

## The Health Sciences Authority of Singapore expedites approval of COVID-19 diagnostic tests as part of our national response to the public health emergency

March 2020

**Dear Chief Executive Officers, Managing Directors and General Managers of Medical Device Companies**

As a major international travel hub, Singapore was amongst the first countries to detect COVID-19 patients.

Accurate and timely diagnosis of COVID-19 is critical to prompt public health surveillance, prevention and control measures. As part of the whole of government network contributing to the fight against COVID-19, HSA has proactively stepped up our efforts to support the development and availability of diagnostic test kits for detecting COVID-19.



HSA has created a Provisional Authorisation process to expedite the availability of diagnostic tests urgently needed to detect and/or diagnose COVID-19 infections. HSA issues Provisional Authorisation based on a risk calibrated review process, which takes into consideration the design aspects of the test and the validation data to support that the test is fit for purpose. HSA evaluates that the tests have reasonably met the essential safety and performance requirements for the intended purpose, with appropriate post marketing follow up actions, before provisionally authorising them.

COVID-19 tests with provisional authorisation from HSA can be supplied to all healthcare institutions, including private hospitals, medical clinics and clinical laboratories, in Singapore. These HSA authorised test kits are now being used in local healthcare institutions to support the testing for COVID-19 in patients, and for screening travellers with fever and/or other symptoms of respiratory illness entering Singapore at various checkpoints.

To ensure that Singapore has a consistent and continual supply of quality and efficient COVID-19 diagnostic tests, HSA encourages interested developers and companies to seek early consultation with us. HSA will provide the necessary regulatory advice, while ensuring that we continue to maintain our service standards for other pre-market evaluations and post-market assessments. In view of the need to optimise our resources, HSA will prioritise our review for COVID-19 test kits that offer clinical advantage in the current situation. Examples are tests kits that can be deployed at point of care, i.e. outside clinical laboratories, and tests with higher throughput, i.e. can screen more patient samples in a shorter time.

For more information on the Provisional Authorisation process for COVID-19 diagnostic tests, please see our website ([link](#)).



**Dr Choong May Ling, Mimi**  
Chief Executive Officer  
Health Sciences Authority  
Singapore

*cc: Regulatory Affairs Managers*