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 or dried blood spots (DBS) 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. The format 96 x 20 has been specially designed for processing on the EUROLabWorkstation ELISA.*
Date of Provisional Authorisation	28 May 2020