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ZEUS SCIENTIFIC ANNOUNCES FDA EUA APPROVAL FOR ZEUS ELISA™ SARs-CoV-2 IgG 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 IgG antibodies to the SARS-CoV-2 virus in human serum and plasma. This test is in stock and is readily available to all clinical laboratories.

The ZEUS ELISA SARS-CoV-2 IgG 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. Using EUA approved RT-PCR assays as the reference method, the ELISA test demonstrated 100% positive agreement and 99.1% negative agreement. The average days between the PCR test result and the specimen draw was 15.97 days, the earliest being 3 days. More specific details on the test system performance can be found on our website.

The SARS-CoV-2 IgG Test System assay follows ZEUS's universal ELISA assay protocol. This protocol offers a high

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degree of flexibility with incubation times allowing for simple, efficient, and flexible automation programming on open pipetting systems. ZEUS has received EUA approval to run the ZEUS ELISA SARS-SoV-2 IgG Test System manually or using the Dynex Agility® Automated ELISA System. The Agility offers high 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.

We also eagerly await the final FDA review of the EUA submitted SARS-CoV-2 Total Antibody Test System, offering laboratories the option to detect IgG, IgA and IgM antibodies to the SARS-CoV-2 virus. Both ZEUS ELISA products are in stock and ready to ship today.

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

Disclaimer: This test has been authorized only for the presence of IgG antibodies against SARS-CoV-2, not for any other viruses or pathogens. Emergency use of this test is limited to authorized laboratories. 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.