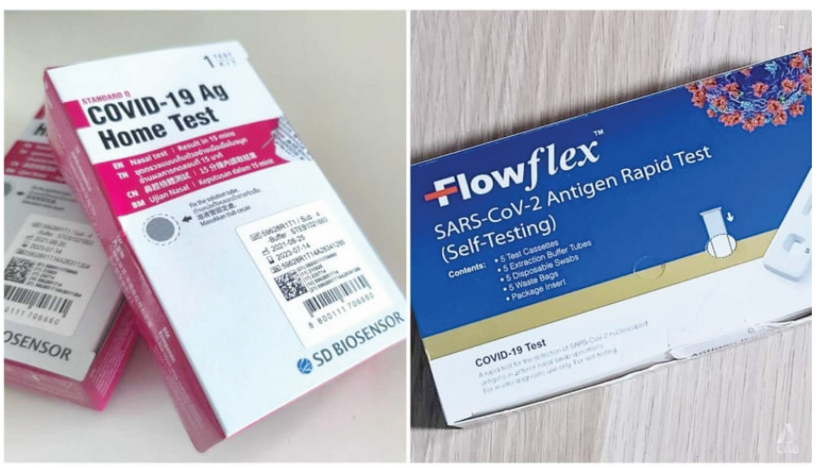
World

HSA says COVID-19 ART kits sold in Singapore not affected by US FDA warning on unauthorised tests



SD Biosensor Standard Q COVID-19 Ag Home Test kits and a Flowflex COVID-19 antigen rapid test kit.

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SINGAPORE: The Health Sciences Authority on Friday (Mar 4) said that antigen rapid test (ART) kits sold in Singapore are not affected by the United States Food and Drug Administration's (FDA) advisory against the use of unauthorised test kits marketed there.

The kits named by the FDA include the SD Biosensor Standard Q COVID-19 Ag Home Test and ACON Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing). Both brands are currently available in Singapore.

These tests have not been authorised, cleared or approved by the FDA for distribution or use in the United States, the US health agency said in an advisory dated Mar 1, adding that they may show false results.

The warning was also issued against unauthorised versions of Celltrion USA's DiaTrust COVID-19 Ag Rapid Test.

The authorised versions of the tests can continue to be used, but consumers should compare the packaging to make sure they do not buy unauthorised tests, the FDA said.

There are currently 16 COVID-19 self-test kits approved for use in Singapore under the Pandemic Special Access Route (PSAR). Of these, four are made by SD Biosensor and one by ACON.

In an announcement posted on its website, HSA said: "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.

There are currently 16 COVID-19 self-test kits approved for use in Singapore under the Pandemic Special Access Route (PSAR). Of these, four are made by SD Biosensor and one by ACON.

In an announcement posted on its website, HSA said: "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.

"Singapore's supplies of test kits under these two brands are not impacted by the US FDA's advisory."

FLOWFLEX ART KITS NOT AFFECTED

Responding to CNA's queries, FlowFlex said its ART kits approved by the Health Sciences Authority (HSA) in Singapore were not affected as they differ from the versions sold in the US and Europe.

Last year, about 200,000 European approved FlowFlex test kits were illegally exported from Europe to the US. The US FDA then issued a recall on this specific batch of tests from the US market.

"This recall pertains to rectifying the illegal imports from Europe to the USA. Product quality or safety has not been the reason for this recall," said FlowFlex.

The company said the safety communication issued by the US FDA is "meant for the US audience" only and does not affect FlowFlex ART kits in Singapore.

No recalls were issued to the FlowFlex test kits in Singapore, it added.

Unlike the ones recalled by the US FDA, the FlowFlex ART kits sold in Singapore do not have the CE Marketing mark or European languages. Instead, the information of the distributor, Alcotech, is shown on the boxes.

The company also reminded consumers in Singapore to only purchase ART kits from authorised retailers such as Guardian, Watsons or NTUC.

The name and information of the distributor, Alcotech, can be seen on the FlowFlex ART kits approved by the Health Sciences Authority (HSA) in Singapore. (Image: FlowFlex)

File photo of SD Biosensor Standard Q COVID-19 Ag Home Test kits in Singapore on Mar 4, 2022.

The US FDA said it has not received reports of injuries, adverse health consequences or death associated with the use of these unauthorised tests.