

Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Beckman Coulter Singapore Pte Ltd
<i>Name of test</i>	ACCESS SARS-CoV-2 IgM
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The Access SARS-CoV-2 IgM is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum, serum separator tubes and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, sodium citrate). The Access SARS-CoV-2 IgM is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The Access SARS-CoV-2 IgM should not be used to diagnose acute SARS-CoV-2 infection.</i></p> <p><i>Results are for the detection of SARS-CoV-2 antibodies. IgM antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion.</i></p> <p><i>The sensitivity of the Access SARS-CoV-2 IgM assay early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.</i></p> <p><i>False positive results for the Access SARS-CoV-2 IgM assay may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second different assay. Samples should only be tested from individuals that are 8 days to 30 days post symptom onset. SARS-CoV-2 antibody negative samples collected 8 days or more post symptom onset</i></p>

should be reflexed to a test that detects and reports SARS-CoV-2 IgG.

Date of Provisional Authorisation

9 December 2020
