Provisional Authorisation for COVID-19 Tests

Applicant	Euroimmun (South East Asia) Pte Ltd
Name of test	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA)
Intended purpose (As per manufacturer's information for use)	*The enzyme immunoassay (ELISA) provides semiquantitative in vitro determination of human antibodies of the immunoglobulin class IgA against SARS-CoV-2 in serum, EDTA, heparin or citrate plasma to support the diagnosis of SARS-CoV-2 infection and constitutes a supplement to the direct pathogen detection. The determination of IgA antibodies is suited for monitoring the development of an immune response after positive direct pathogen detection. The test is not recommended for the screening of asymptomatic persons. The product is designed for use as IVD and can optionally be processed on fully automated equipment. The format 96 x 20 has been specially designed for processing on the EUROLabWorkstation ELISA.*
Date of Provisional Authorisation	28 May 2020