Provisional Authorisation for COVID-19 Tests

Applicant	Ortho Clinical Diagnostics
Name of test	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack
Intended purpose (As per manufacturer's information for use)	*The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test when used in combination with the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Calibrator is for the qualitative measurement of total antibody including IgG, IgA and IgM) to SARS-CoV-2 in human serum and plasma (K2 EDTA) samples from patients suspected of COVID-19 by a healthcare provider, using VITROS ECi/ECiQ/3600 Immunodiagnostic Systems and the VITROS 5600/XT 7600 Integrated Systems. The VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test is an aid in the diagnosis of individuals with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Results from the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test should not be used as the sole basis for diagnosis.* *Results are for the detection of total SARS-CoV-2 antibodies. Reactive results could occur after infection and can be indicative of acute or recent infection.* *Non-reactive results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Results must be combined with clinical observations, patient history, and epidemiological information. The sensitivity of the VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack test early after infection is unknown. False reactive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes.* *At this time, it is unknown for how long antibodies to SARS-CoV-2 virus may persist following infection.*

Date of Provisional Authorisation	8 May 2020