FAQs Lateral Flow Testing Technology

**Key Message**

About one in three people who have coronavirus have no symptoms and will be spreading it without realising it. That’s why….

… Hands, Face and Space is so important

… You need to keep your distance from loved ones and colleagues

… You should open a window and let the air circulate

**About the Product: What are Lateral Flow Devices?**

**I’m confused: how many different types of tests are out there and what’s the difference between them?**

There are two main types of test used to check if people currently have coronavirus.

The first type of test is known as a PCR test, and looks for the virus’s genetic material (Ribonucleic acid or RNA). These tests are currently more commonly used for symptomatic testing. They require a laboratory to be processed.

The second is called a lateral flow antigen test, which detects the coronavirus antigen that is produced when a person is infectious with coronavirus by applying a swab from the nose and throat to a special test kit. These are quicker tests that produce a result within 30 minutes and do not require a laboratory to be processed.

[Validated 09.12.20]

# What Lateral Flow Device is being used, and why this particular test?

In August 2020, the Department of Health and Social Care commissioned Public Health England and the University of Oxford to rapidly identify the most promising LFDs.

More than 130 types of LFD have been assessed and 20,545 evaluations completed. These assessments are ongoing, but one LFD has been prioritised for use based on performance, the ‘Innova SARS-CoV-2 Antigen Rapid Qualitative Test’.

8,774 validation tests have been performed to date to assess the Innova device. This LFD was effective at detecting a high viral load in an individual and registering an appropriate positive result. These are people who are thought to be the most infectious.

[Validated 23.12.2020]

# How does a lateral flow device test work?

LFDs are effective at detecting a high viral load in an individual and registering an appropriate positive result. These are people who are thought to be the most infectious.

Lateral flow device testing involves the processing of nasal and/or throat swab samples. The device detects a protein (antigen) produced by the virus at its most infectious stage. If present in the person's sample, a coloured line appears on the device. This uses a well- established technique called immunochromatography, which draws the sample along the device in a similar way to a home pregnancy test kit.

The swab sample is added to a fluid in the test kit. This fluid acts as an extraction buffer and is optimised to release viral antigens from the specimen if they are present. During the test analysis, these antigens migrate along the strip in the lateral flow device, binding to anti- SARS-CoV-2 (the virus that causes COVID-19) antibodies located in the strip. The antibodies are linked to coloured particles. The presence of a coloured band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. In general, it takes up to 20 minutes for a positive result to appear. The manufacturer's guidance is to wait a full 30 minutes to confirm that a result is negative.

[Validated 23.12.2020]

# Does a Lateral Flow test require a laboratory?

No – as a point of care test, Lateral Flow Devices do not require a lab setting as samples are processed on-site. LFDs can therefore be rapidly deployed across multiple locations without stringent infrastructure requirements.

[Validated 12.11.2020]

# Can the Lateral Flow antigen test tell if you have had coronavirus in the past?

No. Lateral Flow antigen tests detect the current presence of coronavirus at that moment in time by looking for the presence of antigens or protein parts on the outside of the virus within the swab sample. Antigens are materials that stimulate the body to produce antibodies.

This is unlike an antibody test which tests for the antibodies that your body has produced in response to the virus. A positive antibody test means you have had coronavirus in the past.

[Validated 30.10.20]

# Will it replace existing testing technology?

LFD testing technologies are intended to complement, not replace existing testing technology for individuals who have COVID-19 symptoms. The Government is testing a wide range of technologies which we hope can be deployed in time.

[Validated 09.12.20]

# Is the test safe?

Lateral flow tests are validated technology, they are safe and the results are trusted. These tests have undergone rigorous testing and evaluation including at Public Health England’s research laboratories to ensure they are verified for use.

[Validated 09.12.20]

# How accurate is the test?

Lateral flow tests are highly specific, which means that only a very small proportion of people who do not have coronavirus will receive a positive result (false positive).

Clinical validation has found LFD to have high specificity but slightly lower sensitivity at lower viral loads. Sensitivity measures how likely a test will return a positive result when that person is infected. Therefore twice weekly tests are recommended to pick up any cases which were not detected during the first test and to catch any new infections.

If you test positive on a lateral flow test, it is likely that you are infectious at that moment, whereas people testing positive on a PCR test could be in the less infectious early or late stages of disease. This means that by using the lateral flow test we can identify people with a high viral load who are the most likely to spread the virus further.

[Validated 12.11.20]

**Why use Lateral Flow Devices?**

**What are the benefits of the lateral flow device tests?**

We know that between one in four and one in three people who have coronavirus never show any symptoms but that does not mean they are not infectious. These devices can help identify people who have high levels of virus who do not have symptoms and would not otherwise be coming forward for a test, ensuring that they can isolate and prevent onwards infection. We may be able to use these tests to help reduce restrictions for those who test negative, in turn supporting the economy and wider society to return to a more normal way of life.

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The benefits of the LFD testing technology are its ability to be used at the point of care and at scale. Lateral flow testing also has: simpler operational requirements, minimal workforce training, and no requirement for laboratory analysis. LFDs deliver a rapid assessment – in 30 minutes – of whether someone is likely to be infectious or not. This is very quick compared to other routinely available testing options and provides the ability to limit infection spread earlier than with PCR testing.

[Validated 12.01.2021]

# Why are you using LFDs to test asymptomatic people?

Lateral flow antigen tests are a technology that could be used to test a higher proportion of asymptomatic people, better enabling us to identify positive cases and isolate more people who are at high likelihood of spreading virus, and break the chain of transmission.

In doing so we aim to protect those at high risk, find the virus and help enable us to go back to as normal a way of life as possible.

# In which circumstances are you using lateral flow devices to test instead of other types of tests?

Lateral flow devices are being programmed in a number of settings, to see how they can be used for testing at scale, and for testing people who do not currently have symptoms.

[Validated 09.12.20]

# What’s the difference between sensitivity and specificity? Why is there so much variation?

Sensitivity is the proportion of people with the disease that have a positive test. Specificity is the proportion of people without the disease that have a negative test.

Our assessment of variation is that some of this is related to training. It is also important that an individual coughs and blows their nose so that an accurate sample is taken.

[Validated 09.12.20]

# Why are you using lower sensitivity tests? What does that mean?

When a person has low levels of virus in their system, lateral flow tests are less sensitive than some of the other tests we use (such as PCR tests). However, when levels of virus are at their highest and people are most likely to pass it on to others, they can detect the vast majority of cases.

This also means that if you test positive on a lateral flow test, it is likely that you are infectious at that moment, whereas people testing positive on the PCR test could be in the less infectious early or late stages of disease.

[Validated 20.01.21]

# Is 77% sensitivity really enough to tell people to self-isolate?

Absolutely. Sensitivity refers to the proportion of people with Covid-19 that get a positive result. When a person has low levels of virus in their system, lateral flow tests are less sensitive than some of the other tests we use (such as PCR tests). However, when levels of virus are at their highest and people are most likely to pass it on to others, they can detect the vast majority of cases. This means that if you test positive on a lateral flow test, it is likely that you are infectious at that moment.

Specificity is the proportion of people without the disease that have a negative test. The specificity of this test is extremely high – with no more than 5 per 1000 false positives from those tested, and in trained hands lower at 1 to 2 per 1000. This means that there is a very low risk of an individual isolating unnecessarily.

It is of the utmost importance that we all do our bit to stop the spread of the virus and protect other members of society. Participating in the test will help our country fight the pandemic and save lives. Self-isolation, whilst disruptive for those affected, is an essential part of the fight against the virus.

[Validated 26.01.2021]

# Will the lateral flow tests still work to detect the new coronavirus variant found in the UK?

Yes. Scientists at PHE Porton Down have rapidly evaluated the performance of lateral flow antigen tests against the new variant of SARS-CoV-2 that was recently identified across the South East of England. Most of the changes in the new variant are found in the spike protein. The LFD tests currently in use detect a different protein found within the virus that is not affected by this mutation.

The protein that these LFDs detect (nucleocapsid) is found inside the virus, whereas the mutation affects the spike, which is found on the virus’s surface. This means that LFDs can be used to identify infectious positive cases. PHE will continue to monitor the new variant and are keeping our response to it under constant review.

Further information on the study which was undertaken can be found here: [https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-](https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201) [of-vui-20201201/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201](https://www.gov.uk/government/publications/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201/sars-cov-2-lateral-flow-antigen-tests-evaluation-of-vui-20201201)

[Validated 22.12.2020]

# Should testing continue now that vaccination has started?

Testing should continue and all government guidelines should continue to be followed despite vaccination. The clinical trial evidence demonstrates that vaccine reduces clinically severe infection and severe disease. However, the impact on minor infection, asymptomatic carriage and transmission remains unknown. Therefore, the use of LFD for asymptomatic testing should continue and will continue to be reviewed.

[Validated 19.01.2021]

# What do I need to know about the Lateral Flow Device test kit? Does the LFD test kit work in all temperatures?

The LFD devices and reagents should be used at room temperature (between 15˚C and 30˚C). If the kit has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using.

[Validated 06.11.20]

# What is the shelf life of the lateral flow test kits?

A. The shelf life of the Innova LFD test kits is 24 months from the date of manufacture. Expiry date information can be found on the test kit packaging.

[Validated 06.01.2020]

# Are there any hazardous substances contained within the device or the test kit ingredients?

No. The products within the Innova lateral flow test kit (including the devices themselves and the extraction buffer fluid) are not hazardous.

The swabbing and processing of a test does not inactivate the virus so caution should be taken when handling the test and when managing spillages as live virus may be present.

If a spillage does occur use a disposable cloth or paper towel, mop up the spillage and dispose of in the bag provided. The area should then be cleaned and disinfected, again the disposable cloth or paper towel should be disposed of in the bag provided.

[Validated 26.01.2021]

# Can open left over extraction fluid bottles be stored overnight? If yes, at what temperature?

The extraction fluid bottles may be opened and resealed for each assay. The extraction bottle cap should be firmly sealed after each use. The extraction solution is stable until expiration date if kept at 2-30˚C.

[Validated 27.11.20]

# Are the swabs latex free?

Yes, the Innova swabs are latex free. The swabs are also supplied in sterile packaging, labelled as sterile, to protect from exposure to latex within the external environment. This means that if testing staff handling the test kit are wearing latex gloves there should be no impact on the swab itself. If any part of the swab packaging looks damaged in any way, please do not use the test and report this via the appropriate channel.

[Validated 12.01.2020]

# Do the covid tests contain animal products or have they been tested on animals?

The monoclonal antibody technology present in our lateral flow devices are necessarily generated from animal cells. This is in common with other tests of this kind, including commercially available pregnancy tests. The Innova swab itself does not contain animal products.

During development, at no time have any component parts been tested on animals.

The Vegan Society [advises](https://www.vegansociety.com/resources/nutrition-and-health/medications) vegans avoid using products made from animals as far as is practicable and possible and vegans should never stop taking prescribed medications without first talking to your doctor.

[Validated 16.12.2020]

# Are the LFD tests halal?

No animal products have been used in the production of the swabs that come into direct contact with the individual using the test.

The thin paper like material inside the LFD is coated with antibodies from animal cells. No direct contact will be made between the person and this material. The monoclonal antibody technology present in our lateral flow devices are necessarily generated from animal cells. This is in common with other tests of this kind, including commercially available pregnancy tests. It is for individuals to make their own decisions based on their religious practises or dietary choices.

[Validated 26.01.2021]

# If a positive line appears at e.g. 20mins, is it possible it can become negative by 30mins?

No, if the test is read as positive after 20mins no further analysis is needed.

Positive results can be reported at 20 minutes. Negative and Void results must be reported at 30 minutes. If a positive signal appears after 30 minutes, it should not be reported as positive. Line C must be coloured to have a valid test result.

[Validated 16.12.2020]

# Are there any lessons learned about how to avoid void tests?

There are two factors which cause a void or invalid test (i.e. no control line is produced):

* the inner membrane of the test strip is not coated properly
* not enough solution is dripped into the sample well on the device during processing In order to reduce the risk of a void test the guidance for processing a test must be adhered to.

Ensure you complete 10 seconds’ worth of extraction of the sample. The lateral flow device cartridge must be on a flat and level surface throughout. Ensure the 2 drops of extracted sample fluid are air-bubble free before releasing them into the sample well of the lateral flow device cartridge. Check that the liquid can be seen seeping through the cartridge. The results should be read within the allocated time (20-30 minutes). Strong positive results can be reported at 20 minutes, however, negative results must be reported at 30 minutes.

[Validated 08.01.2021]

# What is the typical void rate for lateral flow antigen tests?

According to published lateral flow data, lateral flow tests reported via the existing National Testing Programme infrastructure have a void rate of 0.37%.

[Validated 13.01.2021]

# What is an IFU?

An IFU is the manufacturer’s Instructions for Use (IFU). This is a step-by-step guide to carrying out a lateral flow test.

[Validated 20.01.2021]

# What happens if more than 2 drops of extraction fluid have been dropped on the sample well of the LFD?

For Innova tests, more than 2 drops (3-4) of extraction solution dripped into the sample well will still give a valid test.

[Validated 16.11.2020]

# Will the Innova test kits supplied come with control sets provided (positive and negative controls), so that we can validate our environments?

No. Control sets are for batch validation and are not currently available for onsite quality assurance or training. Batch validation for Innova is being completed centrally for the programme by an independent accredited laboratory and therefore there is not a requirement for this to be done locally. The process of batch validation is in line with the Innova process using the prescribed control sets - for every batch, 100 in every 1,000,000 test kits are sent for batch validation. The outcome of the batch validation will not be communicated to the programme unless the failure rate is greater than 3.5% at which point the entire batch will be recalled from the programme.

[Validated 22.01.2021]

**Who are the Lateral Flow Device tests suitable for?**

**Do lateral flow tests require a professional to perform the test?**

The LFD test has been validated for self-swabbing. This means that subjects will be asked to self-administer a swab and provide their own sample. They do not require a qualified person to conduct the test.

[Validated 12.01.2021]

# Can the test be used on those with nose piercings?

Yes. If you have a nose piercing swab the other nostril. If pierced on both sides, remove the piercing on one side before swabbing.

[Validated 14.01.2021]

**Temporary Suspension of Confirmatory PCR for assisted LFD testing in England: What are the changes and how will they affect me?**

**How do I get my LFD test result?**

Your result will be available within 30 mins of taking the test. They are point of care tests, so don’t need to go to a lab to be processed. Your result will be sent to you via SMS and/or e- mail, or in person in some instances. Results will be communicated at latest within a day of the test. You are legally obliged to self-isolate following a positive LFD test result.

[Validated 26.01.2021]

# Will people who test positive on one of these rapid tests face fines if they don’t self- isolate? Will they be eligible for the £500 self-isolation payment?

From 27 January 2021, LFD test positive results will legally confirm diagnosis of coronavirus and activate legal obligations to self-isolate and the ability to claim the Test & Trace Support Payment for those not self-reporting. Before this date, a confirmatory PCR test was required.

[Validated 26.01.2021]

# What if I take a PCR test after getting an LFD test result and the result is different?

Your LFD test result will be used for qualification for Test & Trace self-isolation payments, contact tracing and legal requirement of self-isolation, not a PCR result.

[Validated 26.01.2021]

# When am I legally obligated to self-isolate?

You are legally obliged to self-isolate following a positive LFD test result. Follow the latest government guidance on self-isolation.

[Validated 26.01.2021]

# Why going forward is your policy X over Y?

Due to the prevalence of coronavirus (COVID-19) increasing to over 1% in the tested population, PHE advised that confirmatory tests should no longer be required following a positive LFD test result at most test sites. When there was lower prevalence of the virus in the UK, and after initially introducing widespread use of LFD tests in community settings, we required a confirmatory test to be taken to confirm the presence of the virus after a positive LFD test result.

[Validated 26.01.2021]

# What if I take two tests with different results? (for those not in the below groups)

* You should not be taking 2 tests unless explicitly instructed to do so.
* If your first LFD test is negative and your second LFD test is positive you must follow government self-isolation guidance from the result of the positive LFD test.
* If your first LFD test is positive and you take a second LFD test which is negative, you must follow government self-isolation guidance from the result of the positive LFD result. You cannot use one LFD result to validate or invalidate another.
* If your LFD test is positive and you take a PCR which is negative, you must follow government self-isolation guidance from the result of the positive LFD test.
* If your PCR test is positive and you take a LFD test which is negative, you must follow government guidance and self-isolate from the result of the positive PCR test.
* If your PCR test is negative and you take a LFD test which is positive, you must follow government self-isolation advice from the result of the LFD test.

For Adult Social Care, the NHS and those who work in primary schools: There are special arrangements for those who have regular LFD tests as part of regular asymptomatic workplace testing programme in these groups. For these groups, if your LFD test result is positive, you and your household should self-isolate and follow the steps above. You should also arrange to have a PCR test.

If this PCR test result is positive, you and your household must complete your full self- isolation period. If this PCR test result is negative, and you have no symptoms of COVID-19, you and your household can stop isolating.

[Validated 26.01.2021]

# What do you do with an inconclusive LFD test result?

If your LFD test result is invalid or inconclusive, you will need to take another as soon as possible.

[Validated 26.01.2021]

# How will contacts be traced from the LFD test result?

Users can input their positive LFT result into the NHS app, using a token ID from CTAS which would then trigger self-isolation and tracing. They can also register their test result online at gov.uk or use the phone number in the test kit’s instructions.

[Validated 26.01.2021]

# Why are NHS England retaining confirmatory PCR within their staff?

In line with clinical advice, confirmatory PCR testing will remain for NHS staff and in Adult Social Care, where the test is taken as part of an asymptomatic testing workplace programme and results may be reported using a self-reporting tool by the individual or by their workplace. It will also remain for those who work in primary schools where testing is done at home, but not for those who work in secondary schools who take tests at school. Utilising confirmatory PCR in settings that use a self-reporting tool will minimise the risk that incorrectly reported positive results are registered. Confirmatory PCR testing will also be used for vaccine and LFD testing surveillance, genome sequencing and for self-administered tests.

Confirmatory PCR will continue for:

* + NHS England staff
	+ Adult Social Care
	+ Primary school workers
	+ Hauliers
	+ Scotland / N. Ireland / Wales
	+ (Those in pilots using self-test reporting tools)

[Validated 26.01.2021]

# Why is this change only happening in England and not in devolved administrations despite having similar prevalence?

This change will take effect in England only as of 27 January 2021. Health is a devolved matter, and it is for each of the four nations of the UK to decide on their own testing policy.

[Validated 26.01.2021]

# Won’t it mean people are less likely to come forward for LFD testing if a positive result places them under a legal duty?

It is essential that anyone who tests positive self-isolates immediately to protect their friends, family, colleagues and local community – and to help stop the spread of the virus and save lives.

[Validated 26.01.2021]

# As an employer, why should I participate in workplace testing if my staff don’t have the opportunity of a PCR test to confirm they have the virus?

With higher incidence of COVID-19 in the general population, expert public health advice is that there is limited value in a confirmatory PCR test. Regular staff testing, with self-isolation for those who test positive, helps to protect other staff from getting the virus and helps to reduce overall absences from work.

[Validated 26.01.2021]

# Why do cross channel hauliers still need to do confirmatory PCR?

Several countries have introduced COVID-19 testing requirements for hauliers. The rules are different in each country. Check the rules before you travel and take the necessary action.

[Validated 26.01.2021]