SCoV-2 *Detect*™ IgM ELISA

FDA Emergency Use Authorized

InBios

Innovative Diagnostics for Infectious Diseases

SCoV-2 *Detect*™ IgM ELISA is

an *in vitro* diagnostic test for the qualitative detection of IgM antibodies to SARS-CoV-2, the virus that causes COVID-19, in human serum. This marks the first FDA EUA granted for an ELISA that specifically detects IgM antibodies to SARS-CoV-2.

This test is intended for use 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 how long antibodies persist following infection and if the presence of antibodies confers protective immunity. This test should be used to diagnose acute SARS-CoV-2 infection.

Features

- Sensitivity: 92.50%
- Specificity: 98.95%
- For use in diagnosing acute SARS-CoV-2 infection
- Kit includes a 96 well plate with all necessary reagents and controls
- Tests 90 unknown specimens
- Time to result - approximately 2.5 hours

About COVID-19

COVID-19 is the infectious disease caused by the most recently discovered coronavirus; it is now a pandemic affecting many countries globally. People can catch COVID-19 from others who have the virus. The disease spreads primarily from person to person through small droplets from the nose or mouth, which are expelled when a person with COVID-19 coughs, sneezes or speaks.

Ordering Information

Catalog No.	Format	Quantity/Kit	Time to Result	Storage	Shelf Life
COVE-M	Indirect	96 wells/plate	~2.5 hours	2-8°C	9 months

For more info about this kit and other InBios COVID-19 products, visit www.inbios.com/covid-19

INBIOS INTERNATIONAL, INC.

307 Westlake Ave. N.
Suite 300
Seattle, WA 98109

Phone: 206-344-5821

E-mail:
inquiries@inbios.com

100% Manufactured in the USA

13485-2016 Certified

Please note: this test (EUA number 201866) has not been FDA cleared or approved; has been authorized by FDA under an EUA for use by authorized laboratories; has been authorized only for the detection of nucleic acid from SARSCoV-2, not for any other viruses or pathogens; and 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.