

Frequently Asked Questions (FAQ) – Asymptomatic testing of healthcare workers and Scottish Ambulance Service and NHS24 call handlers using Lateral Flow Device (LFD) Testing

This guide is designed to provide answers to frequently asked questions regarding asymptomatic COVID-19 testing of healthcare workers.

Why are we testing Healthcare Workers?

Why are staff being offered testing?

Testing provides an additional layer of protection by identifying staff members who are infected with the COVID-19 virus but who do not have symptoms. A positive result means staff should self-isolate immediately and so reduce the risk of infecting colleagues and patients. Household members are also required to isolate in line with existing government guidance.

Why has the guidance changed from twice weekly to daily?

24 November 2021 W.H.O declared the newly identified Omicron variant (B.1.1.529) as a variant of concern. This variant has been observed to have increased transmission compared to the current dominant Delta variant. It is therefore vital to increase efforts to slow the spread of COVID-19 among community and hospital settings.

The benefits of daily testing will allow for asymptomatic healthcare workers to be detected and avoid introducing COVID-19 into the clinical environment, this will protect both your patients and their families, and your work colleagues.

By increasing LFD testing, you can ensure that the health service is able to function during the winter months and continue with essential services.

Who will be tested?

Who will be eligible for the LFD roll out?

The scope of the pathway has now been expanded to include all healthcare workers employed directly by NHS Scotland and within Hospices. It is now no longer solely patient-facing staff who can access testing.

The pathway also includes patient facing staff in primary care independent contractors - general practice, dentistry, optometry and pharmacy. Please note primary care staff currently are required to be patient-facing in order to access testing.

Staff are asked to voluntarily consent to taking part in the testing programme. All staff will be provided with information on how their testing data is used and shared

via the privacy notice on the [online reporting portal](#). LFD test kits are for staff member's use only and must not be used by anyone else.

The staff member will consent to sharing their data as described in the Data Privacy Notice, including with Test and Protect.

Which other health and social care staff are already being tested?

Testing of asymptomatic staff has been in place since July for staff in oncology, elderly care and mental health wards, with stays over three months. Staff in care homes are also offered testing on a weekly basis. These groups have been identified as high risk areas due to staff caring for vulnerable patients, and/or where there is evidence of an increased likelihood of outbreaks.

Staff are also offered testing when asymptomatic as part of incident or outbreak investigation at ward level when unexpected cases are identified. This is carried out in line with existing staff screening policy for healthcare associated infection:

[https://www.sehd.scot.nhs.uk/dl/DL\(2020\)01.pdf](https://www.sehd.scot.nhs.uk/dl/DL(2020)01.pdf)

When should the test not be used?

The LFD test does not detect all cases of COVID-19 and so should not be performed if the member of staff has any symptoms suggestive of coronavirus (COVID-19). A "false-negative" result in staff with symptoms is likely to lead to further infections amongst staff and patients/clients. If coronavirus symptoms are present then the member of staff should immediately self-isolate with other household members and arrange for the more sensitive qRT-PCR testing.

What about isolation exemption/ close contact testing?

Within the healthcare workforce a high number of staff isolating would put additional pressure on already fragile services, therefore, we would like to emphasise that current guidance for healthcare staff should still be applied with one important addition. See [DL\(2021\)24 - Update on isolation exemptions for Health and Social Care staff \(scot.nhs.uk\)](#) for further details.

This existing isolation policy for staff who are household or passing contacts of covid-19 positive cases, exempts them from the requirement to self-isolate for 10 days when they:

- are double-vaccinated;
- are asymptomatic and remain asymptomatic,
- undertake PCR test (which returns a negative test result before returning to work), and;
- undertake daily LFD testing for the remainder of the 10 day period.

An important addition to this is that staff must be:

- double vaccinated and had their booster

LFD test kits from this pathway (not the universal offer) should be used to support the requirement for daily LFD testing for 10 days following last exposure. If you

require additional LFD tests to support this please speak to your line manager or Board LFD Lead. Primary care staff should contact NSS by phone on 0800 008 6587 or by email at nss.PrimaryCareLFDOrderKits@nhs.scot to order additional kits if necessary.

How is the test done?

What testing product is used?

Previously the healthcare worker pathway used boxes of 25 Innova SARS-CoV-2 Antigen Tests and boxes of 7 Orient Gene Rapid COVID19 (Antigen) tests. The pathway is now transitioning to boxes of 20 Orient Gene Rapid COVID19 (Antigen) tests. Innova 25 and Orient Gene 7 LFD test kits remain valid for use until their expiry date. Please ensure any remaining supplies of Innova 25 and Orient Gene 7 LFD test kits are used up before starting to issue Orient Gene 20 test kits to staff. Please note, the instructions for use of each kit differ, therefore please ensure the appropriate written instructions are used for each product.

Please note that we will begin a phased rollout of Orient Gene boxes of 20s (OG20s) from Monday 20 December.

What is the difference between a Orient Gene box of 7 (OG7) and an OG20?

OG20s are similar to OG7s, the differences being the number of kits in each box and the buffer solution will be spread over two bottles, which are required to be portioned across all 20 tests, as opposed to the solution being inside individual vials (as is the case with OG7s). The solution from this bottle is to be used as the solution for all tests in the box.

Health Boards/ Primary Care Independent Contractors will be asked at point of ordering LFDs to confirm that all staff have completed the required training for using the lateral flow test supplied.

A range of training materials and an eFU will be available to guide support HCWs to use OG20 LFD test kits. However, staff are encouraged to request supervision for their first OG20 test if they are unsure or would like extra support.

It is important that OG20s are not used by other members of the family, as MHRA have agreed OG20s can be used as self-test kits by health and social care staff only, this is because they are registered for use as assisted test kits.

How do staff administer the test?

For Innova LFD Test Kits:

In line with the Standard Operating Procedure (SOP) the Innova LFD test can be self-administered by staff at home or in the workplace by using only nasal swabbing at a depth of about 1.5cm in each nostril. A swab is taken from both nostrils and then inserted into the extraction tube with the extraction fluid and then rotated and

pressed to make sure that the sample from the swab is released into the extraction fluid. You then take the extraction tube with the nozzle cap and place 2 drops of extraction fluid into the sample well of the LFD testing device cartridge and wait for the results on the test device. Reagents and devices must be at room temperature (15–30 °C) when used for testing.

The Innova LFD test takes approximately 5 minutes to undertake and results are given in 30 minutes. The timing is critical, as leaving the test for longer can lead to false positive results and the test will need to be repeated. **A negative test does not rule out COVID infection, and as such, you should continue to follow infection prevention and control advice and national COVID guidelines as normal, even if you register a negative result.**

The extraction solution and test cartridges should be stored at 2-30 °C between tests.

For Orient Gene LFD Test Kits (both for OG7s and OG20s):

In line with the Standard Operating Procedure (SOP) the LFD test can be self-administered by staff at home or in the workplace by using only nasal swabbing at a depth of about 2.5cm in each nostril. A swab is taken from both nostrils and then inserted into the extraction tube with the extraction fluid (for OG20s add 10 drops of the buffer solution into the extraction tube before inserting the nasal swab) and then rotated and pressed to make sure that the sample from the swab is released into the extraction fluid. You then take the extraction tube with the nozzle cap and place 4 drops of extraction fluid into the sample well of the LFD testing device cartridge and wait for the results on the test device. Reagents and devices must be at room temperature (15–30 °C) when used for testing.

The Orient Gene test takes approximately 5 minutes to undertake and results are given in 15 minutes. **Please note that the timing of the Orient Gene test differs from the Innova LFD test.** The timing is critical, as leaving the test for longer can void the result and the test will need to be repeated. **A negative test does not rule out COVID infection, and as such, you should continue to follow infection prevention and control advice and national COVID guidelines as normal, even if you register a negative result.**

The extraction solution and test cartridges should be stored at 2-30 °C between tests. If the test kit has been stored in a cool area (less than 15°C), ensure your test is at room temperature (15–30 °C) prior to testing.

How frequently should staff be tested?

Staff should now test themselves daily, preferably prior to their shift. We advise that staff continue to test themselves during periods of leave so that, in the event of a positive test, they can begin their period of self-isolation at that point.

What training will staff require?

Staff will be supported with appropriate training materials developed by NHS Education for Scotland (NES). Staff should then be able to self-administer the tests either at home, or in the workplace.

Training materials are available via TURAS at the following link:

<https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-your-workplace-environment>

For the Orient Gene 7s LFD test kits only, the Manufacturer's instructions for use (IFU) should be followed and are available [here](#). However, please note the following important departures from the IFU for the healthcare worker pathway in Scotland.

- The Orient Gene IFU directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify NSS [IRIC](#).
- When recording test results on the online portal, please ensure you enter the lot number provided on the outer cardboard packaging of the test kit, **not** the ID Number printed on the individual test cassette.

For the Orient Gene 20s LFD test kits only, the Manufacturer's instructions for use (IFU) included in the boxed should be disregarded. In their place please use the healthcare worker specific electronic instructions for use, this will be available to view on both TURAS and Scottish Government's webpages, alongside other training materials for OG20s from 20th December 2021.

It is recommended, but not required, that staff are observed by a trained healthcare colleague the first time they administer an LFD test to identify early on if additional support will be required, or if they are unable to perform the test for whatever reason. Employers should use their discretion as to which staff may require training or additional support. Any staff member who needs support undertaking the test should be provided with appropriate support and training and, where possible, observed on the first occasion. If a staff member is unable to perform the test, employers should enable testing by other technologies where possible.

What to do once you have results

Do staff have to self-isolate if they receive a positive test?

In the event of a positive result, the staff member should self-isolate immediately (along with their household) in line with government guidance, inform their manager and occupational health department, and arrange to have an urgent confirmatory qRT PCR test performed; swabs will be taken in accordance with their organisational protocols and sent to their local designated COVID-19 laboratory for testing. Students on clinical placements should also advise their University.

The positive result of a LFD test will now be used to initiate contact tracing. On receipt of the test result, NHS National Services Scotland will feed this result into the Case Management System which contains all the positive test case information. This

system is used to undertake contact tracing. The person who has tested positive will be advised to undertake a confirmatory PCR test result.

Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy. A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test. Further details are provided below.

Should this test result confirm a false positive on the LFT, then local Health Protection/Test and Protect teams will be informed so that the local Health Protection Team (HPT) can conduct a risk assessment to decide whether or not to reverse the contact tracing process. A person who is LFD pos/PCR neg should not stop self-isolation and should not resume usual duties unless told to do so following a HPT risk assessment. Contact tracing for that person will also continue until the HPT decide it should stop. Should no confirmatory PCR be received within 48 hours, then the case will continue to be considered as a positive case and where applicable relevant authorisation codes for the protect.scot app will be sent.

If symptoms develop subsequently, then the healthcare worker should restart their period of isolation from start of symptom onset, in line with Government guidance. Staff should continue to isolate until they have the results of the PCR test.

In line with existing government guidance, the symptomatic staff member should remain in isolation until 10 days from symptom onset, or longer if certain symptoms persist. The rest of their household should remain in isolation for 10 days from symptom onset in the symptomatic person, even if they don't have symptoms themselves.

What happens if my test is negative, but I have coronavirus symptoms?

The LFD test should not be used in staff members who have symptoms of coronavirus (COVID-19). Staff with COVID-19 symptoms must not be at work. If you have coronavirus (COVID-19) symptoms, please self-isolate as per Government advice and book a PCR test: <https://www.nhsinform.scot/illnesses-and-conditions/infections-andpoisoning/coronavirus-covid-19/test-and-protect/coronavirus-covid-19-testing>

What must staff do if they are negative?

Staff who do not have symptoms of coronavirus (COVID-19) and test negative from a LFD test can continue to work normally. However, it is **essential** that they continue to follow the advice regarding infection prevention and control practices, including appropriate use of personal protective equipment (PPE), as set out in national guidance: <https://www.hps.scot.nhs.uk/web-resources-container/covid-19-infection-prevention-andcontrol-measures/>

Staff who return a negative result by LFD testing should **not** regard themselves as definitely free from infection – the test could be a false negative - they may also go on to acquire the virus in the period before the next test. They should remain vigilant to the development of symptoms that could be due to COVID-19; if these develop they should follow the advice of NHS Scotland:

<https://www.nhsinform.scot/self-help-guides/self-help-guide-coronavirus-covid-19>

Are the antigen LFD tests accurate?

Antigen lateral flow tests have been widely and successfully used to detect coronavirus in asymptomatic individuals. Using antigen LFD tests is crucial in the fight against the virus.

Extensive clinical evaluation has been carried out on antigen lateral flow tests. [Evaluations from Public Health England and the University of Oxford](#) show these tests are accurate and sensitive enough to be used in the community for testing and surveillance purposes.

Antigen LFD tests identify individuals who are most likely to be infectious. These individuals are thought to have a higher likelihood of spreading the virus to many people, and so identification by LFD tests remains important.

We continue to monitor and update guidance as further evidence becomes available. It is vital that staff continue to follow the relevant infection prevention control guidance. LFD tests are just one line of defence against the virus.

How accurate is the test?

LFD 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 evaluation [by Public Health England and Oxford University](#) shows that the tests perform best when levels of virus are at their highest. 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 which we mainly use for people with symptoms. When levels of virus are at their highest and people are most likely to pass on the disease, lateral flow tests can detect [the vast majority of cases](#).

If you test positive on an LFD test, it is likely that you are infectious at that moment, whereas people testing positive on a PCR test could be less infectious in the 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.

Additional Information for Staff

How many tests will staff get?

For Innova LFD Test Kits:

The Innova LFD testing kits will arrive in boxes containing the following:

- 25 foil pouches containing the test cartridge and a desiccant
- two vials of 6 mls buffer solution
- 25 extraction tubes and 25 tube caps
- 25 sterilised swabs for sample collection
- The manufacturer's instructions for use of the device (IFU). NB: you will receive instructions for healthcare workers separately from the box, and it is these that staff should follow instead.

For Orient Gene7s LFD Test Kits:

The Orient Gene LFD testing kits will arrive in boxes containing the following:

- x7 Sterile swabs inside a sealed wrappers
- x7 Test cassette in a sealed pouches
- x7 Extraction tubes with buffers
- x7 Nozzle caps
- x7 Plastic waste bag
- x1 extraction tube holder (reusable, so do not discard)
- The manufacturer's instructions for use of the device (IFU). NB: for Orient Gene test kits, staff should follow the IFU.

For Orient Gene20s LFD Test Kits:

The Orient Gene LFD testing kits will arrive in boxes containing the following:

- x20 Sterile swabs inside a sealed wrappers
- x20 Test cassette in a sealed pouches
- x20 Extraction tubes
- x2 buffer bottles (solution from these 2 bottles are required to be portioned across all 20 tests)
- x20 Nozzle caps
- x1 extraction tube holder (reusable, so do not discard)
- The manufacturer's instructions for use of the device (IFU). NB: Please disregard the IFU issued in the box and use the electronic instructions for use (eIFU) hosted on the Scottish Government web page and TURAS.

How should I store my test at home?

Both Innova and Orient Gene test kits should be kept at room temperature – not in direct sunlight and not in a fridge or freezer. The LFD devices and reagents can be stored at room temperature or refrigerated (between 2-30°C). Do not freeze any of the test kit components.

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, leave it to reach normal room temperature before using. Keep the test kit away from children and animals.

The shelf life of Innova and Orient Gene LFD test kits is 24 months from the date of manufacture. Expiry date information can be found on the test kit packaging, printed on the pouch and kit box after "EXP". If the expiry date has passed, the LFD test kit should not be used.

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.

For Innova LFD Test Kits:

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.

For Orient Gene LFD Test Kits:

Ensure you press the tip against the edge of the extraction tube with force, while rotating it around the tube at least 6 times, before leaving for 1 minute to extract the sample. Make sure you place the lateral flow test cassette on a flat and level surface throughout. Ensure the 4 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 at the allocated time (15 minutes). All results should be reported at 20 minutes.

What should staff do with a used test at home?

Negative LFD tests can be disposed of in domestic waste as normal (the extraction tube holder is reusable, so please do not discard). Positive tests should be double bagged and held for 72hrs before disposal in domestic waste. Regardless of whether the test is negative or positive, it should not be disposed of as clinical waste (i.e. in an orange bag) due to the presence of the test chemicals.

What should staff do with the used test in clinical settings?

Staff are encouraged to test at home to allow self-isolation to begin immediately in the event a positive result is received.

Any swabs, cartridges and devices associated with LFD testing are likely to be contaminated with liquid chemicals. This waste is not clinical, neither is it infectious waste, therefore it must not be placed in an orange bag, nor disposed of via the clinical waste route.

Due to the liquid chemical content it must be treated by municipal incineration i.e. 'Energy from Waste' from waste facilities. It is necessary for this waste to remain 'visible' in the waste management chain in order to prevent mishandling or

inappropriate treatment (for example, landfill); therefore, where possible, it should be placed in a clear bag.

Where clear bags are not available you should speak to your local waste management team to agree an appropriate approach to achieve the desired treatment route (i.e. incineration). You will need to speak to the general waste contractor and ensure that this segregated waste is taken to energy from waste facilities, this may require separate arrangements to be made from other waste you produce. This may mean agreement to use other types of non-clinical waste bags such as white, black or other bags, as long as it is labelled as non-hazardous, chemically contaminated waste.

What should staff do with the used test in primary care settings?

For primary care and independent contractors, the number of staff undertaking daily testing in situ should be taken into account. If only very small numbers of staff are undertaking the test on site, tests should be disposed of in the normal domestic waste stream, as per the At Home waste disposal guidance above. Staff are encouraged to test at home to allow self-isolation to begin immediately should a positive result be received.

I have had a vaccine, do I still need to be tested?

Yes. LFD testing should continue after vaccination. Vaccines reduce the risk of infection after 14-21 days but do not eliminate the risk of infection. Following a review of the clinical evidence in relation to both the AstraZeneca and Pfizer BioNTech vaccines, the Joint Committee on Vaccination and Immunisation has recommended that first doses of vaccine are prioritised for as many people as possible. This reflects the need to reach as many people in the shortest possible timeframe, providing a very substantial initial protection which, in most cases, is likely to raise them from 0% protected to at least 70% protected in typically 14-21 days.

This will be reviewed as we better understand the degree of protection, and duration, the vaccination provides, including whether it is still possible to transmit the virus if you've been vaccinated.

Will the vaccine affect the test?

The vaccination will not impact the test result.

What about other Infection Prevention and Control Measures? What do staff need to do?

It is essential that all staff follow current national IPC guidance. This includes the extended use of face masks in both patient facing and non-patient facing areas, physical distancing and use of PPE and increased environmental cleaning. Staff should continue to be vigilant regarding good hand and respiratory hygiene and should immediately self-isolate if symptoms of coronavirus (COVID-19) develop. LFD testing is carried out in addition to these measures and in no way replaces other IPC measures.

Why are symptoms not a reliable way of identifying infected individuals?

Staff with symptoms should not be at work and should not use the LFD test to “rule out” coronavirus infection. The level of infectivity of asymptomatic or pre-symptomatic individuals is not always known exactly. Studies have shown those with minimal or no symptoms can transmit infection to others, and indeed can be more infectious just before, or at around the time, of first developing symptoms. Thus, screening of staff with no symptoms for the presence of the virus is a method of detecting these individuals and excluding them from work for a period to protect both colleagues and patients.

It is important to emphasise that staff must remain vigilant for symptoms suggestive of infection with COVID-19, and of symptoms in household members, and to follow the advice of NHS Scotland if these develop: <https://www.nhsinform.scot/self-helpguides/self-help-guide-coronavirus-covid-19>. If a staff member or someone in their household becomes symptomatic, they must **not** come to work but follow the advice outlined above. Even if a staff member develops what could be COVID-19 symptoms after a very recent negative LFD test, they should immediately self-isolate (along with their household) and book a PCR test via the usual channels for symptomatic testing.

Will testing be mandated?

No. Testing of staff is offered on a voluntary basis, however we would strongly encourage all eligible staff to undertake regular testing. It is important to reemphasise that testing is designed to reduce the spread of transmission, promote staff safety and the safety of patients and service users, in conjunction with other robust IPC measures.

Will my life insurance policy be affected if I agree to LFD testing?

The British Medical Association (BMA) and the Association of British Insurers (ABI) have released a joint statement on this matter. They have made it clear that healthcare workers should not be discouraged from having a test over concerns surrounding insurance policies:

“Each application for life insurance and income protection will be assessed on an individual basis, regardless of profession, and focused on the person’s health and severity of any symptoms at the time.”

More information can be found at: <https://www.bma.org.uk/advice-and-support/covid-19/your-health/covid-19-your-life-insurance>

How long do you expect the testing of Healthcare Workers to last?

We anticipate that the testing programme will continue for some time, until there is a wider population uptake of the vaccination, and COVID-19 transmission is at a much lower level rate.

Are testing kits latex free?

Both Innova and Orient Gene swabs (LFD kits) 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.

Some PCR testing swabs - while not containing latex- may have been manufactured in areas that have previously handled latex. This applies to those kits that have been distributed via the Department of Health and Social Care (DHSC) across care at home/housing support services.

The PCR kits affected will have a warning clearly stating this and we advise, although the risk is minimal, that staff who have a latex allergy do not use these kits. Where this arises we suggest that staff contact their employer in the first instance. Alternative LFD kits can be provided.

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

No. The products within the 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.

For Orient Gene test kits the extraction buffer fluid is 97.6% water. The extraction buffer contains preservatives which may cause an allergic reaction in some people. If the solution makes contact with the skin or eye, wash with lots of water. If skin irritation occurs get medical attention.

For Innova test kits the extraction buffer fluid is composed of 97.9% water.

Do the lateral flow device tests contain animal products or have they been tested on animals?

The monoclonal antibody technology present in both Innova and Orient Gene 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 swab itself does not contain animal products.

During development, at no time have any component parts in the Innova or Orient Gene test kits been tested on animals. The Vegan Society advises 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.

Are the Innova and Orient Gene 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.

Can remaining supplies of Innova 25 LFD test kits still be used?

Yes, Innova 25 LFD test kits remain valid for use until their expiry date. Please ensure any remaining supplies of Innova 25 product are used up before starting to issue Orient Gene test kits. Please ensure the appropriate written instructions for use of Innova products for healthcare worker testing continues to be followed when using these test kits.

What if nasal swabbing is not suitable for me?

The Orient Gene LFD test requires nasal swabbing only. If nasal swabbing is unsuitable for you (for example because you suffer from nosebleeds or other adverse effects, or have nasal piercings), boxes of 7 Innova LFD tests can, in these circumstances, be used for throat only swabbing.

To access boxes of 7 Innova LFD tests, please first discuss with your Health Board LFD Testing Lead, who can order Innova branded kits from National Services Scotland (NSS) . You should continue to ensure that you record your results on the healthcare worker online result recording portal ([Welcome - COVID Testing Portal \(service-now.com\)](https://www.service-now.com)).

Implications of a Positive LFD Test

At what stage is Test and Protect informed of the result?

The positive result of a LFD test will be used to initiate contact tracing. On receipt of the test result, NHS National Services Scotland will feed this result into the Case Management System which contains all the positive test case information. This system is used to undertake contact tracing. The person who has tested positive will be advised to undertake and confirmatory PCR test result.

Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy. Further details are provided above. A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic

and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test.

Should this test result confirm a false positive on the LFT, then local Health Protection/Test and Protect teams will be informed so that the local Health Protection Team (HPT) can conduct a risk assessment to decide whether or not to reverse the contact tracing process. A person who is LFD pos/PCR neg should not stop self-isolation and should not resume usual duties unless told to do so following a HPT risk assessment. Contact tracing for that person will also continue until HPT decide it should stop. Should no confirmatory PCR be received within 48 hours, then the case will continue to be considered a positive case and where applicable relevant authorisation codes for the protect.scot app will be sent.

What support is available for people self-isolating?

The Scottish Government has taken a supportive approach towards helping people to self-isolate, in line with the latest evidence on compliance and to ensure that people are able to overcome any challenges an isolation period may present.

Support available includes:

- **The Self-Isolation Support Grant.** This is a one-off payment of £500 to people who earn less than the real living wage to help them self-isolate. The Grant is targeted at people on low incomes to support them through a period of isolation, and where they are unable to work from home.
- **Crisis Grants.** Local Authorities have the discretion to issue further crisis grants to people who are in urgent need of financial support and who don't qualify for the above Grant, i.e. those with no recourse to public funds.
- **The National Assistance Helpline.** This is the Coronavirus Helpline which fields general calls and requests for assistance regarding COVID-19. People from across the country can call for support and the helpline will link in with their relevant local authority to assist people as required. The number is 0800 111 4000 and is available Monday to Friday, 9 am to 5 pm.
- **The Local Self-Isolation Assistance Service.** At the point of being contact traced, individuals can opt-in to receive support calls from their local authority. Councils can then provide people with support when they need it in the areas of food and essential medicine delivery, in addition to other services which may be required such as befriending or dog-walking.

In addition, the Scottish Government has provided additional funding of £15 million to GP practices to help them cope with extra pressures arising from coronavirus. This includes funding for locum cover for sickness leave and staff who are self-isolating.

What are the plans to expand support?

The Scottish Government recently announced plans to expand support, including the expansion of eligibility for the Self-Isolation Support Grant to include people who earn less than the real living wage. They also announced that they will work with Public Health Scotland to develop a notification system which employees can then

share with employers to provide a government communication that the individual has to self-isolate. All employers should be supporting isolation, and the Government is currently looking at further measures to ensure that all employers comply, including working with businesses and trade unions to enforce a consistent approach.

The Government also announced regular tracking of an expanded set of Scotland specific data, which will report regularly, and a public-facing media campaign to outline support available to citizens.

Where should people who are self-isolating go for support, in the first instance?

They should contact their local authority or the National Coronavirus Assistance Helpline on 0800 111 4000. Please note the helpline is open from Monday to Friday, 9 am to 5 pm.

If a staff member has a positive PCR COVID-19 test, when should they start the LFD tests again?

Please be advised that there has been a change to the guidance on exemption from LFD testing within 90 days of a positive PCR test. Staff members should continue to LFD test daily within 90 days of a positive PCR result. If a staff member has a positive LFD result or has new symptoms, then they should isolate and get a PCR test.

Are we asking potentially positive staff to come to hospitals for a confirmatory PCR test?

NHS Boards should use their normal processes to access tests for healthcare workers in their area who have symptoms of COVID-19. These processes assume that staff may be infected with COVID-19 and therefore suitable IPC and PPE will be in place. Staff should continue to isolate until they have the results of the PCR test.

If I have a positive lateral flow test result, why follow up with a PCR test?

Health care workers who receive a positive result from their lateral flow device test should follow this up with a confirmatory PCR test. PCR test samples are required to perform Whole Genome Sequencing (WGS).

A proportion of positive samples are sent for whole genome sequencing to improve our understanding of virus transmission chains and determining whether cases are likely to be linked so we can target appropriate public health measures. We are also using WGS to identify and track potentially significant genetic changes that may affect how easily the virus is passed on and the severity of the symptoms it causes. This allows us to target public health interventions to stop the spread of new SARSCoV-2 variants of potential concern and ensure that the tests in use to identify SARSCoV-2 remain fit for purpose.

If a healthcare worker tests positive, will their colleagues be expected to self-isolate too?

In most circumstances, no. All staff members are subject to preventative infection prevention and control measures, including PPE. This will be assessed on a case by case basis by the local Health Protection Team.

Testing is only one measure of protection against COVID-19, alongside a strong emphasis on existing IPC measures - including the use of PPE, the extended use of face masks, physical distancing, increased environmental cleaning, symptom vigilance, and good hand and respiratory hygiene.

Should patients who have been in direct contact with a staff member who tests positive with a LFD test be tested while the confirmatory PCR test result is pending?

Existing protocols for tracing contacts should be followed.

What should a staff member do if they continue to get invalid or inconclusive results?

When an invalid result is observed, the test should be repeated with a new test kit. However, if this issue persists and an individual continues to get invalid results, they should request to be observed by a trained healthcare colleague whilst they administer the test to identify if additional support or training requirements. The test kit should also be replaced in case there is an issue with the batch in question.

Implications for Other Testing Routes

PCR tests are more reliable, why aren't you using these?

PCR tests are more sensitive than currently available LFD tests for COVID-19. That means that they can be done less frequently. But it also means that they may continue to detect viral fragments once someone is no longer infectious. Furthermore, LFD tests have been validated in asymptomatic testing.

Modelling work suggests that LFD tests taken every 3 days prevent a similar amount of transmission compared to PCR swabs taken every 5 days, assuming that all symptomatic persons self-isolate upon onset.

However, because LFD tests are also thought to be slightly less specific than PCR tests, any positive result using a LFD test kit will be confirmed using a PCR test.

Will staff who are currently PCR tested now be tested using LFD tests?

Asymptomatic staff currently weekly PCR tested

Asymptomatic staff who are currently tested using weekly PCR tests should continue to do so based on extant policy, to continue our targeted approach for those patient groups most at risk. However, staff will also be offered the opportunity to be tested using LFD (in addition to their weekly PCR test), so they too can access daily testing (six LFDs and one PCR per week). As there is limited capacity for PCR testing, this cannot be expanded to all healthcare workers at this time, but the LFD tests provide a rapid screening route.

Staff who are participating in research studies

Staff who are participating in studies, such as SIREN, should continue their current method of testing via PCR testing in line with study protocols. However, staff will also be offered the opportunity to be tested using LFD (in addition to their twice monthly PCR test), so they too can access daily testing.

If staff have undertaken an antibody test and the results have indicated they have antibodies, should they still undertake LFD testing?

Yes, staff should still undertake daily LFD testing.

At present, even if someone has previously had COVID-19 (and hence has antibodies), we don't yet know if that protects them from reinfection, or for how long. And the LFD test measures infection (i.e. antigen), not antibody, so a positive result indicates likely active infection.

Please be advised that there has been a change to the guidance on exemption from LFD testing within 90 days of a positive PCR test. Staff should continue to LFD test daily within 90 days of a positive PCR result. If a staff member has a positive LFD result or has new symptoms, then they should isolate and get a PCR test.

What if I was previously accessing testing as an adult care home visiting professional?

Primary care staff who previously accessed LFD testing as adult care home visiting professionals should now use the "Primary Care including Independent" pathway, and should ensure their tests are recorded as such on the [online portal](#) from 22 February 2021.

Care Homes will not require professional visitors who are testing via this pathway to undertake additional testing on arrival at the Care Home, but may ask visiting professionals to confirm that they are participating in the testing programme. It should be noted that LFD testing of professional visitors is not a mandatory requirement but a recommended one - and entry should not be refused on this basis as long as the correct PPE is worn and infection prevention and control principals are adhered to as per national guidance.

Information for students on clinical placements

We have students on clinical placements, are they included and who do they report their tests results to?

Any students on placement should be offered the opportunity to be part of the LFD testing programme whilst on placement. All test results should be recorded via the [online portal](#). Positive results should also be reported to their workplace supervisor whilst on placement. If they are required to be absent from placement, they must follow their university's absence policies.

How will you test students on clinical placements?

All students on placement are included in the LFD testing programme. Students on placement will require to collect their test kit and be provided with information on how to access training materials on the first day in the placement setting. Students may require more support and may prefer to test themselves in the workplace. Boards should take this into account in their local delivery plans.

Do students require a negative test result before coming to placement? It is expected that students on placement will be provided with their LFD tests and information on how to access training materials on their first shift. This is to ensure tests are conducted correctly and to provide an overview of how to capture results.

What training will students receive in relation to self-testing?

Students will be supplied with training materials developed by NES and, in the case of Orient Gene 20 test kits, instructions for use will be provided in addition to being available online via TURAS and Scottish Government websites, these differ from the manufactures instructions for use contained in each box which should be destroyed. This should allow participants to then self-administer the tests either at home, or in the workplace.

Any staff member who needs support undertaking the test should be provided with appropriate support and training and observed on the first occasion. It is recommended that students are observed by a trained healthcare colleague the first time they administer the test to identify early on if additional support is going to be required, or if they are unable to perform the test for whatever reason.

Will I be expected to test myself daily even if I have completed my placement or after I leave the practice area?

Students would not be expected to maintain daily testing after the end of their placement, or when they leave their practice area.

Information for Primary Care Independent Contractors:

Who is eligible for testing?

The scope of the healthcare worker pathway includes:

- All NHS Scotland staff (patient and non-patient facing)
- NHS24 and Scottish Ambulance Service call handlers
- Patient facing primary care independent contractors - general practice, dentistry, optometry and pharmacy. Please note primary care staff currently are required to be patient-facing in order to access testing.
- Hospice staff
- Visiting professionals to a care home

Retail workers in primary care settings are only eligible for LFD testing under this scheme if they are directly involved in the provision of healthcare services, for example pharmacy counter staff.

How will Test Kits be provided to independent contractors?

All primary care independent contractors will receive supplies of LFD test kits based on an estimate of patient-facing staff numbers. Existing supplies of Innova 25 and Orient Gene 7 LFD test kits remain valid for use until their expiry date and any stocks should be depleted before staff are issued with Orient Gene test kits. Test kits will be provided directly to individual premises for onwards distribution to staff. If insufficient test kits are provided, NHS National Services Scotland (NSS) should be contacted by phone on 0800 008 6587 or by email at nss.PrimaryCareLFDOrderKits@nhs.scot to arrange additional supplies. In due course it is intended that contractors will access LFD test kits via PECOS, where available.

The 22 February 2021 deadline for contractors to opt-out of receiving test-kits following consultation with all patient-facing staff has passed. Contractors who have previously opted-out but now wish to participate in the programme can do so by contacting nss.PrimaryCareLFDOrderKits@nhs.scot. If any eligible staff subsequently wish to participate in routine testing, we expect contractors to support them in doing so. Staff can also contact nss.PrimaryCareLFDOrderKits@nhs.scot directly to access testing if necessary.

For reassurance, information on individuals choosing to participate or not participate in testing is protected under data protection however business level information about whole practices who decide not to participate maybe subject to an FOI request.

If contractors receive kits that they cannot (or do not wish to) use they can return kits by contacting NSS on 0800 008 6587 or at nss.PrimaryCareLFDOrderKits@nhs.scot. NSS will arrange for a return label to be send out. Alternatively excess kits can be retained for future use by current staff or for use by visiting locums, students etc.

How should primary care locums access testing?

In the first instance primary care locums should access testing via a practice or pharmacy with which they have an ongoing relationship. Contractors can order test kits from nss.PrimaryCareLFDOrderKits@nhs.scot specifically to provide to locums if necessary. Where the locum works in an Out of Hours Hub or Community Assessment Centre, in addition to within primary care, they will be able to access supplies of test kits within these environments.

Optometry, General Practice and Dentistry locums have been contacted by the relevant Health Board to outline the process for locums to access LFD testing in their Health Board area. Pharmacy locums should contact NSS directly at nss.PrimaryCareLFDOrderKits@nhs.scot to access LFD testing, providing their GPhC number, name and postal address.

Who should independent contractors contact for more information or support?

Primary Care Independent contractors are responsible for allocating test kits to staff and ensuring appropriate training is provided supported by resources developed and made available by NHS Education for Scotland (NES) and detailed further in this

document. These resources are available [here](#). Contractors should contact PrimaryCareLFD@gov.scot for additional support or to escalate clinical or serious incidents or spurious results. Queries or concerns regarding delivery of test-kits should be sent to nss.PrimaryCareLFDOrderKits@nhs.scot.

How should primary care staff record their tests on the online portal? Primary care staff should select “Primary Care including Independent” on the [online portal](#) as the most relevant reason for taking the test. They should then select the area of independent and general practice they work in from the drop down list. The option for primary care staff on the portal will go live on the 22 February 2021. From this date, primary care staff who may have previously used other pathways to access testing such as “Healthcare Worker” or “Care Home – Visiting Professional” should no longer do so.

What if I have more than one working location?

If you work in more than one location, you should select your primary working location from the drop down list on the [online portal](#). You should still provide your current working location even if you are not employed by the relevant NHS Board.

Quality and Contents of Test Kits

Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy. Further details are provided above. A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test.

How are the tests quality assured?

Quality assurance audits of the test kit has been agreed and is managed nationally.

What should I do if the test kit is defective or causes an adverse event?

Report it through your local adverse event reporting system. In primary care settings, adverse events should be notified to NHS National Services Scotland at nss.PrimaryCareLFDOrderKits@nhs.scot if related to deliveries (e.g. items are missing, broken or damaged) or to Board LFD leads for other concerns.

These reports will enable the responsible manager to investigate and identify mitigating actions. You should also report any suspected side effects of medical devices used in coronavirus treatment, or issues relating to spurious results, to [NSS IRIC](#) to ensure safe and effective use. [IRIC](#) is responsible for prompt onward notification of Scottish incident data to [MHRA](#). Arrangements should also be in place with LFD testing lead to rapidly notify complaints to National Procurement.

Please note that the manufacturer’s instructions for use included in the Orient Gene LFD test kits directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify NSS [IRIC](#).

For Orient Gene 20 test kits, the manufacturer's instructions for use should be destroyed. Instructions for use for healthcare workers are accessible via TURAS and Scottish Government webpages.

Performance Monitoring

How will you monitor test results?

The results from the LFD test will be documented by the individual digitally via an [online portal](#). Data from these devices will flow to NHSScotland for use in reporting and any required systems integration. The portal is accessed via this web link (www.covidtestingportal.scot) so that anyone can use their own device to record the results. Guidance on how to use the portal is included in the instruction guide developed by NES.

Staff should currently enter the results of Orient Gene test kits on the online portal only as a registered user or through the single test registration form. Please do not record Orient Gene test results via the bulk upload option.

In response to your feedback, you can now create user accounts in the system. When you create these accounts we will gather all your personal information at the start. Once logged in the system will remember you and you will only need to give us details of the particular test you are reporting. In addition, you can also now upload a number of tests to us at once using a preformatted spreadsheet. This is intended to support areas where testing data is being collected centrally before being uploaded.

Our privacy notice has also been updated, and you should read this to understand how we manage your data. There is a link on the front page of the portal.

Why do I need to record negative and inconclusive tests?

It is vital for performance monitoring purposes that you record the outcome of every test. This gives an indication of both the level of testing across Scotland and provides key data on effectiveness. Tracking the numbers of positive results being reported against the total number of tests being taken helps us to spot patterns and identify outbreaks more quickly. If people only tell us positive results, virus case levels look higher than they really are.

Furthermore, inconclusive data can help to identify any quality assurance issues with kits, or highlight a need for further training.

Do I still need to record the serial number (QR code number) on my test when inputting results?

No. Following feedback from Boards, we have removed the need to capture the serial number (QR Code number) of each individual test. Each box of kits will be

tracked using the ID number instead, please be aware that when entering these numbers that the system is case sensitive.

For Orient Gene test kits please ensure you enter the lot number provided on the outer cardboard packaging of the test kit, **not** the ID Number printed on the individual test cassette. Staff should currently enter the results of Orient Gene test kits on the online portal only as a registered user or through the single test registration form. Please do not record Orient Gene test results via the bulk upload option.

What if I record a result as positive by mistake on the portal?

If you mistakenly record a negative result as positive, then you should undertake a further LFD test and record the correct result in the [portal](#). Because a positive result was initially recorded, it is likely the contact tracing team will contact you. If they do you should explain that there was a mistake. There is no need for you to isolate unless of course the second test result was positive in which case you should self-isolate and book a PCR test. You should also speak to your manager and explain what happened.

What information should employers capture when they issues LFD test kits to staff?

Boards and primary care independent contractors, should keep a record of how many staff have been issued with LFD kits. This will ensure an appropriate audit of number of kits distributed to staff.

When issuing LFD test kits, Boards must ensure the following information is recorded: LOT number (written on the test kit), number of LFD kits distributed, date of distribution and site / event distributed. Confirmation that staff are aware of how to access training materials will also be required. For primary care independent contractors, the number of staff participating in the testing programme should be taken into account. If only very small numbers of staff are undertaking testing, a formal data gathering process may not be proportionate.

Wider use of LFD tests

Can these tests be used for patients?

PCR tests should continue to be used for patients. In addition, in some Boards, LumiraDX devices are being used to test symptomatic patients on admission to hospital.

Can staff use the tests for their symptomatic family members?

No, the LFD kits are for the sole use of the individual staff member. Family members who have symptoms should access tests in the normal way.

Can tests be used as a response to COVID-19 outbreaks?

Should an outbreak be declared in your organisation, testing regimes should be discussed in line with your normal organisational response and local Incident Management Teams.

Why haven't you introduced wider healthcare staff testing before now? This expansion is possible because of increases in our testing capacity – both that delivered through our laboratories and that presented by new testing options.

Given that we now have access to significant numbers of LFD tests, we are able to expand routine asymptomatic testing to other groups, including all healthcare workers as a priority, and to increase the frequency of staff testing to daily.

Asymptomatic healthcare staff are already offered testing if in an outbreak situation, or weekly in certain specialties.

Why am I using a different type of LFD test kit than others in my household?

Different types of LFD test are being used for different testing pathways, including healthcare worker, workforce and schools testing. This may mean that different members of your household are being asked to use slightly different types of LFD test. Please ensure you are using the appropriate instructions for use for each LFD testing product, as instructions differ slightly between products.

All LFD tests that successfully pass through the multiple stage PHE validation process are safe to use and have been shown to exhibit performance characteristics desirable for mass population, community-based testing.

ANNEX A

Version Control

Version	Author	Summary of Changes	Reviewed By	Date
1.0	Scottish Government	Interim FAQ	Expanded Healthcare Worker Testing Programme Board	09/12/20
1.1	Scottish Government	Update to wording following comments from Programme Board members in relation to: <ul style="list-style-type: none"> • Change to isolation requirements • Update on waste disposal • Clarify requirement for LFD testing if already undergoing weekly PCR testing position • Inclusion of question on antibody testing • Expanded scope to include COVID-19 vaccinators 	Pathway lead for expanded healthcare worker testing	18/12/20
1.2	Scottish Government	Update to wording following comments from Programme Board members in relation to:	Pathway lead for expanded healthcare worker testing	11/01/21

		<ul style="list-style-type: none"> • Clarify requirement for continued LFD testing once vaccinated • Inclusion of question on the importance of data capture • Inclusion of question on recording an incorrect result on the portal • Inclusion of extended 'Students on clinical placements' section • Further detail on how to set-up Autofill feature to remove the need for repeated data input • Expanded scope to include Community Workforce and District Nurses 		
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1.3	Scottish Government	<p>Update to wording following comments from Programme Board members in relation to:</p> <ul style="list-style-type: none"> • Further emphasis placed on importance of following IPC measures and national guidelines even if you receive a negative result. • Recognition of other emerging studies on efficacy of LFD tests. • Updated link to Oxford University research on sensitivity. • Further clarity for staff partaking in PCR and LFD tests simultaneously. These groups would have one LFD test and one PCR test per week. • Lot numbers are case sensitive, staff need to be aware of this when inputting data. <ul style="list-style-type: none"> • Update to contact tracing policy. Contact tracing will now commence from the positive LFD test result. • MHRA Coronavirus Yellow Card reporting site added. • Pathway scope further expanded to include additional staff groups • Additional information on support available for people self-isolating 	Pathway lead for expanded healthcare worker testing	25/01/21
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1.4	Scottish Government	<p>Update to wording following expansion of pathway to include primary care independent contractor workforce including:</p> <ul style="list-style-type: none"> • Clarification of best practice that staff are supervised the first time they undertake a LFD test. • Advice regarding waste disposal in primary care setting • Clarification of testing arrangements for care home visiting professionals • Information regarding delivery mechanism of LFD test-kits to primary care premises • Data gathering requirements for primary care context • Expectations regarding supporting staff monitor 90 day period following positive PCR test in primary care setting • Training and adverse event contacts for primary care added • Information regarding how primary care staff should utilise the portal 	Pathway lead for expanded healthcare worker testing	15/02/21
1.5	Scottish Government	Update to wording following comments from NSS IRIC in relation to the Scottish process for alerting to incidents.	Pathway lead for expanded healthcare worker testing	17/02/21

1.6	Scottish Government	<p>Update of wording to include Whole Genome Sequencing information.</p> <p>Updated to reflect additional comments from the Test and Protect Pathways Design Authority and the Scottish COVID Testing Clinical Governance Group</p> <p>Updated to include hyperlinks to online recording portal. Updated to include NES contact details for additional support for training.</p> <p>Updated to include link to NES training material more prominently.</p> <p>Updated to include information regarding delivery of test-kits to primary care independent contractors, and to include new SG mailbox for independent contractors to contact for additional support.</p>	Scottish COVID Testing Clinical Governance Group	
1.7	Scottish Government	<p>Updated to include information on the use of latex in PCR test swabs</p> <p>Updated to clarify Whole Genome Sequencing information.</p>	Pathway lead for expanded healthcare worker testing	15/03/21

		Updated information on ePortal changes.		
1.8	Scottish Government	<p>Updated to include expansion of pathway to all NHS Scotland healthcare workers.</p> <p>Updated information on the use of latex in PCR test swabs.</p> <p>Primary care information updated re: access to testing for locums, practices that have opted out of testing, and NSS mailbox.</p> <p>Updated information on the NSS mailbox for primary care contractors.</p>	Pathway lead for expanded healthcare worker testing	29/03/21
1.9	Scottish Government	<p>Updated to reflect the transition in LFD testing product from Innova 25s to Orient Gene 7s.</p> <p>Updates to reflect transition of primary care testing to BAU.</p>	Pathway lead for expanded healthcare worker testing	16/08/21
2.0	Scottish Government	Updated to reflect change from twice weekly LFD testing to daily testing, move to Orient Gene 20 LFD testing kits and change to the guidance on exemption from LFD testing within 90 days of a positive PCR test.	Pathway lead for expanded healthcare worker testing	13/12/21