

## Twitter Thread by [Jon Deeks](#)

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**MHRA exceptional authorisation of Innova for asymptomatic individuals was issued on 22nd Dec.**

**This is a LIMITED approval, and the details of how and why it is LIMITED are important. It does not cover all current uses of INNOVA by**

Details here have been provided by the [@MHRAGovuk](#) by email. If any fact is incorrect here [@DHSCgovuk](#) [@MHRAGovuk](#) please let me know and I will change – it is a bit complicated and rather unusual.

2/8

First, approved test is called the “NHS Test and Trace COVID-19 Self-Test kit” - the LFT test in it is the INNOVA test.

Second, the test manufacturer is stated as “Department of Health and Social Care”, and not Innova.

This determines who has the duty of care and safety.

3/8

### **Manufacturer: Department of Health and Social Care (DHSC)**

Device/model name: COVID-19 Self-Test to detect infection in asymptomatic individuals

Issue date: 22/12/2020

Expiry date: 22/06/2021

MHRA reference number: DEU/012/2020/003

MHRA confirmed details of the limited approval by email (their emphasis):

“ONLY allows for the test to be used to “find” positive cases.

MHRA HAVE NOT approved the test for use in a ‘test to enable’ scenario.”

4/8

MHRA continue:

“as stated on our webpage, people should not act on a negative result and should continue to follow their local guidelines.”

“Any other use of the kit is outside of MHRA's remit and at the manufacturer's own risk.”

5/8

This indicates that MHRA experts have reviewed the evidence, and decided, like many others (WHO, CMO, SAGE, Royal College of Pathologists and summarised here <https://t.co/nJP8YxE3pD>) that the inaccuracy in the test is too high for it to be approved as a “rule out” test.

6/8

However, [@DHSCgov](#) continues to use the test in “test to enable” scenarios – visiting in care homes, students safely travelling to and from University, school pupils remaining in class after being in exposed to a close contact, lorry drivers returning to France.

7/8

Any situation where people act because they have a negative result is a "test-to-enable" situation.

Given [@MHRAgovuk](#) has explicitly stated the test is not approved for this, the Government must now take notice (and not by tortous act/not act logic). Our health is at risk.

8/8

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