
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	EUROIMMUN (SOUTH EAST ASIA) PTE. LTD.
<i>Name of test</i>	EUROIMMUN Anti-SARS-CoV-2 ELISA (IgA)
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>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 detection. The test is not recommended for the screening of asymptomatic persons. The product is designed for use as IVD. The test can be processed fully automatically.</i>
<i>Date of Provisional Authorisation</i>	28 May 2020
