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COVID-19: Guidance for use of Lateral Flow Device testing - Care at Home Services, Sheltered Housing/Housing with multiple occupancy, Day Care, Personal Assistants

4 February 2021

Lateral Flow Device Testing

Document updates

Version	Date	Update
V1.0	15 January 2021	First version of the guidance
V2.0	4 February 2021	Second version of the guidance

This guidance on the use of Lateral Flow Device (LFD) tests is for care at home, sheltered housing and day care employers and staff.

Kits

The guidance on lateral flow devices is broadly consistent across the four countries but has been adapted for use in the social care setting.

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, 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.

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Introduction

This document provides guidance for care at home, sheltered housing (**and housing with multiple occupancies**) and day care services employers and staff on how to prepare for and manage lateral flow device (LFD) testing. It also covers Personal Assistants providing social care support.

For clarity, the breakdown of the services covered by this guidance is provided below:

Care at Home services
Day Care Services
Sheltered Housing/multiple occupancy
Personal Assistants (self-directed support)

Care at Home services are diverse and varied across the country. For that reason some care at home staff will be tested via the PCR route depending on the advice locally. Guidance on PCR testing can be found here:

https://www.gov.scot/care-at-home_covidtesting

This guidance focuses on LFD testing

It should be noted that LFD testing of the care at home workforce is not a mandatory requirement but a recommended one. Care at Home service providers may ask their staff to participate in the programme to enhance protections for both the recipient of care at home and the workforce. Oversight and monitoring of testing is the responsibility of the individual employers of the care at home workforce.

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.

Testing Expansion – Care at Home, Sheltered Housing, Day Care and Personal Assistants

The table below summarises the testing approach for the above staff groups

Staff member	Start date	Review date	Supply of tests	Test type	Recommended frequency	Location/delivery	Recommended technique
Care at home staff	From 18 th January	February 2021	Direct delivery to main offices (unless alternative arrangement in place)	LFD (or PCR)	Twice weekly	Self testing at home	Throat and nasal swab
Day care staff	From 18 th January	February 2021	PPE hubs	LFD	Twice weekly	Self testing at work	Throat and nasal swab
Sheltered housing	From 18 th January	February 2021	Direct delivery	LFD	Twice weekly	Self testing at work	Throat and nasal swab
Personal Assistants	From 18 th January	February 2021	PPE hubs	LFD	Twice weekly	Self testing at home	Throat and nasal swab

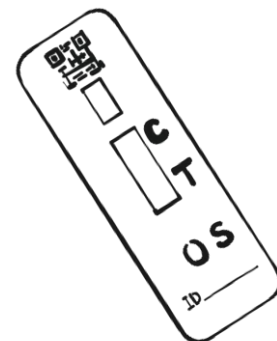
Lateral flow testing Overview

	What to expect	What to do
Testing Kits	Delivery of testing kits will vary by service type – refer to table ‘Testing Expansion’ in Introduction. Re-ordering of kits will vary by service	<ul style="list-style-type: none"> • Start planning in advance so that you are ready to begin testing: • Communicate the testing approach to all staff • Read this guidance and take the online training available at and confirm that you have done so.
Prepare staff	Employers should prepare your staff for the introduction of twice weekly testing	<ul style="list-style-type: none"> • Make clear your expectations as an employer • Circulate the training documentation and ensure that records are stored
testing area	On the day(s) of testing, individuals self-testing should prepare for the test.	<p>Key considerations for the testing area:</p> <ul style="list-style-type: none"> • 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 testing	Undertake self-testing as guidance and training	<p>For EACH day of testing:</p> <ul style="list-style-type: none"> • Prepare kits including the swab, small clean container, extraction fluid (buffer solution), and LFD
Analyse test samples	Analyses and interpret results	<ul style="list-style-type: none"> • Follow the test instructions to prepare, collect and record sample result • Record results into through the NHS Scotland Covid Testing and Registration System. • Dispose of the result in line with supplied waste disposal instructions outlined below.
Results – Next Steps	Actions post result	<p>If an LFD result is positive:</p> <ul style="list-style-type: none"> • The individual must immediately register for a confirmatory PCR test, then isolate immediately in line with guidance. <p>If the LFD result is negative:</p> <ul style="list-style-type: none"> • Work can continue as planned

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 assessing:

- Staff training completion records
- Seeking feedback from staff on testing
- 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 cannot be 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 (as set out above) but regardless should 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

It is mandatory that all staff who will conduct LFD testing complete an online training.

Access to training materials are available online by following [Coronavirus \(COVID-19\): adult care at home testing guidance - gov.scot \(www.gov.scot\)](https://www.gov.scot/adult-care-at-home-testing-guidance)

These will also be made available through the Turas portal.

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 extraction solution at 2-30°C
- Store the test cartridge at 2-30°C

LFD Kits need to be stored and separated from universal kits for confirmatory PCR tests.

Care at Home Services should ensure appropriate stock control processes are in place to ensure reordering takes place for continuous supply and to ensure tests are used only for staff that engaged in provided personal care for recipients of care at homes services.

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. Anyone can use their own device or a workplace device to record the results. Guidance on how to use the [Covid Testing and Registration](#) 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 continues 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 self-isolate **along with their household/bubble** and arrange for a confirmatory PCR test by contacting Test and Protect to arrange a PCR test. Tests can be accessed from the **Government web page** [free NHS test webpage](#). or 0300 303 2713 telephony route if 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 Protect Scotland will be in touch** to contact trace. For more information on testing you can access guidance at www.gov.scot/care-at-home-covidtesting.

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 routine 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 on the LFD test result.

Recording and reporting results

All results for lateral flow tests 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 a social care professional, and you will then be given the option to select from the following:

- Adult Day Centres/Services staff member
- Personal assistants
- Sheltered housing providers / housing with multiple occupancy
- Care at Home

The Portal is available at: [Welcome - COVID Testing Portal \(service-now.com\)](https://www.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 (see list above)
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 quality and governance lead. In most cases this is likely to be the individual responsible for test kit distribution (or its oversight, if people are collecting directly from PPE Hubs) and who will ensure that they:

- Implement appropriate local quality assurance
- Escalate concerns and safety and quality issues 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

Note: This guidance is the main guidance document for rolling out lateral flow testing for Care at home Workstream 2 individuals. 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

Testing at Home

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

Positive tests should be double bagged and held for 72hrs before disposal in domestic waste.

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.

Testing at work facility e.g. sheltered housing

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

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 contractor to agree an appropriate approach. 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.

Ongoing Supply of Testing Kits

The ongoing supply of kit will vary for each service:

Day Care Services – Lateral flow testing kits will be made available through local PPE hubs for operational services.

Sheltered Housing – Lateral Flow Testing Kits are being dispersed directly to facilities.

Personal Assistants - Lateral flow testing kits will be made available through local PPE hubs for operational services.

Care at Home mobile teams – for services using lateral flow testing kits, in most cases these will be distributed directly to your main offices from which point you will distribute kit directly to employees initially. However in some areas HSPPCs have developed alternative arrangements via local PPE HSPPC hubs for onward distribution.

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

Questions and Feedback

If you have any urgent questions or comments please email
CareHomesCPAG@gov.scot

Scottish Government will be organising a series of online workshops aimed at care at home employers and staff and HSPPCs in mid-January 2021 where you can also share your experiences to date and hear from other areas. Details below:

Workshops

Tuesday 19th January 2021, 12-1pm [Click here to join the meeting](#)

Wednesday 20th January, 11-12pm [Click here to join the meeting](#)

Tuesday 26th January, 12-1pm [Click here to join the meeting](#)

Friday 29th January, 2-3pm [Click here to join the meeting](#)

Monday 1st February, 2-3pm [Click here to join the meeting](#)

Tuesday 2nd February, 2-3pm [Click here to join the meeting](#)

Monday 8th February 2-3pm, [Click here to join the meeting](#)

Tuesday 9th February, 12-1pm [Click here to join the meeting](#)

Monday 15th February 2-3pm, [Click here to join the meeting](#)

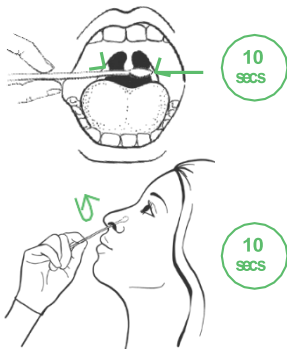
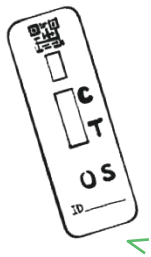
Tuesday 16th February 2-3pm, [Click here to join the meeting](#)

Annex A: Testing Process

To Begin



Sample Collection



1. Testing Kits

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.

2. Testing kit preparation

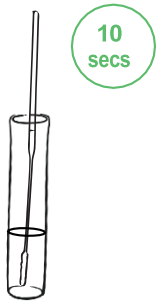
The staff member prepares other parts of the test kit including the extraction tube and extraction solution to process individual samples and then performs the swab

3. Swabbing

Un-package the swab and -administer the self-swab sample for both the throat (tonsil area) and nose.

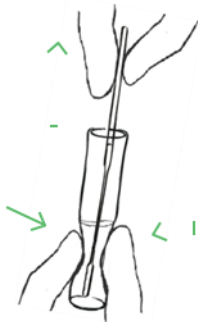
4. Extraction preparation

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.



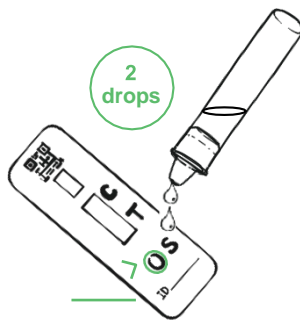
6. Swab extraction

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. LFT cartridge processing

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

Result Analysis



9. Results Development

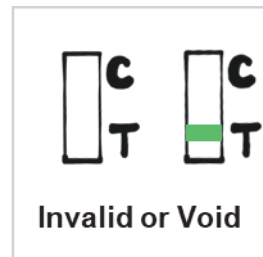
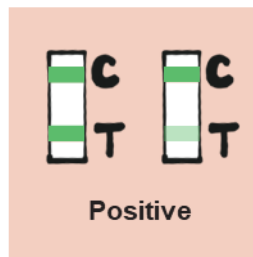
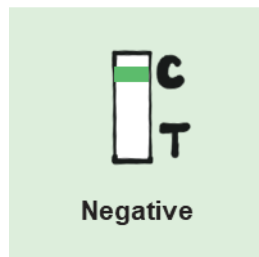
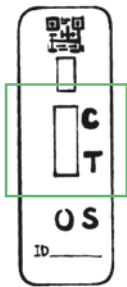
Move the LFT cartridge to an area where results will be processed and start the timer to track the development of the sample. Results can be analysed at 30 minutes.

10. Results Interpretation

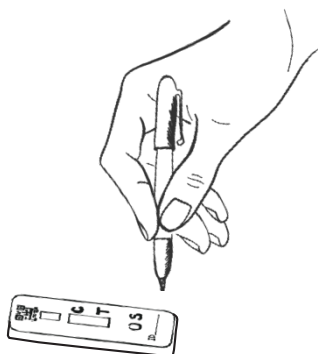
The results are interpreted by examining the presence of coloured lines on the LFT.

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. Line C must be coloured to have a valid test result.



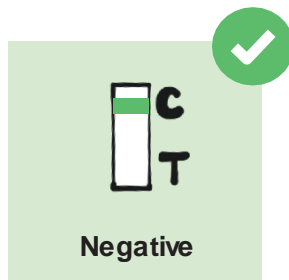
Marking Results



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

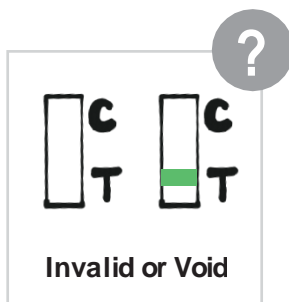
- +** for positives
- V** for invalid and void tests
- for negatives

Results guidance



Negative result

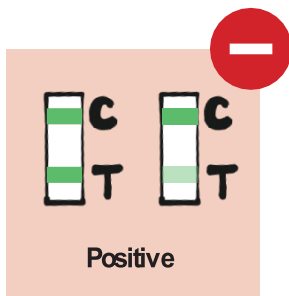
A negative result should not be taken as a guarantee staff are Covid-negative, so staff must continue to wear appropriate PPE including a face mask, gloves, apron and follow IPC measures in line with national policy. IPC measures remain important because the test is not 100% sensitive.



Invalid Result

Re-test using a spare LFT 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. Information on how to do this (including phone number/web portal) is available at: [Coronavirus \(COVID-19\): getting tested in Scotland - gov.scot \(www.gov.scot\)](https://www.gov.scot/getting-tested-in-scotland).

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.

