuals been exposed to or infected with COVID-19[4]. It has demonstrated strong clinical performance with a sensitivity of 97.5% in patients tested >8 days post onset of symptoms and specificity of 99.6%[5].

Benefits of this test:

- Very high sensitivity and specificity
- Proven real-world test performance

SARS-CoV-2 4-Plex Antigen Assay

In collaboration with Rush University Medical Center, this serology/antibody assay uses a Luminex immunobead platform to evaluate IgG and/or total immunoglobulins (IgM, IgG, and IgA) for the indicated antigens to SARS-CoV-2. As opposed to EUA-FDA authorized assays that identify antibodies to only a single antigen, this test uses an algorithm that integrates the results of 4 independent antigen assays (S, N, M, and E glycoproteins), thus yielding a more accurate diagnostic result. Although this assay is RUO, it has demonstrated strong clinical test performance with a sensitivity of 100% and specificity of 98.1%[6].

Benefits of this test:

- Comprehensive assay of all 4 SARS-CoV-2 antigens, including neutralizing antibodies
- Use in vaccine clinical trials for comprehensive monitoring for vaccine response
- Stratification of convalescent plasma
- Detection of antibody isotype response
- Results can be coupled with a SARS-CoV-2 pseudovirus neutralizing assay

[1]Bio-Rad SARS-CoV-2 ddPCR Test Instruction for Use (https://www.fda.gov/media/137579/download)
[2]FDA EUA Letter of Authorization for Bio-Rad SARS-CoV-2 ddPCR Test (https://www.fda.gov/media/137576/download, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
[3]Suo t. et al. ddPCR: A more sensitive and accurate tool for SARS-COV-2 detection in low viral load specimens. Medrxiv (Mar 2020)
[4]FDA Letter of Authorization for Platelia SARS-CoV-2 Total Ab Test (https://www.fda.gov/media/137494/download, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations)
[5]Platelia SARS-CoV-2 Total Ab Test Instruction for Use (https://www.fda.gov/media/137493/download)
[6]Borgia et al. Novel serological test for immune response to SARS-CoV-2 Virus. Rush University Medical School (2020)