Provisional Authorisation for COVID-19 Tests

Applicant	EUROIMMUN (SOUTH EAST ASIA) PTE. LTD.
Name of test	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG)
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 IgG 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. Moreover, serology can be applied to collect epidemiological data. The product is designed for use as IVD. The test can be processed fully automatically.*
Date of Provisional Authorisation	28 May 2020