
Provisional Authorisation for COVID-19 Tests

<i>Applicant</i>	EMERGO by UL
<i>Name of test</i>	AccuraDTect SARS-CoV-2 RT-qPCR Kit
<i>Intended purpose (As per manufacturer's information for use)</i>	<p><i>AccuraDTect SARS-CoV-2 RT-qPCR Kit contains the assays and controls for a real-time reverse transcription polymerase chain reaction (RT-PCR) test intended for the qualitative detection of RNAs (Leader sequence and N gene which are RNA targets present most abundantly in infected cells) from SARS-CoV-2 in upper respiratory specimens (nasopharyngeal or oropharyngeal swabs) from individuals suspected of COVID-19 by their healthcare provider.</i></p> <p><i>Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. Positive results are indicative of active infection.</i></p> <p><i>Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.</i></p> <p><i>The AccuraDTect SARS-CoV-2 RT-qPCR Kit test is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.</i></p>
<i>Date of Provisional Authorisation</i>	1 Jul 2020
