FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
10 JUNE 2021

HSA GRANTS INTERIM AUTHORISATION FOR FOUR COVID-19 ANTIGEN RAPID TEST SELF-TEST KITS

The Health Sciences Authority (HSA) has granted interim authorisation for the following four antigen rapid test self-test kits:

Name of antigen rapid test self-test kit	Name of distributor	Authorisation date
Abbott PanBio™ COVID-19 Antigen Self-Test	Unison Collaborative Pte Ltd	31 May 2021
Quidel QuickVue At-Home OTC COVID-19 Test	Quantum Technologies Global Pte Ltd	2 June 2021
SD Biosensor SARS-CoV-2 Antigen Self-Test Nasal	Roche Diagnostics Asia Pacific Pte Ltd	9 June 2021
SD Biosensor Standard Q COVID-19 Ag Home Test	SPD Scientific Pte Ltd	9 June 2021

These are antigen rapid tests (ARTs) that can be used by consumers (untrained lay-users) for self-testing to detect active SARS-CoV-2 infection in nasal swab samples. ARTs detect the viral proteins in the nasal swab samples of infected individuals and usually work best in the early stages of infection. In general, ARTs can achieve a sensitivity of about 80% for cases with higher viral loads and a specificity range of 97-100%[1].

2 All tests come with instructions for use (IFU) leaflets. Consumers are strongly advised to read the IFU carefully prior to using the test. Users should collect their nasal sample using the swab provided in the kit and prepare their nasal sample using the

[1] Sensitivity refers to the test's ability to correctly detect COVID-19 infection in individuals with the disease. Specificity refers to the test's ability to correctly identify individuals without COVID-19 infection.

buffer and tube provided. Once the sample is ready, users should perform the test using the test device and read the results. While performing the test, consumers should follow the instructions in the IFU closely in order to get valid results.

3 If a positive result is received from the self-test, users should follow MOH's guidelines on the next steps to take. Those who test negative on their self-test should continue to stay vigilant and adhere to prevailing Safe Management Measures.

4 With a lower sensitivity than Polymerase Chain Reaction (PCR) tests, ARTs have a higher chance of false negative results. Incorrect sample preparation or testing process when using the test, or a low viral protein level in the user's nasal sample (e.g. 1-2 days from potential exposure), could also result in a false negative result. Anyone with acute respiratory infection symptoms should consult a doctor.

5 As part of HSA's interim authorisation, the test developers are required to collect the relevant accuracy and safety data and monitor the use of their tests. HSA also requires additional data from ongoing clinical studies to be submitted post-approval for HSA to ensure the continued safety and efficacy of these tests being used by consumers.

6 As these tests are meant for use by consumers, they can be bought by consumers without a doctor's prescription. HSA is working with the Ministry of Health (MOH) to make these tests widely available through designated local retail pharmacies from 16 June 2021 and will be made available at more retail locations progressively. MOH has also developed educational materials to advise consumers on the correct use of the ARTs when self-testing and the appropriate follow-up actions based on the results of the self-testing. This will be rolled out through various media channels and the MOH website from 16 June.

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.