ZEUS Scientific
Diagnostic innovation. Worldwide application.

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ZEUS SCIENTIFIC ANNOUNCES NEW ZEUS ELISA SARs-CoV-2 TOTAL ANTIBODY TEST

ZEUS Scientific announced today the submission for an Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) for its *in vitro* ELISA diagnostic test for the semi-quantitative detection of IgG, IgM and IgA antibodies to the SARS-CoV-2 (novel 2019 Coronavirus) in human serum and plasma. ZEUS has notified FDA that the test has been validated according to the guidelines established for serological assays, meeting the criteria to be distributed to laboratories and is available now.

This is the third SARS-CoV-2 antibody test system released by ZEUS Scientific, the first being a rapid device for the qualitative detection of IgG and/or IgM antibodies and the second being another ELISA assay for the detection of IgG antibodies. With these three test systems available, ZEUS is positioned to work across the spectrum with facilities looking to incorporate automated antibody testing, rapid antibody testing, or those looking to incorporate an orthogonal testing algorithm for positive results to increase positive predictive value, all from the same manufacturer.

The ZEUS ELISA SARS-CoV-2 Total Antibody 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. Assay performance has been validated using FDA's current EUA guidelines. The assay utilizes a dual antigen combination of recombinant S1 receptor binding domain (RBD) viral protein and recombinant nucleoprotein for optimal performance. Using PCR as the reference method, the ELISA test demonstrated 100% clinical sensitivity and 97.1% clinical specificity. The average days between the PCR test result and the specimen draw was 15.97 days, the earliest being 3 days. Using serology as the reference method the assay achieved 98% sensitivity and 100% specificity. Combining both PCR and serology as "Clinical Truth", the ZEUS ELISA SARS-CoV-2 Total Antibody Test System yielded 98.8% sensitivity and 99.1% specificity. Additional data on the performance includes studies using normal pre-pandemic donors and pre-pandemic potentially cross-reactive donors, with specificity in these two cohorts determined to be 100%.

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' patented SAVe Diluent, a unique component which changes color when serum is added ensuring no well is missed!

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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. During these difficult times we have concentrated our focus to the COVID-19 pandemic and the SARS-CoV-2 virus. For more information please visit ZeusCovid.com or email sales@zeusscientific.com for pricing today!