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Agilent unveils immunoassay kit to detect SARS-CoV-2 antibodies

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Kit marks first of multiple planned for 2021 aimed at COVID-19

Agilent Technologies Inc. has announced the launch of the Agilent Dako SARS-CoV-2 IgG Enzyme-Linked Immunosorbent Assay (ELISA) kit intended for the qualitative detection of immunoglobulin G (IgG) antibodies to SARS-CoV-2 in human serum or plasma.

The kit, which marks Agilent's entrance into SARS-CoV-2 testing in the US, has completed the notification process to FDA in accordance with Section IV.D of FDA's "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)".

The assay is planned to be registered in other markets in 2021 including Canada, Europe, and selected Asia Pacific and Latin American countries.

The kit is a qualitative two-step indirect ELISA for the detection of human IgG antibodies to the SARS-CoV-2 S1 RBD protein. It is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

In Agilent's clinical study, the SARS-CoV-2 IgG ELISA kit is a highly accurate immunoassay with 98.9% sensitivity and 98.8% specificity.

The ELISA kit includes consumables that meet the needs for small to medium-sized clinical labs to ensure easy and sustainable access to serology tests when the demands arise. By providing a kit that contains all the necessary reagents – including negative, positive, and cut-off controls – Agilent has developed a ready-to-use solution that enables labs to consistently execute dependable SARS-COV-2 serological testing.