



Care Home Visitors COVID-19 Testing Guidance

Lateral Flow Test Kits

This guidance is for all care homes who are receiving Lateral Flow Tests (LFT). The guidance includes information about preparing your home for visitor testing and testing for coronavirus (COVID-19) with the new test kits.

Before you do any testing

- Read this guidance in its entirety
- Make sure you have received all parts of your order
- Ensure that your staff and visitors are fully prepared for testing day(s)

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Introduction

The purpose of this document is to provide guidance on how to prepare and manage lateral flow testing for visitors. This process is part of an effort to further enable visitation to care home communities while increasing the safety of all residents and staff.

You will be using Lateral Flow Tests (LFT) to conduct testing.

Lateral Flow Antigen testing involves the processing of swab samples with a Lateral Flow device. The device detects a protein (antigen) when the person is infectious, highlighting a coloured strip on the device to show a positive result. Because results are determined within 20 to 30 minutes of swab collection and do not require a lab for processing, they are designed to be intuitive and require minimal training to operate.

All positive results require a confirmatory PCR test and results submitted to the CTAS for trace to follow up with close contacts.

Prepare your care home and visitors for testing.

This will help to ensure you are ready to test visitors who are scheduled for a visit.

- Discuss the testing approach with your staff. Spend time preparing visitors and explaining the procedure to them
- Make sure that you obtain written consent for testing and sharing personal information
- Ensure you are signed up to the NHS PPE Portal (using your CQC -registered email address) by 2 December to qualify for a one-off push of PPE to support visiting: https://nhs-ppe.co.uk/
- Ensure a proper workstation is available for preparing and un-packing the tests
- Look out for the delivery confirmation email letting you know when tests will be delivered
- Have a workflow to allow tests to be easily recorded, conducted and registered as swiftly as possible— it is recommended to have two staff members; one to checck visitors in and one Processing Operative to conduct the test and the other to record the test result

Lateral flow testing process overview

	What to expect:	What to do :
Initial Order	Test kits will be ordered on your behalf and you will be sent an initial order confirmation when they are sent. You will receive LFD kits, universal test kits, and a managed device (labelled "Jigsaw") for logging results.	Start planning in advance so that you are ready to begin testing when the test kits are delivered to you: Communicate the testing approach to all staff who will conduct the testing Take the NHS online training and read this guidance Plan out your testing area and workflow Ensure you have enough of the appropriate PPE for staff and visitors Prepare Quality Assurance to test your staff in tandem with your weekly PCR testing
Prepare visitors	Along with preparing your staff and home, schedule visits as usual and inform visitors of testing guidance and expectations.	 Communicate the testing plan to visitors who wish to vis. Share the Visitors Letter and appropriate guidance on PPE Prepare consent forms to gain formal consent for testing and sharing personal information (with logging results and supporting with the registration process) Schedule visitor testing in tandem with other staff and resident testing processes.
Prepare testing area	On the day(s) of testing, set up the testing area in your care home, including a check-in area and place to conduct testing and await results.	 Key considerations for the testing area: Make sure there is a separate area for visitors to enter, test and await results without entering with other parts of the home If possible, provide a clear sign to designate the visitor entrance Make sure the visitor can enter and immediately put on PPE Follow other key considerations include social distancing, disability access, and fire safety regulations
Conduct testing	Prepare for testing day(s). Each visitor must be tested prior to entry.	 For EACH day of testing: Provide visitors with PPE upon entrance and gain their consent to be tested Make sure your home's Unique Organisation Number is visible to register and log test results Prepare test kits including the swabs, extraction materials, test tube racks, LFD devices, and barcodes Sign yourself into the Log Results App before each visit Make sure to support the visitors with registering their kit online, if needed
Analyse test samples	The Processing Operative analyses and interprets results then logs results into the Log Results app.	Follow the test instructions to prepare, collect and record sample results Note the barcode number on each device against the time each sample was placed onto the LFD device
Results	Communicate the results to each visitor after the test result is recorded.	If an LFT is positive, the visitor needs to take and register a confirmatory PCR test on site. Then instruct them to isolate immediately and return home.

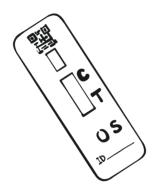
Lateral flow testing technology

Overview

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

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 Test Kits. The clinical evaluation of the test showed an overall specificity of 99.68%. This means the false positive rate is 0.32%. The overall sensitivity was 76.8% for all PCR positive individuals. However the test detects over 95% of individuals with high viral loads (those more likely to be infectious).



Safety Considerations

It is important that visitor testing is not conducted without considering other safety and risk management protocol.

- Visitors donning PPE during testing and visit, and complying with existing care home guidance on infection prevention and control measures (see Page 6 for PPE guidance)
- Separating the visitor testing workflow from other parts of the home
- Cleaning the testing area between tests and following PPE contamination protocol
- Using clean and dirty entrances for the testing area, if possible
- Having an agreed upon procedures set for invalid LFD tests and any visitors who cannot or refuse to test

Assurance:

As part of routine staff PCR testing, an internal quality assessment process (IQA) should be put in place to dual swab at least 30 staff when they complete their PCR tests. This means that staff should take both a PCR and LFT test at the same time, then manually record the results of both to measure concordance.

The care home manager is responsible for reviewing the 30 dual swabs and checking results for concordance. If any of the swab results do not align, please contact 119.

If there are issues with false positives or false negatives, then 119 may ask that you implement re-training and repeat the QA process.

Training:

It is mandatory that all staff who will conduct LFD testing complete the NHS online training. Each home will receive access to the training portal through **testertraining@dhsc.gov.uk**.

Each care home manager needs to ensure that testing staff have access to the training portal and should contact the above DHSC mailbox if you did not receive access.

Once access is granted, all staff members are required to watch the training videos and complete the online assessment.

Storage

Kits can be stored at room temperature:

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

Test kits need to be stored and separated from universal test kits for confirmatory PCR tests and routine testing of residents and staff.

Ordering more kits

This test kit supply will last your home one month. You will receive further information from DHSC on how to order more kits.

Ordering PPE:

Ensure you are signed up to the NHS PPE Portal (using your CQC -registered email address) by 2 December to qualify for a one-off push of PPE to support visiting: https://nhs-ppe.co.uk/

If you have any issues accessing the portal, please contact the customer support service at **0800 876 6802.**

Lines open from 7am - 11pm daily

Preparing your visitors

These test kits are available for testing visitors prior to every visit.

LFT kits can also be used for staff and residents as long as they are conducted alongside routine PCR testing within the home. LFT for staff and residents should follow the same safety protocols for visitors.

Who is a visitor?

A visitor is defined as any relative or friend wishing to visit a resident. Visitors need to be tested every time that they visit.

Visitor Expectations

Visitors will need to be prepared to:

- Consent to testing and sharing test results
- Register their own test kits online, or consent to sharing personal information if you support them with registration
- Complete a self-assisted throat and nasal swab
- Prepare to wait 20 30 minutes for a result before visiting
- Wear PPE during testing and visit
- Follow all other infection control protocols and safety requirements during visit
- Complete a confirmatory PCR test if LFD test is positive

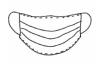
Visitor prep checklist:		
	Share visitors letter with objectives of testing and expectations for visit	
	Prepare consent forms to receive written consent to testing and sharing personal information	
	Schedule visits according to time it will take to test each visitor (approx 45 min - 1 hour)	
	Ensure you have enough PPE and can support visitors with putting on and taking off	
	Provide visitors with your UON and web devices to support with registration	

PPE Requirements

Visitors need appropriate PPE upon entry into the care home including:







Disposable gloves

Disposable plastic apron

Surgical, fluid resistant face mask

PPE should be worn during testing and visits. Visitors can continue to wear the same PPE for the duration of their visit unless it is contaminated, in which case they should change their PPE. For additional allowances for the visit, see **Page 17**.

Registration of test kits

Visitors must register their test kit individually at https://gov.uk/enter-lateral-flow-test. You will need to provide a web-enabled device if they cannot use their own mobile device.

Visitors can complete registration before or after swabbing, depending on what workflow works best for your home.

You can help them with this process if you receive formal consent.

What the visitor will need for registration:

- The test site ID your unique organisation number (UON). You can find it at https://organisation-number-lookup.test-for-coronavirus.service.gov.uk/
- The barcode number of their test kit
- Date and time of their test
- Contact information
- Personal details including DOB

1 Prepare the testing area

Before you start

Prepare for day of testing and make sure:

- There is a separate area for visitors to complete a self-assisted swab and wait on results, maintaining social distancing.
- You have your visiting schedule planned accordingly to take into account time for testing.
- You have prepared written consent forms for all visitors to be tested in line with your normal policies and procedures.
- Devices are set up for registration and the UON is visible for visitors to register online.
- Devices are set up to use the Log Results app.
- You are prepared to have a clear record of which barcode matches which result.
- You have a mirror, timer, permanent markers, hand sanitiser, and clinical waste bins in the testing area.

Testing process checklist:			
Visitor checks in and registers test (before or after swab)			
Take swab sample (tonsils then nose)			
Process the sample and apply it to the rapid test			
Wait 30 minutes then read results			
5 Enter result into Log Results App			
6 Post-test action			

Prepare the check-in area



Test Registration cards (used to register kits)



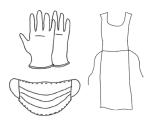
Devices for registration support (if visitor cannot use mobile phone)





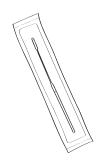


Barcodes (4 copies / individual)



PPE for visitors

Prepare the testing area



Swab, inside sealed wrapper



LFD cartridge



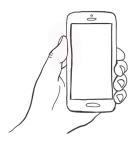
Extraction tube



Clean cup to prop up the extraction tube



Extraction solution



Managed devices (Log Results App)

Visitor arrival









Check visitor in

As each visitor enters they are provided PPE, checked in against the visitors list, asked to consent to testing and confirm they do not have symptoms.

Each visitor is issued with 4 copies of their unique barcode and a registration card:

- 1x for registration test card
- 1x for device
- 2x copies





Visitor self-registers for test

The visitor registers their test kit online at gov.uk/enter-lateral-flow-test to link their test sample and share details to receive their test results. This step can be done before or after swabbing.

They will need to enter:

- The individual barcode
- The test site ID your UON
- Personal information (including date of birth)
- Contact details
- Time and date of test

They can add one copy of their barcode to the reg card and keep it for their records.





Visitor moves to swabbing area

The visitor can now move to the testing area.

The visitor hands one copy of the barcode to the Processing Operative.

3 Sample collection



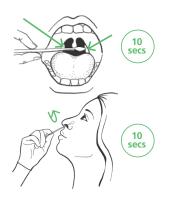


Test kit preparation

The Processing Operative attaches the visitor's barcode to the back of the LFD cartridge.

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

The Processing Operative then hands the visitor the packaged swab.





Visitor self- swabs

The visitor un-packages the swab and self-administers the swab sample for both the throat and nose.

The visitor should hold their used swab until the Processing Operative is ready to process their test sample. It is critical that no one touches the end of the swab.





Extraction preparation

The Processing Operative 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).

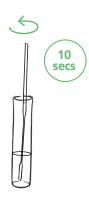




Swab Handover

The Processing Operative then takes the used swab from the visitor. The visitor can move into the waiting area after they hand over the swab.

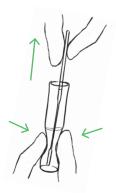
Sample analysis





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.





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 the clinical waste bin.





Prepare nozzle

Press the nozzle cap tightly on to the tube.





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.

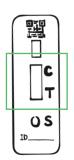
Results analysis





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 after 20-30 minutes.



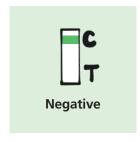


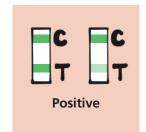
Results Interpretation

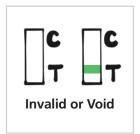
The results are interpreted by examining the presence of coloured lines on the LFD.

Positive results can be reported at 20 minutes. Negative results can be reported after 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 +
- for invalid and void tests
- for negatives

Process and record results

Using the Mobile App

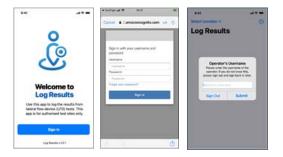
All managed devices are provided by HMG and delivered in a box labeled "Jigsaw." The Log Results app will be available on the managed devices provided to you. The care home manager or testing staff member must log into the app and enter a username at the start of each shift

The app is used to scan the barcode of the LFD, confirm the barcode, and then select whether the result was positive, negative or void. Results are uploaded via the app are sent to the national Test and Trace system. Results notifications are triggered to the participants.

If you require any technical support for the app, contact the technical support team:

Email: NHSsupport@jigsaw24.com

Phone number: 03332 409 229





Log into the app

The staff member must log into the app and enter the username of the Processing Operative using the device.





Enter Test Site Location

The tester then selects the test site location using your home's UON. This must be done at the start of each shift for each managed device.

Lines open from 7am - 11pm daily







Scan and confirm barcode

Point the camera at the barcode so it sits inside the box. You may be required to re-enter the barcode from the test kits, to ensure data accuracy.

The scanner is very sensitive, so make sure to place the barcode on a clean white space to avoid picking up other items.







Enter test results

You will be required to re-enter the barcode from the test kits, to ensure data accuracy







Review and confirm results

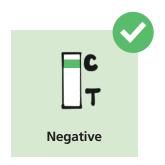
Selects the result of the test, and taps confirm.

Visitor Notification

The Test & Trace system will link the visitor's registration record with the test result. Result will be sent to the visitor via SMS and/or e-mail. Results will be communicated within a day of the test.

Results guidance

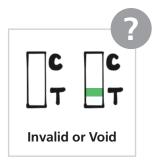
Once the result is logged, you can notify the visitor and follow the associated guidance on their visit.



Negative result

The visitor can proceed with the visit if other IPC measures are adhered to.

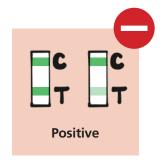
The visitor is allowed a more meaningful visit similar to what a normal visit would look like, for example hand-holding or entering the resident's room. The visitor should only enter designated parts of the care home and must wear appropriate PPE including a face mask, gloves, apron and follow IPC measures in line with the care home and national policy. IPC measures remain important because the test is not 100% sensitive.



Invalid or void result

Re-test using a spare LFT kit to receive a conclusive result.

If the retest comes back as invalid, it is up to the care home to make a decision whether the visitor can enter the home for their planned visit. You may wish to consider a visit in line with current national visiting guidance.



Positive result

The visitor can no longer proceed with the visit and requires a confirmatory PCR test.

Provide the visitor with a PCR test kit and ask the visitor to test on site then isolate at home immediately, avoiding public transport (if possible) and wearing a face mask.

Before the visitor leaves, they will need to register the kit on-line using the"testing yourself at home" instructions. After registration is complete, you will need to schedule a courier to pick up the test kit.





Need help?

If you have any questions or problems with this test kit, please call us.

Helpdesk number 119.

Lines are open everyday, 7am to 11pm.

It is free of charge from any mobile or landline.

Thank you for supporting us.