# MHRA issues exceptional use authorisation for NHS Test and Trace COVID-19 Self-Test device

News story

An application for exceptional use of a COVID-19 rapid test, to be used by members of the public, has today been approved by the Medicines and Healthcare products Regulatory Agency (MHRA).


The MHRA has issued an authorisation to the Department of Health and Social Care to allow the use of the NHS Test and Trace COVID-19 Self-Test kit to detect infection in asymptomatic individuals.

This is an antigen lateral flow test (antigen LFT) which can give a result in 30 minutes.

The device can be used to identify new cases of COVID-19 in people who do not have symptoms. Anyone receiving a positive test should follow the information in the instructions for use provided with the kit.

A negative test result means that the test has not detected the presence of the COVID-19 virus, at the time the test was taken. Anyone receiving a negative test result should continue to follow the latest guidance for their area.

The MHRA follows a robust assessment procedure when considering applications for exceptional use of a medical device, this includes test kits. Information on the type of evidence that needs to be submitted as part of an application can be found on our website.

A self-test device can be used by a member of the public with no previous experience of testing, in their own home or another community setting such as a place of work. The self-test device should be straightforward to use and give results which are easy to understand. The instructions for use provided with the self-test device must be easy to follow and be available in a range

of languages and formats.

Anyone who experiences any harm, injury, false positives or negatives, or difficulties in using the self-test device should report this to MHRA via the Coronavirus Yellow Card website.

## Notes to Editor

1. The Medicines and Healthcare products Regulatory Agency is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. All our work is underpinned by robust and fact-based judgements to ensure that the benefits justify any risks.
2. The MHRA is a centre of the Medicines and Healthcare products Regulatory Agency which also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA is an executive agency of the Department of Health and Social Care.
3. The MHRA operates the UK medical device vigilance system. This includes carrying out market surveillance, enforcing the legislation and working in collaboration with healthcare and regulatory stakeholders both in the UK and worldwide.
4. Manufacturers of testing kits are encouraged to contact the MHRA if they have questions, including those on data requirements, how to apply for a derogation and timeframes for approval.

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