
Provisional Authorisation for COVID-19 Tests

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| <i>Applicant</i> | Siemens Healthcare Pte Ltd |
| <i>Name of test</i> | Siemens Atellica® IM SARS-CoV-2 Total (COV2T) |
| <i>Intended purpose (As per manufacturer's information for use)</i> | <p><i>The Atellica® IM SARS-CoV-2 Total (COV2T) assay is for in vitro diagnostic use in the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum and plasma (EDTA and lithium heparin) using the Atellica® IM Analyzer.</i></p> <p><i>This assay is intended as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection and as an aid in identifying patients with an adaptive immune response to SARSCoV-2, indicating recent or prior infection.</i></p> |
| <i>Date of Provisional Authorisation</i> | 29 May 2020 |
