

Test maker targeted by FDA says it responded to US concerns

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This Oct. 14, 2015 file photo shows the Food and Drug Administration campus in Silver Spring, Md. On Wednesday, June 17, 2020, the FDA said it has sent warning letters to three companies for marketing adulterated and misbranded COVID-19 antibody tests. The companies targeted by FDA include: Medakit Ltd. of Hong Kong, Antibodiescheck.com of the United Arab Emirates and Sonrisa Family Dental D.B.A. My COVID19 Club of Chicago. (AP Photo/Andrew Harnik, File)

A company targeted by the Food and Drug Administration for selling unauthorized coronavirus antibody tests says it has responded to regulators' concerns, though it has no business operations in the U.S.

The Food and Drug Administration announced Wednesday it had sent warning letters to three companies selling at-home blood tests, none of which have been reviewed or authorized by the agency. At-home testing can carry extra risks for patients due to the risk of faulty results. The FDA has not authorized any COVID-19 test to be used completely at home

A representative for Hong Kong-based Medakit Ltd. said Wednesday via email it responded to the agency's letter with a series of steps, including blocking U.S. purchases from its website and adding a disclaimer that its products have not been reviewed or approved by the FDA. Additionally the [company](#) said it is reviewing the promotional language it uses for the test, which it said is only intended for use by health professionals, not consumers.

The company said it mostly operates in Europe and has no business presence in the U.S.

The warning letters come as FDA tries to police dozens of antibody tests that the agency allowed onto the market earlier this year without evidence that they worked. After coming under fire from experts and members of Congress, the FDA changed course last month, telling companies to submit testing data to remain on the market.

Antibody tests are different from the nasal swab tests used to diagnose most active infections. The tests instead look for blood proteins called antibodies, which indicate someone had a previous infection. Most of the tests use a finger-prick of blood on a test strip.

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