<u>Action taken to halt sales of</u> <u>fingerprick coronavirus (COVID-19)</u> <u>antibody testing kits</u>

News story

Anyone supplying these types of tests should temporarily stop this service.



The MHRA is asking providers of laboratory-based COVID-19 antibody testing services using capillary blood collected by a fingerprick, to temporarily stop providing this service until home collection of this sample type has been properly assessed and validated for use with these laboratory tests.

This does not affect rapid, point of care tests or laboratory tests performed using blood taken from the vein.

The Agency has <u>recently updated its guidance on home antibody testing kits</u>, to ensure that the public and industry have the latest information on the reliability of test results and what they mean.

Graeme Tunbridge, MHRA Interim Director of Devices, comments:

Patient safety and public health are our main priorities and it is in the interests of everyone for antibody tests to be as reliable and meaningful as they can be.

There are several UK providers of testing services who offer COVID-19 antibody testing using a fingerprick sample of capillary blood collected in a small container.

We are asking all providers of laboratory-based COVID-19 antibody testing services using capillary blood collected by a fingerprick

to temporarily stop providing this service until home collection of this sample type has been properly assessed and validated for use with these laboratory tests.

Use of unvalidated sample types may lead to unreliable results and as such we are working closely with the service providers, laboratories and test manufacturers to resolve the regulatory and patient safety issues.

People who have purchased one of these sampling kits, and received an antibody test result, should not consider the result to be reliable and should not take any action based on it.

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