Diazyme gets second EUA for COVID-19 antibody test

written by CAP TODAY
October 19, 2020

October 2020—Diazyme Laboratories announced it received FDA emergency use authorization for the Diazyme DZ-Lite SARS-CoV-2 IgM CLIA test. The test is highly sensitive and specific and does not cross-react with the HKU1, OC43, NL63, and 229E coronavirus strains.

The IgM test is typically used together with the IgG test for a more complete serology profile, the company says, and it runs on the fully automated DZ-Lite 3000 Plus chemiluminescence analyzer.

In other news, Diazyme announced a partnership with Maccura Biotechnology (USA). The companies launched an FDA EUA–approved SARS-CoV-2 RT-PCR diagnostic test.

The SARS-CoV-2 Fluorescent PCR Kit is intended for the qualitative detection of SARS-CoV-2 viral nucleic acids in upper respiratory specimens (oropharyngeal swabs, nasopharyngeal swabs, nasal swabs, and mid-turbinate swabs) from individuals suspected of COVID-19 infection.

Diazyme Laboratories, 888-342-9963