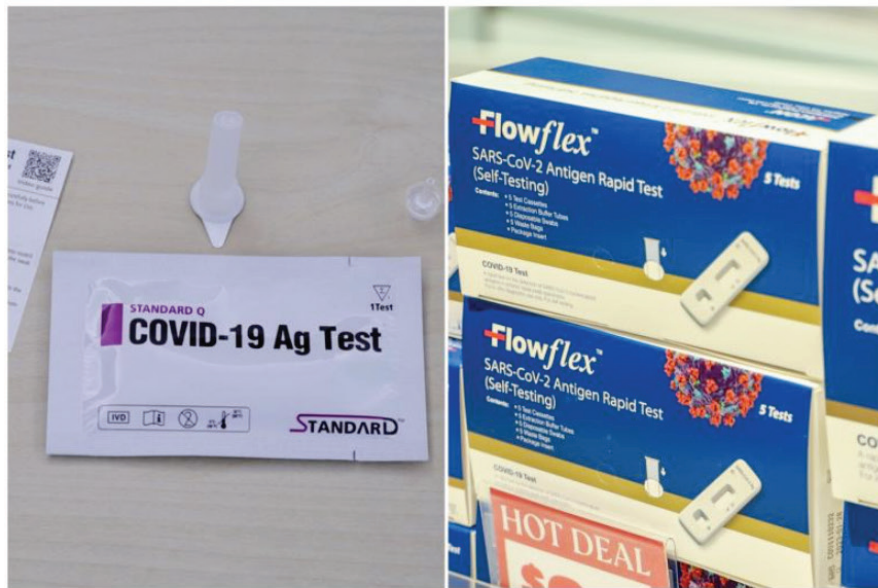


## SD Biosensor, Flowflex Covid-19 test kits fit for use in S'pore despite warnings in the US: HSA



HSA said that Singapore's supplies of test kits under the SD Biosensor and Flowflex brands are not impacted by the US FDA's advisory.  
PHOTOS: ST FILE, LIANHÉ ZAOBAO

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PUBLISHED 4 MAR 2022, 8:11 PM SGT



SINGAPORE - The Health Sciences Authority (HSA) said SD Biosensor and Flowflex antigen rapid test (ART) kits involved in a recall in the United States are safe and fit for use in Singapore.

The statement on Friday (March 4) comes after the US Food and Drug Administration (FDA) issued a warning on Tuesday (March 1) to stop using some versions of the test kits because they have not been approved in the US.

HSA said it received several inquiries on the announcements in the US which concern the SD Biosensor Standard Q Covid-19 Ag Home Test and Acon Laboratories Flowflex Sars-CoV-2 Antigen Rapid Test (Self-Testing) kits.

Both kits are sold here.

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

"HSA has evaluated these test kits to meet the required safety, quality and efficacy standards before granting Pandemic Special Access Route authorisation or full registration."

In separate notices on both test kits, the FDA said on Tuesday: "The test is not authorised, cleared or approved by the FDA for distribution or use in the United States. The FDA is concerned about the risk of false results when using this unauthorised test."

It added that both distributors have initiated a recall for all unauthorised test kits in the US and that it is working with them to resolve the issue.

The FDA also said that it has not received any reports of injuries, adverse health consequences or death linked to the use of these two products.

HSA said there can be many versions of ART kits supplied under the same manufacturer's brand, which can vary in how the products are packaged and labelled.

"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," HSA said in the statement.

"The FDA's announcements are not related to any specific quality, safety or accuracy issues," said HSA.

In a statement on Friday, Mr Inchul Chung, a business head at SD Biosensor, said: "The post on the US FDA website is not a warning of our performance or customer safety but of the illegal importation of Standard Q-branded Covid-19 tests to the US market."

These test kits, which typically come in a white box with pink accents, have been certified in Europe, Canada, Australia and other parts of the world, he added.

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A spokesman for SPD Scientific, SD Biosensor's local distributor, said: "There is no recall for SD Biosensor test kits in Singapore.

"We have not been informed by SD Biosensor on quality or accuracy issues."

A spokesman for Alcotech, the local distributor of Flowflex ART kits, said the quality and supply of kits in Singapore were not affected by the recall.

The spokesman said: "A group of rogue traders in Europe illegally exported around 200,000 European-approved tests to the US.

"When this happens, the ART kits do not go through the correct medical device supply chain which makes it difficult for FDA to ensure accountability."

The FDA then issues a recall of this specific batch of test kits from the US market in order to protect its consumers, he said.

"The Singapore HSA-approved version differs from both the US and Europe versions and is not affected by this recall."

Consumers are advised to buy ART kits from reputable local retailers and pharmacies, said HSA.

There are currently 16 Covid-19 self-test kits approved for use here.

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