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Beckman Coulter launches COVID-19 test in countries accepting CE mark

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Beckman Coulter is also developing a SARS-CoV-2 antigen test and quantitative IgG assay

Beckman Coulter has announced the launch of its Access SARS-CoV-2 Immunoglobulin M (IgM) assay in countries accepting the CE Mark. The new IgM antibody test demonstrated 99.9% specificity with 1,400 negative samples and 98.3% sensitivity at 15-30 days post-symptom onset.

Beckman Coulter's IgM assay is part of a full suite of testing solutions the company is developing to inform clinical and public health decision making during the COVID-19 pandemic. Beckman Coulter is also developing a SARS-CoV-2 antigen test and quantitative IgG assay. Beckman Coulter's antibody assays and its other planned SARS-CoV-2 offerings run on the organization's award-winning immunoassay analyzers, including the DxI 800 high-throughput analyser, which is capable of processing 200 samples per hour.

The full suite of testing solutions, including the IgM & IgG assays currently available and the antigen and quantitative IgG assay under development, provide valuable information in clinical decision making for patients suffering from COVID-19. The Beckman Coulter IgM assay detects antibodies that may emerge earlier in the course of infection and then dissipate, while the IgG test detects antibodies associated with the longer-term immune response.

Beckman Coulter's assays can be performed in automated or high-throughput immunoassay formats. The Access SARS-CoV-2 IgM test can also be run on Beckman Coulter's Access 2 analyser, a compact, table-top analyser enabling high-quality serology testing to be carried out in small hospitals and clinics. Additionally, this test seamlessly integrates into laboratory workflows, making it easy to add serology testing to routine blood tests performed during inpatient and wellness testing.