

# Update on Randox test kits



The Medicines and Healthcare products Regulatory Agency has instructed Randox to recall the 'Randox COVID-19 Home Testing Kit' with the Catalogue Number: EV4429 from NHS Test and Trace testing settings.

This decision has been taken as a precautionary measure to prevent any further use of these Randox tests. Anyone who is in possession of this Randox test kit should follow the below instructions on how to return kits to Randox.

Action to be taken:

- discontinue use of and quarantine any stock of the Randox COVID-19 Home Testing Kit immediately
  - follow the instructions listed below to ensure the return of any stock of the Randox COVID-19 Home Testing Kit to Randox Laboratories Limited:
1. For the Care Home Channel: making use of the original shipping carton or the return boxes that were provided to Care Homes, package all remaining COVID-19 Home Testing kits into these boxes. If no suitable packaging is available, packaging may be requested (details to follow). A return label will be provided and must be affixed in a prominent position to the outer package for return to Randox Laboratories Limited. A courier will collect the unused kits within a specified time period, different to that for the collection of staff and resident samples that are being processed for COVID-19 testing.
  2. For kits at a Warehouse facility: Randox will arrange for collection and transport of this stock to Randox Laboratories Limited. The Warehouse facility will be requested to advise on the number of cartons to be collected.
  3. For the at Home Channel: a return postage paid envelope is included in the Randox COVID-19 Home Testing kit. Therefore, the kit should be opened and the contents repackaged in the return envelope and the return postage label affixed. The label will direct the kit to the Royal Mail Collection Centre in Northern Ireland. Randox will take receipt of these deliveries.

On July 15 NHS Test and Trace were notified that some test kits produced by Randox laboratories may not meet our required safety standards for

coronavirus testing. Alongside the Lighthouse Laboratories, NHS Test and Trace has a separate contractual arrangement with Randox laboratories. As a precautionary measure and while we investigate further, NHS Test and Trace paused the use of these Randox test kits with immediate effect.

The risk to safety is low and test results from Randox kits are not affected.

We have been supporting all testing settings to receive replacement kits as soon as possible.

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1. 8 August 2020

Updated to make it clear that this recall only applies to the 'Randox COVID-19 Home Testing Kit' with the Catalogue Number: EV4429.

2. 7 August 2020

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