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Covid-19: UK extends lateral flow test authorisation despite US warning not to use them

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The UK medicines regulator has extended the authorisation for the lateral flow tests used as part of the mass covid-19 testing programme, despite concerns raised by the US regulator over the main test—the Innova SARS-CoV-2 antigen rapid qualitative test.

Last week the US Food and Drug Agency (FDA) warned the public to stop using the Innova test for detecting infection and suggested that any unused tests should be destroyed, binned, or returned.¹

The agency published a class 1 recall—the most serious kind—of the test after an investigation uncovered “significant concerns that the performance of the test has not been adequately established, presenting a risk to health.”

However, the Medicines and Healthcare Products Regulatory Agency (MHRA) said its decision to extend the exceptional use authorisation (EUA) in the UK followed a “satisfactory outcome” of a review in response to US concerns. But despite the apparently positive findings, the MHRA has only extended the authorisation for two months—until 28 August 2021.

MHRA director of devices Graeme Tunbridge said, “We have now concluded our review of the risk assessment and are satisfied that no further action is necessary or advisable at this time. This has allowed us to extend the EUA to allow an ongoing supply over the coming months. People can be assured of the MHRA’s work to continuously monitor the tests in use; as is our standard process.”

In the UK, the lateral flow tests are authorised for use in detecting positive cases of asymptomatic covid-19 and are used in schools and before larger events, such as Euro 2020 matches. The public can also order two tests per week for general use.

Experts have previously warned that the tests may miss as many as half of covid-19 cases, depending on who is using them, and provide false reassurance to people who receive a negative test result.²

Sheila Bird, former programme leader at the MRC Biostatistics Unit, University of Cambridge, said, “The MHRA may need some time to tackle fully the plethora of study design, regulatory, and transparency problems raised by the FDA. Needing some time may explain why the MHRA accorded the Department of Health and Social Care an interim two month extension and has yet to make public the basis for its interim judgement.”

She said that the MHRA’s transparency failures, including that it has not provided details on how the recent review was carried out or its findings, must be immediately redressed.

1 Iacobucci G. Covid-19: US regulator raises “significant concerns” over safety of rapid lateral flow tests. *BMJ* 2021;373.

2 Mahase E. Covid-19: Innova lateral flow test is not fit for “test and release” strategy, say experts. *BMJ* 2020;371:m4469doi: 10.1136/bmj.m4469.

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