COVID-19: Guidance for use of Lateral Flow Device testing for Professionals who attend Care Homes

6th January 2021
Lateral Flow Testing
Document updates

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Update</th>
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<tr>
<td>V1.0</td>
<td>6th Jan 2021</td>
<td>First version of the guidance</td>
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<tr>
<td>V1.1</td>
<td>15th Jan 2021</td>
<td>Contact email addresses updated</td>
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</table>
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.

This document provides guidance 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, it is proposed that roll out to visiting professionals to care homes will begin in week beginning the 4 January.

Visiting professionals include:

- Health staff such as district and community nurses and allied health professionals employed by the NHS
- Social care staff, social workers, other non NHS Allied Health Professionals, care inspectors

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 podiatrists and optometrists. 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; results would be recorded in the same way.

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

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<td>• Read this guidance and take the online training available at and confirm that you have done so.</td>
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<td>• Make sure that they have a clean flat surface with adequate light</td>
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<td>Undertake self-testing as guidance and training</td>
<td>• Prepare kits including the swab, small clean container, extraction fluid, and LFD kit.</td>
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<td><strong>Analyse test samples</strong></td>
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<tr>
<td>Analyse and interpret results</td>
<td>• Following the test instructions to prepare, collect and record sample result</td>
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<td>Record the result and take the appropriate next steps</td>
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<td>• The person must immediately register for a confirmatory PCR test, then isolate immediately in line with guidance.</td>
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<td>If the LFD result is negative:</td>
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<td>• Visiting professionals can continue with planned work visits.</td>
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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.

Assurance:

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
*Exclusions (e.g. those non-consenting to test)
*Eligibility may change depending if self-swabbing or assisted swabbing, requiring training and extra workforce

**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)
Training

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

The 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:


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. 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 immediately and arrange for a confirmatory PCR
test by contacting Test and Protect. Tests can be accessed from [https://www.gov.uk/get-coronavirus-test](https://www.gov.uk/get-coronavirus-test) or 0300 303 2713 telephony route if the individual does not have internet access.

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 don’t 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:

- Disposable gloves
- Disposable plastic apron
- Surgical, fluid resistant facemask

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:

Welcome - COVID Testing Portal (service-now.com)

The following data elements are captured by the NHS Scotland Covid Testing and Registration System. These fields may change in the early weeks of January 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
- 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

Negative LFD tests can be safely disposed of in domestic/household waste as normal.

Positive tests should be double bagged and held for 72 hrs before disposal in domestic waste. Regardless of whether the test is negative or positive, it must not be disposed of in clinical waste (i.e. in an orange bag) due to the presence of test chemicals.

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

If you have any urgent questions or comments you can share these by emailing the COVID-19 Care Homes Clinical and Professional Advisory Group mailbox on CareHomesCPAG@gov.scot
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

2. Test kit preparation

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.
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 required. 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.