

Negative PCR tests following positive LFD tests A communications update

PURPOSE OF THIS DOCUMENT

The purpose of the pack is to support the Department of Education with their school communications in response to the significant number of negative PCR tests following positive LFD tests being reported.

NHS Test and Trace has suspended the processing of tests with a private laboratory services provider as a precautionary measure.

This pack provides the Department of Education and their supporting communications teams with the latest information, approved key messages that follow national guidance, and a Q&A providing answers you can use when responding to queries regarding this issue.

It is important to note that the general guidance for schools remains the same: <u>Schools COVID-19 operational</u> guidance - GOV.UK (www.gov.uk)

If you have any queries about any content in this document, or would like to discuss your communication approach, please contact Oliver Lacey (<u>Oliver.Lacey@dhsc.gov.uk</u>), Rebecca Morgan (<u>Rebecca.Morgan@dhsc.gov.uk</u>) or the Testing Comms Team: <u>testingcomms@dhsc.gov.uk</u>.

KEY PRINCIPLES

National communications

An announcement was issued on 14 October 2021 confirming that NHS Test and Trace has suspended testing at a recently contracted private laboratory as a precautionary measure following a significant number of negative PCR tests following positive LFD tests being reported. The announcement can be <u>read here</u>.

Locally-led communications

Following the national announcement, communications teams are encouraged to engage with their audiences/ local communities to:



Emphasise the important role that regular LFD and PCR testing plays in reducing the spread of COVID-19



Provide **accurate information and reassurance** that NHS Test and Trace services are robust and reliable and that NHS Test and Trace are working hard to resolve this issue as rapidly as possible



Provide clarity on the guidance around the raise awareness and understanding of how to access **the** regular testing offer for people without symptoms

Negative PCR tests following positive LFD tests

- Following reports of people receiving negative PCR test results after they have tested positive on a Lateral Flow Device, NHS Test
 and Trace has investigated and testing has been suspended at a private laboratory.
- At present, there is no evidence of technical issues with the LFD or PCR test kits themselves and people should continue to test as normal. Other labs are operating normally.
- Anyone with COVID-19 symptoms should book a PCR test. Those with a positive LFD test should get a follow up PCR test to confirm they have COVID-19.
- NHS Test and Trace (NHS TT) have suspended testing operations provided by Immensa Health Clinic Ltd at its laboratory in Wolverhampton, following an investigation into reports of people receiving negative PCR test results after they have previously tested positive on a Lateral Flow Device.
- While investigations are underway into the precise cause, NHS Test and Trace estimate that around 400,000 samples have been processed through the lab, the vast majority of which will have been negative results, but an estimated 43,000 people may have been given incorrect PCR test results between 8 September and 12 October, mostly in the South West of England.
- This is an isolated incident attributed to one laboratory but all samples are now being redirected to other laboratories. The number of tests carried out at the Immensa laboratory are small in the context of the wider network and testing availability is unaffected around the country.
- NHS TT is contacting the people that could still be infectious to advise them to take another test. Close contacts who are symptomatic will
 also be advised to take a test in line with normal practice. Anyone with COVID-19 symptoms should book a PCR test. Those with a positive
 LFD test should get a follow up PCR test to confirm they have COVID-19.



APPROVED MESSAGES

KEY MESSAGES

- NHS TT have recently seen a rising number of positive LFD results subsequently testing negative on PCR. As
 a result of our investigation, NHS TT are working with one laboratory to determine the root cause to any issue
 which could potentially have led to inaccurate PCR results being issued to people.
- NHS TT have immediately suspended testing at this laboratory while we continue the investigation.
- There is no evidence of any faults with LFD or PCR test kits themselves and the public should remain confident in using them and in other laboratory services currently provided.
- If you get a positive LFD test, it's important to make sure that you then get a follow up PCR test to confirm you
 have COVID-19. If you have symptoms of COVID-19, self-isolate and take a PCR test.
- Testing advice remains the same:

- People with a positive LFD test result should self-isolate in line with the <u>stay at home guidance</u> <u>for households</u> with possible or confirmed coronavirus (COVID-19) infection. They will also need to <u>get a</u> <u>free PCR test to check if they have COVID-19</u>.

- Whilst awaiting the PCR result, the individual should continue to self-isolate.

- If the PCR test is taken within 2 days of the positive lateral flow test, and is negative, it overrides the self-test LFD test and there is no longer need to self-isolate as long as the individual doesn't have COVID-19 symptoms.





APPROVED Q&As

How long has this lab been processing tests for NHS Test and Trace? What is the total number of tests that could have been affected, and over what period?	This lab has been processing tests since September 2021. While investigations are underway into the precise cause, NHS Test and Trace estimate that around 400,000 samples have been processed through the lab, the vast majority of which will have been negative results, but an estimated 43,000 people may have been given incorrect negative PCR test results between 8 September and 12 October, mostly in the South West of England.
Will people whose tests were processed by this lab need to get another test?	NHS TT is contacting the people that could still be infectious to advise them to take another test. Close contacts who are symptomatic will also be advised to take a test in line with normal practice. We will also contact all those who may have had a negative test over the last 4 weeks to inform them of this incident and to apologise.

APPROVED Q&A

How confident are you that the issue of positive LFDs followed by negative PCR tests is totally down to this lab failure? Are there not reports from other areas beyond the South West – or could they have been processed at this lab too?	Our investigations into the root cause of this issue are ongoing and includes reports and data from across the UK.
Can you rule out / have you ruled out a new variant accounting for these reports?	We are ruling out any new variant accounting for these reports at this time.
Does this mean NHSTT's supervision of labs is insufficiently rigorous? How can we have confidence in the wider lab network in the light of this and the Milton Keynes Panorama programme?	Rigorous quality control and safety procedures are in place across the laboratory network, and we expect the highest standards to be met. We regularly review and inspect our partner laboratories, as do external inspectors, to ensure strict protocols are adhered to. It is also important to remember that we have sufficient capacity within our laboratory network to accommodate any redistribution of tests to other laboratories. NHS Test and Trace successfully carries out hundreds of thousands of tests every day and, in the overwhelming majority of instances, there are no issues with the process.

APPROVED Q&A

Can we explain why it has taken weeks to detect the issue, and why no action has been taken till now?	While we had anecdotal reports of a higher rate of false negative PCR results following a positive LFD result, we did not have enough data to be able to pinpoint the cause. We discussed and reviewed multiple causes during the investigation. On Monday (11 Oct 2021) additional data was shared with the team that made it clear there was a specific, geographical indicator, which led to a review of previous assertions.
What are we doing to ensure this doesn't happen again?	We are in the process of conducting a rigorous investigation into this issue. The laboratory involved is also conducting its own investigation and a root cause analysis into what is responsible for this issue. Once the investigation is complete, we will take appropriate remedial action to ensure that this issue does not arise at any of our labs again. NHS Test and Trace successfully carries out hundreds of thousands of tests every day and, in the overwhelming majority of instances, there are no issues with the process.

APPROVED Q&A

Is it possible this could happen at other labs that NHS Test and Trace use to process tests? Laboratories are required to comply with ISO15189 and complete regular internal and external quality assessment processes in line with international best practice. We are working with the Laboratory concerned to understand the operational issues that may have occurred and will ensure that lessons are shared with other laboratories. We have not identified any issues with other laboratories in the network at this time.



Get in touch

For questions about anything in this briefing pack or to discuss your communications plans please get in touch: <u>testingcomms@dhsc.gov.uk</u>