



# Frequently Asked Questions (FAQ) – Asymptomatic testing of patient-facing healthcare workers using Lateral Flow Testing

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

#### Why are we testing Healthcare Workers:

#### Why are staff being offered testing?

Testing provides an additional layer of protection, working to identify patient-facing staff members infected with the virus who do not have symptoms, and allow them to self-isolate, so reducing the risk of infecting colleagues and patients. If shown to be positive for the virus, staff will have to self-isolate immediately, along with their household in line with exitisting government guidance.

#### Who will be tested:

#### Who will be eligible for the LFD roll out?

All staff members who are in a patient-facing role who work in NHS Scotland hospitals, the Scotlish Ambulance Service, COVID-19 Assessment Centres, COVID-19 Vaccinators, Community Workforce and District Nurses are eligible for the twice weekly LFD testing. This includes (but may not be limited to) students on placement, porters, cleaners, volunteers, chaplains, healthcare scientists, AHPs, doctors, nurses, bank/agency staff, administrative/ward clerks, ward based pharmacists and hospital based social workers and addiction staff. The subject will consent to sharing their data as described in the Data Privacy Notice, including with Test and Protect.

The scope of the pathway continues to expand and will now also include patient facing staff in primary care, general practice, dentistry, optometry and pharmacy. This includes, but is not limited to: administrative staff such as receptionists, cleaners, Allied Health Professionals (AHPs), students on placement, Doctors, Nurses, Dental Nurses, Pharmacists, Pharmacy Technicians, Dentists and Optometrists. The scope will also extend to Hospice staff, all health professionals who visit care homes and Healthcare Improvement Scotland inspectors, as well as non-patient facing critical roles including office based Emergency Service Control room staff across the Scottish Ambulance Service and staff operating in the NHS24 call centres.

#### Who is 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 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: <a href="https://www.sehd.scot.nhs.uk/dl/DL(2020)01.pdf">https://www.sehd.scot.nhs.uk/dl/DL(2020)01.pdf</a>

#### **How is the test done:**

#### How do staff administer the test?

In line with the SOP, the LFD test can be self-admistered 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 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 completely rule out COVID, 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 2-30C between tests.

#### How frequently should staff be tested?

Staff should test themselves twice a week – every three to four days – to fit with shift patterns – for example, Wednesday and Sunday, or Monday and Thursday. 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 and guidance documents. These have been developed by NHS Education for Scotland (NES) and include an instruction video, simple-to-use written guidance and a poster outlining how to undertake the test, how to interpret the results, how to dispose of waste, and where they should store the box containing the test. Staff should then be able to self-administer the tests either at home, or in the workplace. The MHRA have advised that the LFD training video can be used as the observed test for the purposes of the competency assessment.

Training materials will made available via TURAS at the following link: <a href="https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-your-workplace-environment">https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-your-workplace-environment</a>





It is recommended, but not required, that staff 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. 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 LFT 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 an confirmatory PCR test result.

Should this test result confirm a false positive on the LFT, then contact tracing will stop, the relevant traced contacts will be notified and the "positive" case can resume their usual duties. Should no confirmatory PCR be received within 48 hours, then the case will be continue to considered a positive case and where applicable relevant authorisation codes for the protect.scot app will then 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?

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: <a href="https://www.nhsinform.scot/illnesses-and-conditions/infections-and-poisoning/coronavirus-covid-19/test-and-protect/coronavirus-covid-19-testing">https://www.nhsinform.scot/illnesses-and-conditions/infections-and-poisoning/coronavirus-covid-19/test-and-protect/coronavirus-covid-19-testing</a>





#### What must staff do if they are negative?

Staff who 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 are negative on 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

#### What is the specificity and sensitivity of this particular test?

The government has published its latest research on these tests: Oxford University and PHE confirm lateral flow tests show high specificity and are effective at identifying most individuals who are infectious | University of Oxford

This validation found, when used by trained personnel, the Innova LFD test has a sensitivity of 76.8% - meaning it will identify more than 7 in 10 positive cases of COVID. This rises to over 95% of those with high viral loads – who are those most likely to be infectious.

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.

#### **Additional Information for Staff:**

#### How many tests will staff get?

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 heathcare workers separately from the box, and it is these that staff should follow instead.

#### How should I store my test at home?

The test kit should be kept at room temperature – not in direct sunlight and not in a fridge or freezer. Keep the test kit away from children and animals.





#### What should staff do with the used test at home?

Negative LFD tests can be disposed of in domestic waste as normal. 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 <u>not</u> 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 should a positive result be 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 <u>not</u> 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 mis-handling 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 type 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 twice weekly 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 recived.

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

Yes, for now at least. 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.

However, without the increased protection of a second dose it is essential for testing to remain in place. 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?

Testing is an addition to help us minimise the spread of COVID-19, therefore we would ask that as staff access their test kits they are regularly reminded of the importance of following national IPC guidance – this includes the use of PPE, the extended use of face masks, physical distancing, increased environmental cleaning, symptom vigilance, and good hand and respiratory hygiene.

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

<u>Staff with symptoms should not be at work</u>. The level of infectivity of asymptomatic or presymptomatic individuals is not always known exactly, but studies have shown they can transmit infection to others, and indeed people can be more infectious just before, or at around the time, of first developing symptoms. Thus, screening of staff for the presence of virus is a method of detecting these individuals and excluding them from work for a period to protect others, including patients, until they are no longer infectious.

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: <a href="https://www.nhsinform.scot/self-help-guides/self-help-guide-coronavirus-covid-19">https://www.nhsinform.scot/self-help-guides/self-help-guide-coronavirus-covid-19</a>. 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 the 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 focussed 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.

#### **Implications of a Positive LFD Test:**

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

The positive result of a LFT 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 and confirmatory PCR test result.

Should this test result confirm a false positive on the LFT, then contact tracing will stop, the relevant traced contacts will be notified and the "positive" case can resume their usual duties. Should no confirmatory PCR be received within 48 hours, then the case will be continue to considered a positive case and where applicable relevant authorisation codes for the protect.scot app will then 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 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 os 0800
  111 4000 and is available Monday to Friday, 9am to 5pm.
- 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 Scotlandspecific data, which will report regularly, and a public-facing media campaign to outline the support available to citizens.

Where should people self-isolating who need support go 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, 9am to 5pm.

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

A staff member who tested positive from a PCR test would commence/recommence LFD testing 90 days after their PCR positive test was taken. The staff member will need to track the date at which the retesting should start. Boards will put in place local processes to ensure that staff are reminded to begin testing again 90 days after PCR positive test. Primary care independent contractors employing staff may wish to consider establishing a similar process if it is proportinate to do so.

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

In most circumstances, no. Patient-facing 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 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 is required. The test-kit should also be replaced in case there is an issue with the batch in question. In this case, the test-kit batch number should be reported via the MHRA Yellow Card reporting site.

#### **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 for example. 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

Asympatomaitc 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 twice weekly testing (one LFD 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 weekly PCR test), so they too can access twice weekly testing.

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

Yes, staff should still undertake twice weekly 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.

The only exception is if someone has tested positive for COVID-19 via PCR test within the past 90 days. A staff member who has tested positive via PCR should not commence/recommence regular COVID testing until 90 days after their positive test was taken. Board employed staff will need to liaise with their NHS Board to track the date at which the retesting should start. Primary care independent contractor staff should track this date themselves, although their employer may have processes in place to support staff if it is proportionate to the setting to do so. However, as above, if the staff member develops COVID-19 symptoms during that 90 day period, they must self-isolate in line with government guidance and arrange 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.

#### <u>Information for students on clinical placements:</u>

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

Any students on placement (and in a patient-facing role) should be offered the opportunity to be part of the LFD testing programme whilst on placement. They will need to report positive test results via the online portal, to both their workplace





supervisor whilst on placement <u>and</u> their University and follow any university absence policies.

#### How will you test students on clinical placements?

All students on placement are included in the LFD testing programme. Students on placement in January 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 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 supported with appropriate training materials and guidance documents, including an instruction video, simple-to-use written guidance and a poster outlining how to undertake the test, how to interpret the results, how to dispose of waste, and where they should store the box containing the test. 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 twice weekly even if I have completed my placement or after I leave the practice area?

Students would not be expected to maintain twice weekly testing after the end of their placement, or when they leave their practice area. The LFD testing programme is designed for patient-facing roles only.

### I am in in a practice learning experience where no testing is taking place. Why is this the case?

This would not be defined as a patient-facing role. The LFD testing programme is for patient-facing roles only.

#### **Information for Independent Contractors:**

#### How will Test Kits be provided to independent contractors?

All primary care independent contractors will receive an initial supply of Innova LFD test-kits based on an estimate of patient-facing staff numbers. Test-kits will be provided directly to individual premises for onwards distribution to staff. If insufficient test-kits are provided, NHS National Services Scotland should be contacted at <a href="mailto:nss.PrimaryCareLFDOrderKits@nhs.scot">nss.PrimaryCareLFDOrderKits@nhs.scot</a> to arrange additional supplies. In due





course it is intended that contractors will access LFD test-kits via PECOS, where available.

Contractors who wish to opt-out of the testing programme can do so by contacting NHS National Services Scotland at <a href="mailto:nss.PrimaryCareLFDOptout@nhs.scot">nss.PrimaryCareLFDOptout@nhs.scot</a> by 22 February 2021 at 1700hrs. We expect that contractors will consult with their staff before making a decision to opt out.

#### 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. Contractors have been provided with the contact details of their board LFD Testing Lead, to whom they can escalate clinical or serious incidents or concerns.

#### 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 previously have 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:**

#### How are the tests quality assured?

Quality assurance audits of the test-kit will be agreed and 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. This will enable the responsible manager to investigate and identify mitigating actions. You should also report any suspected side effects to medical devices used in coronavirus treatment via the <a href="MHRA Yellow Card reporting site">MHRA Yellow Card reporting site</a> to ensure safe and effective use.

In primary care settings, adverse events should be notified to NHS National Services Scotland at <a href="mailto:nss.PrimaryCareLFDOrderKits@nhs.scot">nss.PrimaryCareLFDOrderKits@nhs.scot</a> if related to deliveries (e.g. items are missing, broken or damaged) or to Board LFD Leads for other concerns. As above, suspected side effects should also be reported via the <a href="mailto:MHRA Yellow Card">MHRA Yellow Card</a> reporting site.





Arrangements should also be in place with LFD testing Lead to rapidly notify complaints to National Procurement and adverse events to <u>IRIC</u>, which is responsible for prompt onward notification of Scottish incident data to <u>MHRA</u>.

#### Is the buffer solution hazardous?

As set out in the manufacturer's safety instructions, the buffer solution is not hazardous; however, if accidentally ingested, a medical practitioner should be informed.

### Why are the instructions given by NHS Scotland different to the manufacturer's instructions?

The manufacturer's instructions for use (IFU) are included in the box and are detailed and very technical. These do not need to be followed as healthcare workers will use the test in a slightly different way, which has been agreed with experts, discussed with Medicines and Healthcare products Regulatory Agency (MHRA), and the manufacturer informed. This is particularly in relation to use of the test for asymptomatic people, self-administration of the test, and the use of nasal swab inside the lower part of both nostrils. The rest of the process (i.e. the way the test is performed, and the results are interpreted) is the same as set out in the manufacturer's instructions.

A simplified written guide for staff self-testing has been developed nationally by NES; it includes how to undertake the test, how to interpret the results, how to dispose of waste, and where they should store the box containing the test. Local information will need to be provided by Boards, for example, numbers to call for any queries or concerns related to the use of devices and outcome of results. Primary care independent contractors can contact their Board LFD Lead or NES for additional support with training, for example Webinars.

# Why is the testing method different from that described in the manufacturer's original instructions for use?

We are recommending the swab is used and the sample taken in a different way to the instructions for use, with more rotation of the swab at a lower level of penetration, to enable easier self-administration of the test. This is based on advice from experts. The manufacturer has been informed of the planned use of the tests for self-administered asymptomatic staff testing within the healthcare system. All NHS Boards should agree a local point of contact to assist staff with any queries relating to the use of the device, and to support with further training if necessary. Primary care independent contractors can contact their Board LFD Lead or NES for additional support with training, for example Webinars.

#### When deliveries arrive what size of space should be allocated for them?

Tests will arrive on pallets. There are 20 boxes on a pallet that contain 27 smaller boxes which contain 25 tests in each – 13,500 tests in total per pallet. Boards will receive sufficient LFD tests to provide one box of 25 tests to each patient-facing member of staff as soon as possible. Primary care independent contractors will





receive one box of 25 tests for each patient-facing member of staff based on an initial estimate of patient-facing staff numbers.

#### **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 on a web link so that anyone can use their own device to record the results. For ease, we would encourage users to enable the autofill function in their browser, smartphone or tablet. This can be accessed and updated in either the browser, or device, "settings". This will remove the need to input repeat information for each recorded test.

Guidance on how to use the portal is included in the instruction guide developed by NES. Further communications will be issued by the Directorate For Health Performance And Delivery in relation to weekly performance monitoring.

#### 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. 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 lot number instead, please be aware that when entering these numbers that the system is case sensitive

#### 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 an 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.

When issuing LFD test kits, Boards must ensure the following information is recorded: staff name, payroll number, the date the staff member received their box of tests, when they will require their next box (approx. 12 weeks), the batch number,





their contact details and confirmation that staff are aware of how to access training materials. 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 sympatomatic 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 heathcare 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 patient-facing healthcare workers as a priority.

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





#### **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:  • 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:  • 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	Pathway lead for expanded healthcare worker testing	11/01/21





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		<ul> <li>Expanded scope to include Community Worforce and District Nurses</li> </ul>		
1.3	Scottish Government	Update to wording following comments from Programme Board members in relation to:  • Further emphasis placed on importance of following IPC meausres and national guidelines even if you receive a negative result.  • Recognistion 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.  • 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
1.4	Scottish Government	Update to wording following expansion of pathway to include primary care	Pathway lead for expanded healthcare worker testing	15/02/21



