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ZEUS SCIENTIFIC ANNOUNCES EUA FOR ZEUS ELISA SARS-CoV-2 TOTAL ANTIBODY TEST SYSTEM

ZEUS Scientific announced today that it has received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA) for its *in vitro* ELISA diagnostic test for the qualitative detection of total (IgG/IgM/IgA) antibodies to the SARS-CoV-2 (novel 2019) Coronavirus in human serum and plasma. This test is in stock and is readily available to all clinical laboratories.

The ZEUS ELISA SARS-CoV-2 Total Test System is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The assay utilizes a dual antigen combination of recombinant S1 receptor binding domain (RBD) viral protein and recombinant nucleoprotein for optimal performance. By detecting a total antibody response to both the Nucleocapsid and Spike SARS-CoV-2 antigens the test is uniquely positioned as an ideal serological screening assay or first tier assay in an orthogonal testing algorithm as it can detect what others may miss.

Using FDA authorized RT-PCR assays as the reference method, the ELISA test demonstrated 96.0% positive percent agreement. 98.9% negative percent agreement was

demonstrated using a cohort comprised of RT-PCR negative and pre-pandemic patient specimens. More specific details on the test system performance can be found on our website.

The SARS-CoV-2 Total Antibody Test System assay follows ZEUS's universal ELISA assay protocol. This protocol offers a high degree of flexibility with incubation times allowing for simple, efficient, and flexible automation programming on open pipetting systems. ZEUS has validated assay performance on the Dynex Technologies suite of instruments (DS2®, DSX®, Agility®). The Agility offers the highest throughput and takes advantage of the SmartKit™ Gold packaging, providing the ability to fully automate the procedure from sample to result with a throughput meeting all laboratory requirements. The new test system also includes ZEUS' proprietary SAVe Diluent, a unique component which changes color when serum is added ensuring no well is missed!

For over 40 years, laboratories have trusted ZEUS Scientific to provide high quality *in vitro* diagnostic immunoassays for numerous infectious diseases. With over 125 U.S. FDA cleared assays in our menu, our company has a proven skillset of developing, manufacturing and distributing a family of products to aid in the diagnosis of complex infectious agents including a variety of known viral pathogens. The SARS-CoV-2 Total Antibody Test System joins our previously FDA authorized SARS-CoV-2 IgG Test System offering laboratories the option to detect IgG antibodies to the SARS-CoV-2 virus.

ZEUS Scientific

Diagnostic innovation. Worldwide application.

For more information please visit ZeusCovid.com or email sales@zeusscientific.com for pricing today!

FDA EUA Disclaimer: This test has been authorized only for the presence of total antibodies against SARS-CoV-2, not for any other viruses or pathogens. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has not been FDA cleared or approved; This test 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 Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.