

COVID-19:
Guidance for use of
Lateral Flow Device
testing for
Professionals who
attend Care
Homes: Social Workers,
Care Inspectors & Allied
Health Professionals not
employed by the NHS

12th April 2021 Lateral Flow Testing

Document updates

Version	Date	Update	
V1.0	6 th Jan 2021	First version of the guidance	
V1.1	15 th Jan 2021	Contact email addresses updated	
V 1.2	20 th Jan 2021	Update to advice on obtaining a PCR confirmatory test	
V1.3	26 th Jan 2021	Addition of advice for care homes to ensure stock control and audit processes	
		Advice added on urgent resupply and on a workaround to entering test results on Covid Portal, if tests with irregular batch numbers are used	
V1.4	12 April	Update on helpline New SEPA advice on waste disposal of LFDs (removes the need to double bag and store positive test kits for 72 hours)	

This guidance is for visiting professionals to care homes only.

Kits

The guidance on lateral flow devices is broadly consistent across the four countries but visiting professionals to care homes in Scotland should follow the documentation that has been prepared and reviewed by the Scottish Government.

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 exactly as they test in a slightly different way, which has been agreed with experts, discussed with the Medicines and Healthcare Regulatory Authority (MHRA) and the manufacturer has been informed.

Before you do any testing

- · Read this guidance in its entirety
- · Complete the testing training and checklist
- · Make sure you have received all parts of your order
- Familiarise yourself with the NHS Portal where you result must be recorded.

Introduction

This guidance is aimed at social workers, care inspectors and Allied Health Professionals not employed by the NHS.

It provides advice for individuals who visit care homes and residential settings in a professional capacity on how to prepare for and manage lateral flow testing. Within Scotland, Lateral Flow Device (LFD) testing commenced from 4 January.

Visiting professionals include:

- Health staff such as district and community nurses and allied health professionals employed by the NHS. Guidance available here: <u>Coronavirus</u> (COVID-19): asymptomatic staff testing in NHS Scotland
- Social care staff, social workers, other non NHS Allied Health Professionals, care inspectors (Guidance set out below)

Visiting NHS professionals and visiting Care Inspectorate and social work professionals will not be tested at care home sites. They will be tested twice weekly through a programme delivered through their employer. NHS staff will be tested via the health care workers pathway and will follow the Healthcare Workers Standard Operating Procedures and guidance. Non-NHS staff, such as social care staff, social workers, other non NHS Allied Health Professionals, care inspectors will be also tested via their employer.

It should be noted that LFD testing of professional visitors is not a mandatory requirement but a recommended one. Care Homes may ask visiting professionals to confirm that they are participating in the programme. However, oversight and monitoring will sit with the employer of the visiting professional.

There may be a small number of visiting professionals to care homes that have not been covered by the wider pathway, for example private podiatrists and maintenance staff. If this is the case then they can be tested on arrival at the care home as part of the designated and essential visitors testing pathway see guidance here:

Coronavirus (COVID-19): adult care home visitor testing guidance - gov.scot (www.gov.scot)

It is important that the tests are only used by employees that are regularly working within care home environments or in the case of social work are supporting elderly adults in receipt of social care services within their home.

It is important to always remember that, while testing can reduce the risk of transmission, it does not completely remove the risk of infection. When used alongside robust Infection Prevention and Control (IPC) measures such as PPE,

testing can provide an additional layer of protection to support the health and wellbeing of residents and the workforce.

Lateral flow testing Overview

	What to expect	What to do
Testing Kits	Test kits for social workers will be collected from PPE Hubs.	Start planning in advance so that you are ready to begin testing:
	For visition NIIIO staff and	Communicate the testing approach to all staff
	For visiting NHS staff and Care Inspectorate staff, delivery of kits will be organised through your employer.	Read this guidance and take the online training available at and confirm that you have done so.
Prepare staff	Employers should prepare staff for the introduction of	Make clear your expectations as an employer
	twice weekly testing	Circulate the training documentation and ensure that records are stored
Testing	On the day(s) of testing,	Key considerations for the testing area:
area	individuals self-testing should prepare for the test.	Make sure they have access to a digital device to record results.
		Make sure that they have a clean flat surface with adequate light
		Make sure the competency training has been completed.
Do the	Undertake self-testing as	For EACH day of testing:
testing	guidance and training	Prepare kits including the swab, small clean container, extraction fluid, and LFD kit.
Analyse test samples	Analyse and interpret results	Following the test instructions to prepare, collect and record sample result
		Record results into will be recorded through the NHS Scotland Covid Testing and Registration System.
		Dispose of the result in line with supplied waste disposal instructions outlined below.
Results – Next	Record the result and take	If an LFD result is positive:
Steps	the appropriate next steps	The person must immediately register for a confirmatory PCR test, then isolate immediately in line with guidance.
		If the LFD result is negative:
		 Visiting professionals can continue with planned work visits.

Overview

Lateral Flow Antigen testing involves processing a throat and nasal swab sample with an extraction fluid and a lateral flow device.

The LFD detects a COVID-19 antigen that is produced when a person is infectious with COVID-19. If this antigen is present, then a coloured strip on the LFD will appear to show a positive result within 20 – 30 minutes.

We will be providing you with Innova SARS-CoV-2 Antigen Rapid Qualitative Kits. Lateral Flow Devices (LFDs) find at least half of the cases that PCR testing detects and about three-quarters of those who have very high amounts of virus present when an individual is tested. They are helpful in detecting cases that would not be detected by other testing strategies in use routinely. Like with other testing processes, lateral flow testing is not a fool-proof solution: it should be seen as an addition to PPE and other IPC measures and **must not** be seen as a way of relaxing their use.



The ongoing evaluation process of the use of lateral flow testing across social care will be part of the overall testing evaluation process.

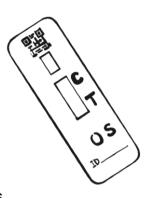
This may include the following elements:

- 1. Ongoing quantitative analysis of results from routine data e.g. positives, negatives, and void LFD tests.
- 2. However, employers are responsible for their own internal quality assurance. These might include measuring:
 - Staff training completion records
 - Survey of feedback and complaints
 - Operational challenges such as challenges with test kits, staff availability to support testing etc.

Eligibility

Subject eligibility criteria will be prescribed by the organisation, but the following assumptions apply:

- The subject will be asymptomatic
- The subject will consent to participation in testing
- The subject will consent to sharing their data as described in the Data Privacy Notice, including with Test and Protect
- The subject will be 18 years, or older



Frequency of Testing

Individuals should test themselves twice per 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. The assumption being that test kits are not taken on flights, where storage temperatures can not been maintained. Individuals must be allowed to conduct the swabbing process at their own pace and must not be hurried.

Testing Area

Testing may be conducted at home or in the workplace, but in both cases will be conducted on a clean, flat surface with adequate light.

Reagents and devices must be at room temperature (15–30 °C) when used for testing.

The analysis area will include dedicated space for:

- LFD timing, reading and recording
- Results uploading

Required at workstation/testing area:

- LFD cartridges
- Extraction fluid
- Extraction tubes
- Extraction tube nozzles
- Tube rack
- Appropriate waste bin/bag
- Disinfectant spray bottle
- Paper towel roll
- Pen/Pencil
- Timing clock(s)
- Permanent marker pens (see below for requirements)

^{*}Exclusions (e.g. those non-consenting to test)

^{*}Eligibility may change depending if self-swabbing or assisted swabbing, requiring training and extra workforce

Training

All staff who will conduct LFD testing should complete the online training resources and competency assessment. https://learn.nes.nhs.scot/41992

The Medicines and Healthcare Products Regulatory Agency (MHRA) have advised that the LFD training video can be used as the observed test for the purposes of the competency assessment.

All staff members performing testing are required to watch the training video, read the staff guidance and complete the online assessment available on the TURAS web platform:

Assisting care home visitors to test for COVID-19 using a Lateral Flow Device (LFD) | Turas | Learn (nhs.scot)

Storage

LFD Kits can be stored at room temperature:

Store the extraction solution and test cartridges at 2-30°C

LFD Kits need to be stored and separated from universal kits for confirmatory PCR tests and used only for designated visitor testing.

Results

The results from the LFD test will be documented by the individual digitally via an online portal: https://nhsnsstest.service-now.com/covidtesting?id=test_home. Data from these devices will flow to NHS Scotland for use in reporting and any required systems integration. As with the visitor testing the portal is on a web link so that anyone can use their own device or a workplace device to record the results. Guidance on how to use the portal is included in the instruction guide developed by NES.

The results from the device must be recorded digitally by the staff member after 30 minutes has passed via the online portal. The timing is critical, as leaving the test for longer than 30 minutes can lead to false positive results and the test will need to be repeated. Results must be recorded in line with the following:

Negative: The presence of only the control line (C) and no test line (T) within the result window indicating a negative result.

Positive: The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicating a positive result. The presence of any test line (T), no matter how faint, indicates a positive result. **Invalid result**: If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

When an invalid result is observed, the test should be repeated with a new test kit. If this issue persists and an individual continue to get invalid results, they should seek advice and support from their manager and the Board point of contact for LFD testing.

Positive Result:

If an individual tests positive, they should isolate <u>immediately self-isolate</u> and arrange for a confirmatory PCR test. Tests can be accessed from <u>Get a free NHS test to check if you have coronavirus - GOV.UK (www.gov.uk)</u> or 0300 303 2713 telephony route if individual does not have internet access. For more information on booking a test see <u>Coronavirus (COVID-19): Testing in Scotland | NHS inform</u>

If the individual's confirmatory PCR is positive, their household/bubble will also need to self-isolate and NHS Test and Trace may be in touch to contact trace.

Until the PCR result is confirmed, the staff member must self-isolate in line with government guidance. At the point the confirmatory PCR test result is known, and this is positive, test results will, as normal, be referred to Test and Protect so that full contact tracing can commence. If the PCR result is negative, the staff member would be able to attend immediately for duties.

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. 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.

Negative Result:

Staff who are negative on LFD testing must **not** regard themselves as 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 and existing Infection Prevention and Control (IPC) measures - including the use of PPE, the extended use of face masks, physical distancing, increased environmental cleaning, and good hand and respiratory hygiene — all remain critical to minimise the risk of transmission of COVID-19.

Symptomatic Staff

Staff should not be at work if they have symptoms of COVID 19. If staff have coronavirus (COVID-19) symptoms they must self-isolate as per Government advice and book a PCR test as per usual symptomatic testing channels.

If COVID symptoms develop whilst participating in testing, then the staff member must start their period of isolation for the full 10 days from start of symptom onset. Staff must continue to isolate until they have the results of the PCR test.

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

The LFD testing programme, and ongoing need for other IPC and PPE measures, also applies to staff who are participating in the vaccination programme. Staff who have been vaccinated should still partake in twice weekly LFD testing and adhere to existing IPC measures. The need for testing will be in place until we better understand the degree of protection, and duration, that the vaccination provides, including importantly whether it is possible to still transmit the virus if you've been vaccinated. The vaccination will not impact the LFD test result.

PPE Requirements

Visiting Professionals to care homes will still need appropriate PPE upon entry into the care home and during the visit, including:



PPE should not be taken off at any point. Visiting Professionals can continue to wear the same PPE for the duration of their visit unless it is contaminated, in which case it should be changed.

Recording and reporting results

All results for lateral flow test carried out in Scotland will be recorded through the *NHS Scotland Covid Testing and Registration System*, which is completed by the individual undertaking the test. There will be a drop down menu that allows you to record the test as one for a visiting professional to a care home:

https://nhsnsstest.service-now.com/covidtesting?id=test_home

The following data elements are captured by the Covid Testing and Registration system.. These fields may change to reflect refinement of the portal as more testing pathways are added:

- 1. CHI Number (if known)
- 2. Last name
- 3. First name
- 4. DOB
- 5. Sex
- 6. Home address (inc p/code)
- 7. At least one contact method: telephone, mobile phone or email
- 8. Do you currently stay at your residential address? (y/n)
- 9. Select most relevant reason for taking test (healthcare worker; visiting professional to Care Home; visitor to Care Home)
- 10. Serial number from test kit
- 11. Date test was taken
- 12. Time test taken (Hour/Min)
- 13. Result: positive/negative/ inconclusive.

Testing Quality and Governance

Employers should designate a member of the team to act as a quality and governance lead. In most cases this is likely to be the individual responsible for test kit distribution who will ensure that they:

- Implement appropriate local quality assurance including stock control and audit processes
- Concerns and safety and quality issues need to be escalated to the local public health team where COVID related
- Report to Scottish Government on quality assurance concerns, incidents, risks and mitigations
- Agree for a local process for implementing and monitoring training, if required
- This guidance is the main guidance document for rolling out lateral flow testing for visiting professionals. It is aimed mainly at employers and those who will undertake self-testing Supporting materials by NES and the competency form are focussed on the testing process itself in the main
- Document staff training and supervision and review staff testing performance
- Ensure the promotion of good quality practice
- Undertake quality audits

Waste Management

Updated advice from SEPA 30 March 2021

The external packaging of LFD testing kits should be recycled.

The LFD test itself (swab, cartridge/device) is not recyclable and should be disposed of in your residual ('black bag') waste bin.

Waste from lateral flow device testing is not considered infectious waste and therefore **does not** need to be double bagged and stored for 72 hours even in the event of a positive test, including testing undertaken at home.

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.

Ongoing Supply of Testing Kits

NSS have put in place a regular cycle for automatically delivering testing kits in 4 weeks supply each time, out to the agreed locations. There will be no requirement to re-order stock

If you have any stock issues or concerns please email nss.nationallabsprogramme@nhs.scot

Questions and Feedback

A free helpline is available to provide advice on testing. Tel: **0800 008 6587** available 09:00 to 17:00 every day

If you have an urgent request relating to 1. Outbreaks (eg for care homes) or 2. Insufficient stock to test your staff, please email nss.covid19testorderrequests@nhs.scot mailbox

When making these necessary urgent requests, it is helpful to confirm the following in the email you send to clarify your requirements:-

- Care Home Service Number (CS200XXXXXXX)
- Number of staff
- The nature of the urgent request (e.g Outbreak (eg for care homes), stock depleted due to a specific reason) If you are experiencing an outbreak, please add OUTBREAK in the email subject line.
- Number of Lateral Flow devices you have remaining for staff twice weekly testing.

Annex A: Testing Process To begin

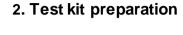
1. Testing Kit



Note the lot number and test serial number for entering into e-platform. The lot number is on the outer foil package of the device and the test serial number is found on the device underneath the QR code.

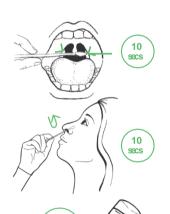
Sample collection





The staff member prepares other parts of the test kit including the extraction tube and extraction solution to process individual samples.

The staff member then performs the swab (unless the visitor expresses a preference to self-swab)



3. Swabbing

Un-package the swab and – administer the self-swab sample for both the throat and nose.

4. Extraction preparation

The individual puts the extraction tube into a small cup and puts 6 drops of the extraction solution into the tube (without touching the edge of the tube).



5. Swab processing

The swab is inserted head-first into the extraction tube. Hold and press the swab head against the wall of the tube while rotating for about 10 seconds. Squeeze the lower end of the tube while removing the swab in order to remove as much liquid as possible from the swab.



6. Swab extraction

Take out the swab while squeezing the tube and fabric end of the swab to squeeze as much fluid out as possible. Place the swab into the plastic bag provided and dispose of it in a clear bag



7. Prepare nozzle

Press the nozzle cap tightly on to the tube.

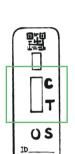


8. LFD cartridge processing

Squeeze 2 drops of the solution into the sample well of the LFD cartridge and record the time of test (for example, "Drop @ HH:MM") in marker on the LFD.

Result Analysis





9. Results Development

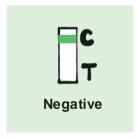
Move the LFD cartridge an area where results will be processed and start the timer to track the development of the sample. Results can be analysed at 30 minutes.

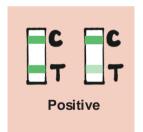
10. Results Interpretation

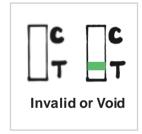
The results are interpreted by examining the presence of coloured lines on the LFD.

Positive results may appear after 20 minutes. Result should ONLY be read and reported at 30 minutes.

If a positive signal appears after 30 minutes, it should not be reported as positive. Waiting longer than 30 minutes can create false positives Line C must be coloured to have a valid test result.







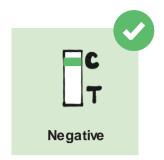


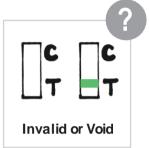
Marking Results

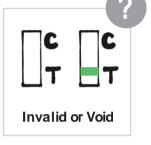
The test is then marked by a permanent marker and removed from the desk.

- + for positives
- V for invalid and void tests
- for negatives

Results guidance







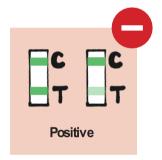
Negative result

When visiting a care home visiting professionals should still only enter designated parts of the care home and must wear appropriate PPE including a face mask, gloves, apron and follow IPC measures in line with national policy. IPC measures remain important because the test is not 100% sensitive.

Invalid or void result

Re-test using a spare LFD kit to receive a conclusive result

If the retest comes back as invalid, a second test should be undertaken. If a second test kit is inconclusive then a discussion with the employing organisation should be had and a precautionary PCR may be deemed appropriate to enable normal work practices to resume.



Positive result

Immediate arrangements for a confirmatory PCR should be made.

Isolation until the PCR result is known is regruied. If PCR test is negative then the individual can resume duties. If it is positive then isolation for 10 days from point of LFD test should begin.