



INTERNATIONAL, INC.

307 Westlake Ave. N.

Suite 300

Seattle, WA 98109

www.inbios.com

Tel. 206 344 5821

Fax. 206 344 5823

Frequently Asked Questions SCoV-2 *Detect*[™] IgG ELISA Kit

Regulatory Status:

InBios received an EUA for the SCoV-2 *Detect*[™] IgG ELISA Kit on June 10, 2020.

What is the EUA number for this kit? EUA 201632

What is the GMDN code for this kit? 64824

What is the intended use of this assay?

The SCoV-2 *Detect*[™] IgG ELISA Kit is an *in vitro* diagnostic test for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum. The test 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. The SCoV-2 *Detect*[™] IgG ELISA should not be used to diagnose acute SARS-CoV-2 infection.

Is a specific analyzer required? No specific analyzer is required for this assay, making it versatile and suitable for many qualified laboratories.

What is the sensitivity and specificity of this test? In performance studies, the kit demonstrates 97.8% sensitivity and 98.9% specificity.

What is the quantity per kit? The kit includes all reagents and controls required to run 90 test specimens.

What is the storage of the kit? 2-8°C

What is the shelf life of the kit? 12 months.

Where can the test be performed?

Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.

Where is the test manufactured?

The test is manufactured in the InBios facility located at 307 Westlake Ave. N., #300, Seattle, WA 98109 USA

How long does the test take to run?

Incubation time is 111 minutes. Total run time is approximately 2 1/2 hours.