
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	Qiagen Singapore Pte. Ltd.
<i>Name of test</i>	QIAstat-Dx® Respiratory SARS-CoV-2 Panel
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>The QIAstat-Dx Respiratory SARS-CoV-2 Panel is a qualitative test intended for analyzing nasopharyngeal swab (NPS) samples for the presence of viral or bacterial nucleic acids. The QIAstat-Dx Respiratory SARS-CoV-2 Panel is able to accept both dry swabs and transport medium liquid samples. The assay is designed for use with the QIAstat-Dx Analyzer 1.0 for integrated nucleic acid extraction and multiplex real-time RT-PCR detection.</i></p> <p><i>The QIAstat-Dx Respiratory SARS-CoV-2 Panel detects SARS-CoV-2 and 21 additional pathogens (Influenza A, Influenza A subtype H1N1/2009, Influenza A subtype H1, Influenza A subtype H3, Influenza B, Coronavirus 229E, Coronavirus HKU1, Coronavirus NL63, Coronavirus OC43, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Respiratory Syncytial virus A/B, human Metapneumovirus A/B, Adenovirus, Bocavirus, Rhinovirus/Enterovirus*, Mycoplasma pneumoniae, Legionella pneumophila, and Bordetella pertussis).</i></p>
<i>Date of Provisional Authorisation</i>	28 May 2020
