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HSA UPDATES

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HSA UPDATES ON RECENT US FDA ANNOUNCEMENTS ABOUT CERTAIN COVID-19 ANTIGEN RAPID SELF-TEST KITS

The Health Sciences Authority (HSA) has received several enquiries on the recent antigen rapid self-test kit announcements by the United States Food and Drug Administration (US FDA).

2 In Singapore, only COVID-19 antigen rapid self-test kits that have been authorised by HSA under the Pandemic Special Access Route (PSAR) or full registration can be supplied. HSA has evaluated these test kits to meet the required safety, quality and efficacy standards before granting PSAR authorisation or full registration.

3 There can be several versions of antigen rapid self-test kits supplied under the same manufacturer’s brand. Companies may seek marketing authorisation of specific versions in different countries. The differences between different versions include labelling and/or packaging.

4 The US FDA has advised people to stop using some versions of the test kits because they have not been evaluated and authorised by the US FDA. The US FDA’s announcements are not related to any specific quality, safety or accuracy issues.

5 Singapore’s supplies of test kits under these 2 brands are not impacted by the US FDA’s advisory.

6 Consumers are advised to purchase their antigen rapid self-test kits from reputable local retailers and pharmacies. The full list of COVID-19 self-test kits HSA has authorised for use in Singapore can be found at https://www.hsa.gov.sg/consumer-safety/articles/details/covid19_selftests.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
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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 Updates**

The “HSA Updates” seeks to provide current information, in a consistent and accurate manner, on topics of public interest. For all issues of HSA Updates, please visit www.hsa.gov.sg, click “News”, and select “HSA Updates”.

Media representatives are welcome to send any queries to the Corporate Communications Department @ HSA.