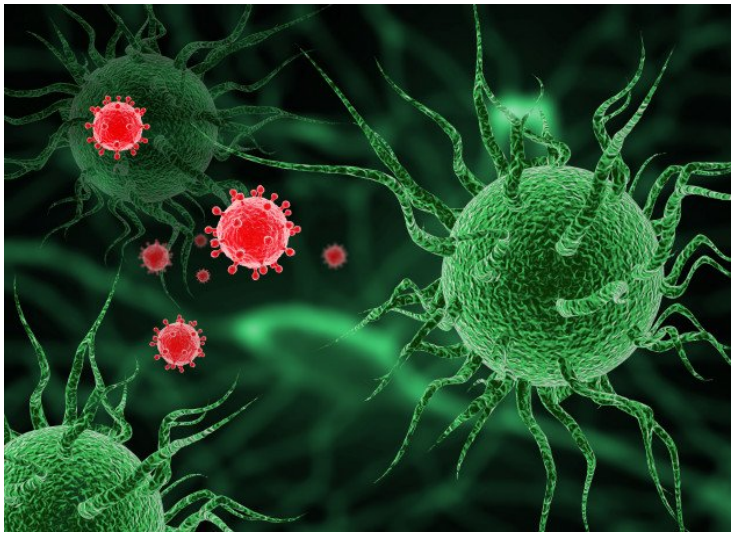
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Roche SARS-CoV-2 antigen test to support high-volume testing of COVID-19 suspects

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The ElecsysÃ?Â®Ã?Â SARS-CoV-2 Antigen test is an automated laboratory assayÃ?Â is a new solution which will run on all Roche cobas e-immunochemistry analyzers around the world, thus helping to increase testing capacity



Roche announced on 13 Oct 2020 that it intends to launch a high-volume SARS-CoV-2 Antigen test as an aid in the diagnosis of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) infection. The test is planned to be made available at the end of 2020 for markets accepting the CE Mark. Roche also intends to file for Emergency Use Authorisation (EUA) from the U.S. Food and Drug Administration (FDA).

The Elecsys® SARS-CoV-2 Antigen test is a highly accurate laboratory immunoassay for the in vitro qualitative detection of the nucleocapsid antigen of SARS-CoV-2. The test is performed by healthcare professionals and uses nasopharyngeal or oropharyngeal swab samples from patients with signs and symptoms suggestive of COVID-19, or people with either known or suspected exposure to SARS-CoV-2.

The Elecsys SARS-CoV-2 Antigen immunoassay runs on all cobas e immunochemistry analysers which are widely available around the world. These fully automated systems can provide test results in 18 minutes for a single test (excluding time for sample collection, transport, and preparation), with a throughput of up to 300 tests per hour from a single analyser, depending on the analyser. A laboratory-based automated antigen assay allows for cost and error reduction due to removal of manual handling as well as fast turn-around times and high test throughput.

The test will be another addition to the comprehensive Roche diagnostic portfolio of solutions to help healthcare systems combat COVID-19 through testing in the laboratory and at the point of care. These solutions include both tests to detect an acute SARS-CoV-2 infection and tests measuring the body’s immune response upon infection or vaccination. The following table provides an overview of Roche’s current COVID-19 test portfolio for the detection of an acute SARS-CoV-2 infection or immune response:

Roche’s Elecsys SARS-CoV-2 Antigen is highly beneficial where reliable laboratory PCR testing is not available or where there are challenges in testing capacity. A positive result with the Elecsys SARS-CoV-2 Antigen test most likely indicates an active SARS-CoV-2 infection. A negative result may require to be confirmed with a PCR test or repeated (antigen test) after one to two days, if other clinical indications point to a SARS-CoV-2 infection. Performance evaluations around sensitivity and specificity of the test are ongoing and will be shared at the time of launch.