Provisional Authorisation for COVID-19 Tests

Applicant	Ortho Clinical Diagnostics
Name of test	VITROS Immunodiagnostic Products SARS-CoV-2 Antigen Reagent Pack
Intended purpose (As per manufacturer's information for use)	*The VITROS Immunodiagnostic Products SARS-CoV-2 Antigen test is a chemiluminescent immunoassay intended for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasopharyngeal (NP) specimens from individuals who are suspected of COVID-19 within one to five days of the onset of symptoms using the VITROS 3600 Immunodiagnostic System and the VITROS 5600/XT 7600 Integrated Systems.* *Results are for the identification of SARS-CoV-2 nucleocapsid antigen. This antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.* *Negative results from patients with symptom onset outside of one to five days should be treated as presumptive. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.*
Date of Provisional Authorisation	4 December 2020