
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	SDT Molecular Pte Ltd
<i>Name of test</i>	altona Diagnostics RealStar™ SARS-CoV-2 RT-PCR Kit 1.0
<i>Intended purpose (As per manufacturer's information for use)</i>	<i>The RealStar™ SARS-CoV-2 RT-PCR Kit 1.0 is an in vitro diagnostic test, based on real-time PCR technology, for the qualitative detection of lineage B-beta coronavirus (lineage B-βCoV) and severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) specific RNA. It is intended to be used as an aid for diagnosis in individuals with signs and symptoms of coronavirus disease 2019 (COVID-2019) in conjunction with clinical and epidemiological risk factors.</i>
<i>Date of Provisional Authorisation</i>	15 May 2020
