

## Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Ortho Clinical Diagnostics
<i>Name of test</i>	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack when used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Calibrator is a chemiluminescent immunoassay test intended for the qualitative detection of IgG antibodies to SARS-CoV-2 in human serum using VITROS Eci/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. The VITROS Anti-SARS-CoV-2 IgG test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.</i></p> <p><i>At this time, it is unknown for how long antibodies persist following infection or if the presence of antibodies confers protective immunity. The VITROS Anti-SARS-CoV-2 IgG test should not be used to diagnose acute SARS-CoV-2 infection.</i></p> <p><i>Results are for the detection of SARS-CoV-2 antibodies. IgG antibodies to SARS-CoV-2 are generally detectable in blood several weeks after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.</i></p> <p><i>The sensitivity of VITROS Anti-SARS-CoV-2 IgG test in early infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is</i></p>

*necessary. False positive results for VITROS Anti-SARS-CoV-2 IgG test may occur due to cross-reactivity from pre-existing antibodies or other possible causes.*

*Date of Provisional Authorisation*

3 June 2020

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