SCoV-2 *Detect*™ IgG ELISA

FDA Emergency Use Authorized & CE Marked

InBios

Innovative Diagnostics for Infectious Diseases

SCoV-2 *Detect*™ IgG ELISA

is an *in vitro* diagnostic test for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum or plasma (dipotassium EDTA) run manually or using the Dynex DSX® Automated ELISA System.

The SCoV-2 *Detect*™ IgG ELISA is intended 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. Refer to the Instructions for Use for complete details.

Features

- PPA (Sensitivity) : 91.89%
- NPA (Specificity): 98.95%
- Specimen: Human serum or plasma (dipotassium EDTA)
- Tests up to 90 unknown specimens
- No specific analyzer required-versatile for many qualified laboratories
- Authorized for use with Dynex DSX® Automated ELISA System

Dynex DSX® Automated ELISA System

Ordering Information

Catalog No.	Format	Quantity/Kit	Time to Result	Storage	Shelf Life
COVE-G	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
Web: www.inbios.com

CE

100% Manufactured in the USA

InBios is GMP compliant, FDA registered, USDA licensed and ISO 13485:2016 certified.

This product has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.

This product has been authorized only for detecting the presence of IgG antibodies to SARS-CoV-2, not for any other viruses or pathogens.

The emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.