Covid-19: US regulator raises "significant concerns" over safety of rapid lateral flow tests

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The US Food and Drug Agency (FDA) has raised concerns about the safety and the marketing of rapid lateral flow covid-19 tests, which are the cornerstone of the UK’s mass testing programme.

On 10 June, the agency warned the public to stop using the Innova SARS-CoV-2 antigen rapid qualitative test for detecting infection and suggested the tests should be destroyed and binned or returned to the manufacturer.

The FDA published a class 1 recall of the test after an investigation carried out between March and April uncovered “significant concerns that the performance of the test has not been adequately established, presenting a risk to health.” Class 1 is the most serious kind of recall and indicates that use of the tests may cause serious injury or death.

In addition, the FDA said that “labelling distributed with certain configurations of the test includes performance claims that did not accurately reflect the performance estimates observed during clinical studies,” and that the test “has not been authorised, cleared, or approved by the FDA for commercial distribution or use in the US, as required by law.”

In a warning letter to the manufacturer, the agency wrote, “The clinical performance estimates reported in the labelling of the 25T configuration and 7T configuration devices are false or misleading as they do not accurately reflect the performance estimates observed during the clinical studies of your devices.”

The FDA also noted that the clinical study data Innova submitted in its emergency use authorisation (EUA) request for the test was “identical to data previously provided by other manufacturers” in separate requests. “The data reliability and accuracy problems noted herein raise significant concerns that the performance of the SARS-CoV-2 antigen rapid qualitative test has not been adequately established, and that the products distributed by Innova without FDA approval, clearance, or authorisation could present a serious risk to the public health.”

In a statement, Innova said it has “worked diligently and proactively to tackle the FDA findings,” adding that “none of the inspectional observations concern the performance of the test.” The company said, “We have voluntarily recalled the products as a result of labelling that was not consistent with FDA regulatory requirements. We are confident that we are on the pathway to fully comply with FDA requirements.”

Innova added, “Since Innova rapid antigen tests have not received EUA in the US, Innova is not shipping these products for commercial use. We intend to seek FDA authorisation to commercialise our rapid antigen test in the US.”

The FDA’s notice came just days after the Royal Statistical Society (RSS) called for new standards for diagnostic tests in the UK in response to regulatory gaps identified during the covid-19 pandemic.

Following the FDA’s warning, Jon Deeks, professor of biostatistics at University of Birmingham, who co-chaired the RSS’s working group on diagnostic tests, said, “There have been many problems with transparency in the evidence to support the government’s policies for use of this lateral flow test, which negatively impacts on uptake. Given the more serious concerns identified by the FDA, it is essential that full explanations and data are provided to explain decisions made about its continued use, if that is the decision made.”

The Department of Health and Social Care said it had confidence in lateral flow tests. “The Innova test has already gone through the UK’s rigorous Porton Down assessment process, and we have a robust quality assurance process in place,” said a spokesperson.

Graeme Tunbridge, Medicines and Healthcare Products Regulatory Agency (MHRA) director of devices, said, “The MHRA are reviewing all available information and are working closely with NHS Test and Trace to ensure that a full risk assessment is undertaken, as is our normal process, to understand any implications for products being used in the UK. Patient safety is our priority and we will publish safety information as and when necessary.”

