

Covid-19 antigen rapid test kits in Singapore not affected by US FDA advisory: HSA

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Published March 4, 2022
Updated March 4, 2022



Flowflex and TODAY file photo

Samples of antigen rapid test kits: (from left) Acon Flowflex Sars-CoV-2 Antigen Rapid Test (Self-Testing) and SD Biosensor Standard Q Covid-19 Ag Home Test.

SINGAPORE — The supplies in Singapore of two brands of Covid-19 antigen rapid test kits that were not authorised for use by the United States Food and Drug Administration (US FDA) have been evaluated to meet the required safety, quality and efficacy standards here.

On Friday (March 4), the Health Sciences Authority (HSA) said that it had received several enquiries following the recent announcement by the US FDA, which warned the public against using unauthorised versions of the kits being marketed there because it could produce false results.

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The brands are SD Biosensor Standard Q Covid-19 Ag Home Test and Acon Flowflex Sars-CoV-2 Antigen Rapid Test (Self-Testing) — both of which are available in Singapore.

“Singapore’s supplies of test kits under these two brands are not impacted by the US FDA’s advisory,” HSA stressed.

“In Singapore, only Covid-19 antigen rapid self-test kits that have been authorised by the 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.”

PSAR facilitates early access to critical new vaccines, medicines and medical devices during a pandemic.

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HSA noted that there could be several versions of the test kits that are 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," HSA said.

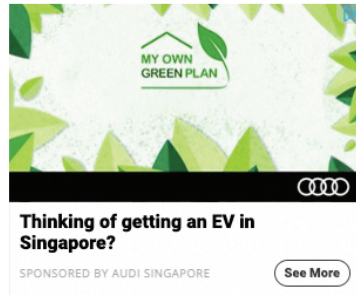
It added: "The US FDA has advised people to stop using some versions of the test kits because they have not been evaluated and authorised by the US FDA. The US FDA's announcements are not related to any specific quality, safety or accuracy issues."

HSA stressed that consumers should only buy their antigen rapid test kits from reputable retailers and pharmacies in Singapore.

In response to TODAY's queries, Flowflex said that the US FDA safety communication is meant for the users in the US and does not affect the kits sold in Singapore.

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"The recall is not a safety or performance recall.

"It is to tackle a very specific problem in the US where shipments of Flowflex (antigen rapid self-test kits) from Europe was illegally shipped into the US. When this happens, the kits do not go through the correct medical device supply chain, which makes it difficult for the US FDA to ensure accountability," the firm said.

Flowflex added that its test kits sold here includes the name of Alcotech Pte Ltd, which is registered with PSAR.

"For this reason, the safety communication issued by the US FDA does not affect Flowflex antigen rapid self-test kits in Singapore," it said.

Reiterating HSA's call to purchase antigen rapid self-test kits from reputable retailers, Flowflex said that the public should buy its products from retailers such as NTUC FairPrice, Guardian, Unity and Watsons.