Siemens lab-based CoV2Ag test for high-throughput analyzers

Feb. 25, 2021–Siemens Healthineers announced the company's laboratory-based SARS-CoV-2 Antigen Assay obtained the CE mark; the test runs on the Atellica IM analyzer, which has the capacity to run 440 tests per hour, and the Advia Centaur XP and XPT immunoassay systems.

The CoV2Ag test on the Atellica has a sensitivity greater than 94 percent and a specificity of 100 percent. It detects the nucleocapsid antigen and has been designed with five monoclonal antibodies, with the objective to maximize its sensitivity to current and future SARS-CoV-2 variants. The pretreatment process inactivates the virus, which helps protect laboratory staff, the company says, without compromising the quality or validity of patient test results.

The CoV2Ag assay is for in vitro diagnostic use in the qualitative detection of SARS-CoV-2 in nasopharyngeal swab and nasal swab specimens within the first seven days of symptom onset, or from asymptomatic individuals. The test has been submitted to the FDA for emergency use authorization.