

Care Home Visitors COVID-19 Testing Guidance

Lateral Flow Device (LFD) Test Kits

This guidance is for all care homes who are receiving Lateral Flow Device (LFD) test kits. LFDs can be used for visitor testing, including visiting professionals who are not part of a regular testing programme.

We are doing everything we can to support visiting in care homes. However, when rates of infection are high in the community and to protect care home residents, the local Incident Management Team may recommend visiting is suspended, irrespective of whether testing is available. This guidance focuses on information about preparing your home for visitor testing and how to use the new test kits to test for coronavirus (COVID-19).

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 days

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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. Testing visitors can reduce the risk of COVID-19 but it does not completely remove the risk of infection. When used alongside robust Infection Prevention and Control (IPC) measures such as Personal Protective Equipment (PPE) and social distancing it can support care homes to safely maintain a balance between infection control and the vital benefits of visiting to the health and wellbeing of residents.

Care Home providers will need to order LFD test kits through an on line portal system. Attached is a link
[Request-testing.test-for-coronavirus.service.gov.uk](https://request-testing.test-for-coronavirus.service.gov.uk)

Lateral flow testing process overview

Initial Order

What to expect:

You will receive LFD kits, universal test kits for confirmatory PCR tests, and a box of supplementing kit once you have ordered on the on line portal.

What to do :

- Communicate the testing approach to all testing staff
- Read this guidance and ensure all relevant staff take the NHS online training
- Plan out your testing area and workflow
- Ensure you have enough of the appropriate PPE for staff and visitors

Prepare visitors

Along with preparing your staff and home, schedule visits as usual and inform visitors of testing guidance and expectations.

Make sure you:

- Share the Visitors Letter and Visitors Guidance with visitors who plan to have planned visits
- Prepare consent forms to gain formal consent for testing and sharing results
- Schedule visitor testing

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 other parts of the home
- If possible, this area should have a separate entrance. If this is not possible, visitors should don PPE before entering the care home
- 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 every visit.

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 (UON) is available to register test results
- Prepare test kits including the swabs, extraction materials, test tube racks, LFD devices
- Prepare devices to use for registering visitor tests and results
- Make sure to support the visitors with registering their kit online, if needed

Analyse test samples

A trained member of staff analyses and interprets results.

Follow the test instructions to prepare, collect and record sample results.

Keep track of the barcode number on each LFD device against the time each sample was placed onto the LFD device.

Results

Communicate the results to each visitor. The visitor then registers their test kit result online (or Processing Operative on behalf of visitor).

If an LFD is positive, the visitor needs to take and register a confirmatory PCR test on site. Then they should return home and isolate immediately. If their confirmatory PCR is positive, their household/ bubble will also need to self-isolate and The Wales Test Trace Protect Service may be in touch to contact trace. It is vitally important that test results are uploaded.

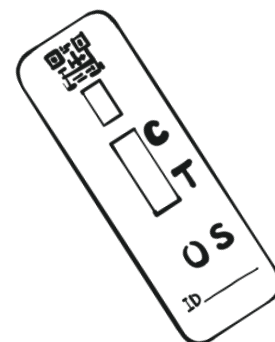
Lateral flow testing technology

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 will appear which indicates a positive result .

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



Safety Considerations

Visitor testing must be conducted in line with other safety and risk management protocols, such as:

- Separating the visitor testing workflow from other parts of the home
- Cleaning the testing area between tests and following PPE contamination 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)
- Keeping any devices used for registration kept clean between each use and following contamination IPC measures carefully
- 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
- For further information on risks to consider, please review the visiting arrangements in care homes guidance: [gov.uk/government/publications/visiting-care-homes-during-coronavirus](https://www.gov.uk/government/publications/visiting-care-homes-during-coronavirus)

Assurance:

We are developing a Quality Assurance (QA) process for care homes to ensure the high quality and consistent quality standards are delivered. This QA process is still under review and we will provide more information as soon as it is ready. You will not need to take any action until further information is provided.

Training:

It is essential that all staff who will conduct LFD testing complete the online NHS Test and Trace training. Visit the NHS training portal: <https://go.tessello.co.uk/TestDeviceTraining/> to set up an account or login. When prompted enter the token: 3wkcVi4UTX.

Each care home manager needs to ensure that testing staff have access to the training portal. 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 the standard PCR test kits that have been provided for routine testing of residents and staff (and confirmatory PCR tests for those visitors who return a positive LFD result).

Ordering more test kits and PPE

Care Homes will be able to order LFD kits through the on line portal. Attached is the link [Request-testing.test-for-coronavirus.service.gov.uk](https://request-testing.test-for-coronavirus.service.gov.uk)

Preparing your visitors

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

Who is a visitor?

A visitor is defined as any relative or friend wishing to visit a resident. Each resident should have a 'designated visitor' who can visit up to twice a week. A nominated deputy can visit if the designated visitor is unable to visit. Visitors need to be tested every time that they visit. For further guidance on visiting, please review visiting arrangements in care homes guidance: gov.wales/visits-care-homes-guidance-providers

Who is a visiting professional?

A visiting professional is defined as anyone visiting the care home in a professional capacity, for example a chiropodist, district nurse, social worker or Care Inspectorate Wales inspector.

Visitor Expectations

Visitors will need to be prepared to:

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

Visitor prep checklist:

- Share Visitors Letter and Visitors Guidance** with objectives of testing and expectations for visit
- Prepare consent forms** to receive written consent to testing
- 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

What happens with a positive result?

If a visitor tests positive, the visit cannot occur. The visitor will need to **take a confirmatory PCR test kit on site and immediately self-isolate**, following government guidelines whilst awaiting their PCR result. Make sure that:

- You provide the visitor with a PCR test kit and they complete testing on site
- You schedule a priority courier pick up
- The visitor registers their test kit online using the "testing yourself at home" instructions

The visitor should then immediately return home, avoiding public transport and wearing a face mask. If the visitor's confirmatory PCR is positive, their household/ bubble will also need to self-isolate and The Wales Test Trace Protect Service may be in touch to contact trace. For more information on visiting results guidance, see **page 19**.

PPE Requirements

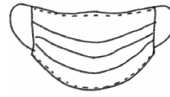
Visitors need appropriate PPE upon entry into the care home and throughout their visit, including:



Disposable gloves



Disposable plastic apron



**Surgical, fluid
resistant face mask**

PPE should be worn during testing and throughout the visit. Visitors should not take off their PPE. They 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 19**.

It is the care homes' responsibility to ensure appropriate IPC measures are followed in line with the care home and national policy.

Obtaining consent and registering results

Visitors will need to provide consent to be tested and share their results. Consent needs to be obtained before any testing occurs. You can modify any consent forms you currently use to reflect this new process.

Once test results are determined, visitors should register their tests kits online using a self-test registration form: [gov.uk/report-covid19-result](https://www.gov.uk/report-covid19-result). You should provide a web-enabled device, if possible, to support any visitor that does not have a mobile phone.

A web-enabled device includes a mobile phone or iPad, or a computer. Make sure the device is kept clean between each use and that IPC measures are carefully followed. If a member of staff or visitor has to use a device in the middle of the testing process, the device should be cleaned and PPE should be replaced appropriately.

What the visitor will need for registration:

- Personal details including Date of Birth (DOB), gender, ethnicity
- Contact information
- The barcode number of the test kit
- Date and time of the test
- The test kit result
- Your unique organisation number (UON). You can find it at:
organisation-number-lookup.test-for-coronavirus.service.gov.uk/

Registration should happen as soon as the test result is determined (and no later than one day after testing).

If a visitor is unable to register their own result, you can register the test on their behalf. Because the registration form asks for personal information, you will need these details from each visitor and must state how you will use those details, how long you will keep that information, and who you will share it with. Make sure that you delete or destroy any forms containing the visitor's personal details as soon as you complete with the online registration. For more information on registering test results, see **page 15**.

1

Prepare the testing area

Before you start

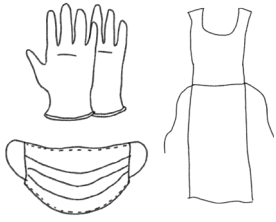
Prepare for day of testing and make sure:

- 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.
- 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:

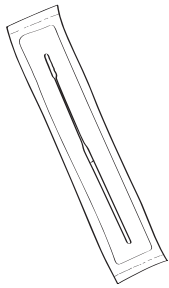
- 1 Visitor checks in and consents to testing
- 2 Take swab sample (tonsils then nose)
- 3 Process the sample and apply it to the rapid test
- 4 Wait 30 minutes then read results
- 5 Register test kit and result onto the online registration form
- 6 Post-test action

Preparing the check-in area



PPE for visitors

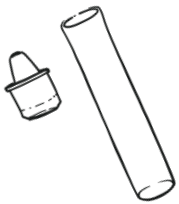
Preparing the testing area



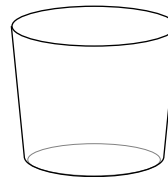
Swab, inside sealed wrapper



LFD cartridge



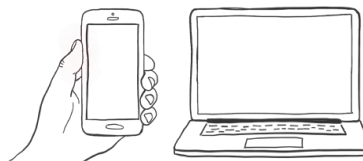
Extraction tube



Clean cup to prop up the extraction tube



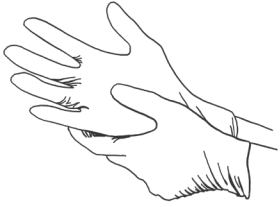
Extraction solution



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

2

Visitor arrival



1

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.

2

Take down registration details (if visitor cannot register their own kit)

If a visitor will not be able to register their own result online, make sure to explain that you are asking for their personal information to register the test kit on their behalf (see page 15).

To complete the registration form, take down the following personal details of each visitor being tested. These details can be recorded before or after the testing process occurs:

- Full name
- Date of birth
- Gender
- Ethnic group
- Home address
- Contact details, including mobile number and e-mail address



3

Visitor moves to swabbing area

The visitor can now move to the testing area.



If you have any questions please call

119

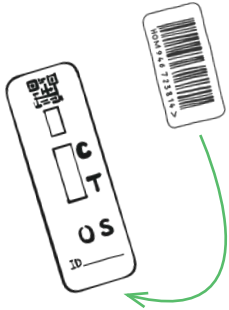
Lines open from 7am - 11pm daily

For people who have hearing
or speech impairments, please call

18001 0300 303 2713

3

Sample collection

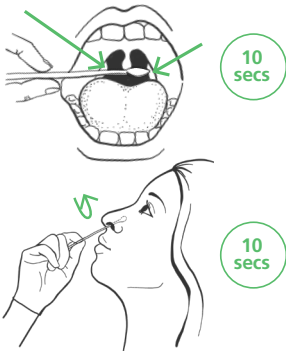


4

Test kit preparation

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

The Processing Operative then hands the visitor the packaged swab.



5

Visitor self- swabs

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

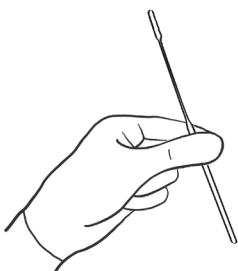
The visitor should hold their used swab until the Processing Operative is ready to process their test sample. It is critical that no one touches the end of the swab.



6

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).



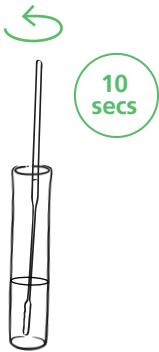
7

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.

4

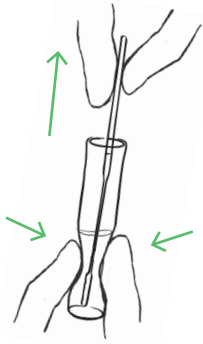
Sample analysis



8

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.



9

Swab extraction

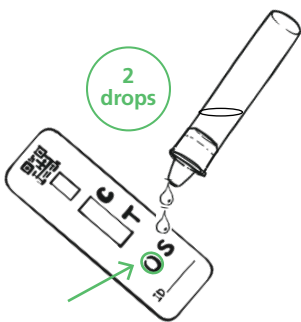
Take out the swab while squeezing the tube and fabric end of the swab to squeeze as much fluid out as possible. Place the swab into the plastic bag provided and dispose of it in the clinical waste bin.



10

Prepare nozzle

Press the nozzle cap tightly on to the tube.



11

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.

5

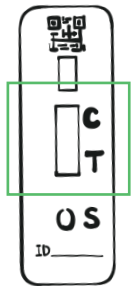
Results analysis



12

Results Development

Move the LFD cartridge to 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.



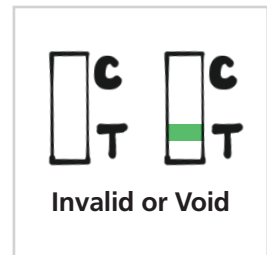
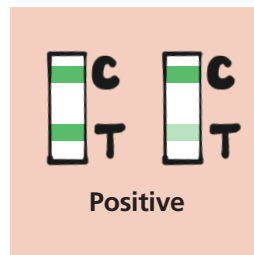
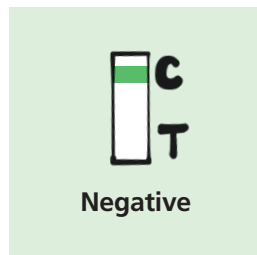
Results Interpretation

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.



14

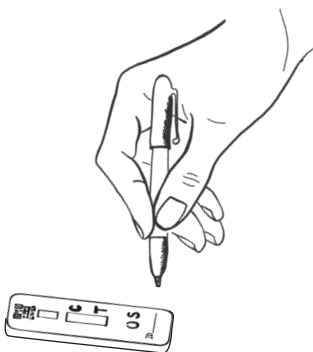
Marking Results

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

+ for positives

V for invalid and void tests

- for negatives



Communicating results

You should now communicate the result to the visitor and register the test result online.

6

Register and record results

Using the Online form

The visitor can complete these step themselves unless they are unable to do so. If you are completing registration on their behalf, make sure that you have explained why you are taking down this information and how it will be used.

The online form links the visitor to their test kit barcode and test result. The form will ask for the individual's personal details, barcode of the LFD, and whether the result was positive, negative or void. Results are not sent to The Wales Test Trace Protect Service system, but notifications will be sent to the visitors via SMS or e-mail.

Registration should happen as soon as the test result is determined (and no later than one day after testing).

GOV.UK Report your COVID-19 test result

ALPHA This is a new service - your feedback will help us to improve it.

Report a COVID-19 self-test result

Use this service to:

- report your result to the NHS after using a coronavirus (COVID-19) self-test kit (also called a lateral flow test kit)
- find out what your result means and get the latest advice on what to do

Report the result:

- every time you use a self-test kit
- as soon as possible after you get the result

You can't report a result after more than 24 hours.

[Start now >](#)

15

Navigate to the online form

Navigate to gov.uk/report-covid19-result.

Tap Start Now to enter into the form.

GOV.UK Report your COVID-19 test result

ALPHA This is a new service - your feedback will help us to improve it.

< Back

Why did you take this test?

If you're reporting a result for someone else, answer for them.

I am at a care home

I have been instructed to take a test as part of the NHS staff testing programme

None of the above

[Continue](#)

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Enter why you took the test

Select "I am at a care home" then select Continue.

GOV.UK Report your COVID-19 test result

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Which of these best describes you?

If you're reporting a result for someone else, answer for them.

I work in a care home

I'm a resident in a care home

I'm visiting a care home

[Continue](#)

17

Enter your role

Select "I am visiting a care home" then tap Continue.

18

Enter your UON

Enter your UON then select Continue.

19

Select your country location

Select the appropriate country for the care home.

20

Enter date of the test

Enter today's date (unless you are completing the form after the testing day).

21

Enter test kit ID number

Enter and re-enter the test kit ID number.

The ID number can be found via the QR code on the lateral flow device.

Report your COVID-19 test result

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What's your name?

If you're reporting a result for someone else enter their name.

First name

Last name

[Continue](#)

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What's your date of birth?

If you're reporting a result for someone else enter their date of birth.

Day Month Year

[Continue](#)

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What's your gender?

If you're reporting a result for someone else enter their gender.

Female

Male

[Continue](#)

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What's the first line of your address and home postcode?

Enter the first line of your address and home postcode (ideally the one you gave your GP). If you're reporting a result for someone else enter their details.

First line of address

Postcode

[Continue](#)

Report your COVID-19 test result

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Do you have an email address?

If you're reporting a result for someone else use their email.

Contact details are used for service related messages (for example, to confirm a result has been reported). If a result is positive, the NHS may also use them for [contact tracing](#).

Yes, I have an email address

Email address

No, I don't have an email address

[Continue](#)

What's your mobile number?

If you're reporting a result for someone else use their mobile.

Contact details are used for service related messages (for example, to confirm a result has been reported). If a result is positive, the NHS may also use them for [contact tracing](#).

[Don't have a mobile number?](#)

Mobile phone number

Confirm mobile phone number

[Continue](#)

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Enter the visitor's personal details

You will need to enter the visitor's personal details including:

- Full name
- Date of birth
- Gender
- Ethnic group
- Home address

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Enter visitor contact details

Enter the visitor's following contact details:

- Email address (if they have one)
- Mobile number

If the visitor does not have a mobile number, they can enter a relative's number. If they do not have a relative's number to add, they should contact 119 to complete the form.

Visitor Notification

Results will be sent to the visitor via SMS and/or e-mail. Results will be communicated within a day of the test.

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Enter NHS number (if available)

The form will ask if you know your NHS number. If applicable, select “Yes, I know my NHS Number” and enter it.

Otherwise, select “No, I do not know my NHS Number” and tap Continue.

25

Enter test results

Selects the result of the test, and tap “Continue.”

26

Review and submit result

Check the answers you have provided and change them if needed. Click “Report Result” when you confirm all your responses are correct. The results page will appear.

If you are entering multiple test results at once, continue using the same online form link to register each test result.

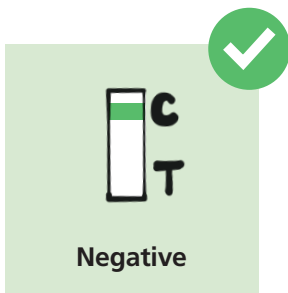
Visitor Notification

Results will be sent to the visitor via SMS and/or e-mail. Results will be communicated within a day of the test.

7

Results guidance

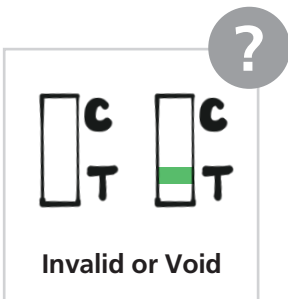
Once the result is determined, your home and the visitor should follow the associated guidance for their visit.



Negative result

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

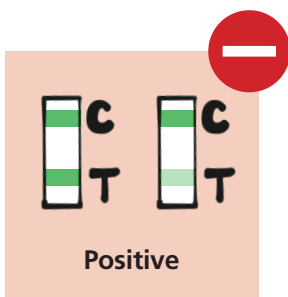
The visitor should only enter designated parts of the care home and must wear appropriate PPE including a face mask, gloves, apron and follow IPC measures in line with the care home and national policy. IPC measures remain important because the test is not 100% sensitive. If these measures are followed, the visitor is allowed to enter the resident's room. Social distancing should be maintained and hand holding or physical contact is not recommended.



Invalid or void result

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

If the retest comes back as invalid, we recommend that you do not allow the visitor to complete the visit. The visit should only occur if both the home and visitor are in an area of very low community prevalence, and other IPC measures, including social distancing and PPE, are followed.



Positive result

The visitor can no longer proceed with the visit and needs to immediately take 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 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.

DHSC Terms and Conditions

The Secretary of State for Health and Social Care of 39 Victoria Street, Westminster, London, SW1H 0EU, United Kingdom (“DHSC”) and care homes in the United Kingdom are seeking to collaborate to combat the SARS-CoV2-19 (“Covid-19”) pandemic. In these terms and conditions (the “T&Cs”), “Institution” means the care home to which the T&Cs have been provided to. DHSC and the Institution have agreed that DHSC will support the Institution to carry out Covid-19 testing at the Institution to test any individual (including visiting professionals who are not part of a regular testing programme) who wishes to visit a resident of the Institution (“Test Subjects”). Individuals who are part of a regular testing programme do not need testing on the door of the care home.”

The key objective of the Testing (as defined below) is to ensure the ongoing safety of the entire care home community, while enabling residents to see their loved ones. The Testing has the additional objectives of seeking to ascertain:

- what is the most appropriate technology to use for visitors in care homes, and what physical limitations may prevent testing; and
- how access to testing can support residents’ wellbeing alongside wider infection, prevention, and control measures, and feed into a holistic risk-based approach to visiting.

Commencement of the Testing by the Institution is deemed as acceptance of the T&Cs. For the purpose of Decision 2012/21/EU of the European Commission of 20 December 2011, the T&Cs entrusts the Institution with the performance of public service obligations, which are set out in the T&Cs. DHSC and the Institution have agreed to proceed with the Testing upon and subject to the following terms.

Clause 1: Term

1.1 The agreement between the parties under the T&Cs will begin on commencement of the supply by DHSC of DHSC Supplies (as defined below) and/or Testing by the Institution under the T&Cs (whichever is earlier) (“Commencement Date”).

1.2 The agreement shall continue from the Commencement Date for as long as the Institution continues to carry out the Testing (“Term”), at which point the agreement shall expire unless any extension is agreed in writing between the parties.

1.3 Any work such as training or preparation for the Testing by the parties prior to the Commencement Date shall be treated as having been performed under the T&Cs.

Clause 2: Standard Operating Procedure

2.1 The Institution has been provided with this Care Home LFD Testing of Visitors Guidance (“Guidance”), which sets out a detailed description and plan of the testing and ancillary responsibilities that are to be carried out by the Institution under the T&Cs.

2.2 The Institution agrees to carry out Covid-19 testing on Test Subjects in accordance with the Guidance (“Testing”).

2.3 DHSC may update the Guidance during the Term from time to time and following such update will provide or make available to the Institution with a copy of the updated Guidance as soon as reasonably practicable.

2.4 If DHSC makes a change to the Guidance which would have a material adverse impact on the Institution, the Institution may request that DHSC makes further changes to the Guidance to avoid or mitigate that impact. If DHSC does not make such further changes to the Guidance within 7 days, either party may immediately on written notice terminate the agreement.

2.5 In the event of conflict between the Guidance and the terms of the T&Cs, the terms of the T&Cs shall prevail.

Clause 3: Primary Responsibilities

3.1 Each Party agrees to perform the obligations that are allocated to it in the Guidance in accordance with the Guidance, the T&Cs and all applicable laws and regulations.

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Clause 4: Additional Responsibilities - Institution

4.1 In addition to clause 3, the Institution shall:

Communication and Set up

- 4.1.1 liaise with the appointed representative(s) of any stakeholders at or connected to the Institution in connection with the Testing;
- 4.1.2 cooperate with DHSC in liaising with the applicable local authority bodies as required in connection with the Testing;
- 4.1.3 undertake and deliver all communications in accordance with DHSC guidance, including the communication of the Testing to potential Test Subjects; and
- 4.1.4 be responsible for the set-up and configuration of the Testing at the Institution and for ensuring the configuration is in accordance with applicable laws and guidance, including appropriate Covid-19 measures and appropriate site risk assessment;

Procurement of personnel and materials

- 4.1.5 provide, procure or otherwise arrange for the supply of suitably competent personnel to perform each of the roles set out in the Guidance designated to be provided by the Institution and to ensure that such personnel perform in accordance with the Guidance;
- 4.1.6 ensure that personnel who are to be involved in the Testing shall attend all training as required by the Guidance or by DHSC in advance of being involved in the Testing, and shall perform their role in relation to the Testing in accordance with any such training;
- 4.1.7 provide DHSC with appropriate evidence that each person has completed the training in clause 4.1.6;
- 4.1.8 provide such items as are necessary to carry out the Testing, except for any items which are to be provided by DHSC as listed in the Guidance.;
- 4.1.9 inspect the DHSC Supplies in accordance after delivery in accordance with clause 5.3.2;
- 4.1.10 store appropriately and securely any tablets, smartphones and other devices supplied by DHSC under the agreement (“Managed Devices”) (which shall be held on loan from DHSC during the Term); and
- 4.1.11 solely use the Managed Devices or the Web Results Portal for the Testing and not seek to circumvent any security protections or other restrictions installed on or applied to the Managed Devices or the Web Results Portal;

Carrying out of the testing

- 4.1.12 be responsible for obtaining any necessary consents from Test Subjects in connection with the Testing;
 - 4.1.13 at all times comply with applicable laws and regulation in carrying out the Testing, including but not limited to the Control of Substances Hazardous to Health 2002;
 - 4.1.14 perform the Testing with all reasonable skill and care and in accordance with the Guidance and applicable regulations;
 - 4.1.15 solely use the test kits provided by DHSC for the purpose of the Testing pursuant to this Agreement;
 - 4.1.16 cooperate in an independent or internal quality assurance programme that will be run to ensure sites are performing at the appropriate level. This will involve sites running known samples at periodic intervals. For care homes, this will be phased over time and the QA plan and timelines will be agreed with the care home management teams. It will be overseen by the National Testing Programme’s Quality Assurance team. Further guidance will be provided on the timing and scope of this process.
 - 4.1.17 separately from any business as usual waste, safely dispose any clinical waste, including testing kits, kit peripherals and PPE, and any waste suspected of being contaminated with Covid-19, in accordance with relevant biohazard waste disposal regulations and the NHS COVID-19 waste management standard operating procedure (Ref 001559);
 - 4.1.18 report any material problems or incidents with the DHSC Supplies to DHSC as soon as reasonably practicable in accordance with any processes agreed by the parties from time to time; and
 - 4.1.19 provide such aggregated and anonymised data relating to potential Test Subjects as the parties may agree from time to time.
- 4.2 For the avoidance of doubt, the Institution has the right to deny a potential Test Subject who is displaying symptoms of Covid-19 from participating in the Testing and shall instead direct the individual to the appropriate symptomatic guidelines and practices.

Clause 5: DHSC Responsibilities

5.1 In addition to clause 3.1, DHSC shall:

- 5.1.1 provide a playbook to support the Institution’s carrying out of the testing;
 - 5.1.2 cooperate with the Institution in liaising with the applicable local authority bodies as required in connection with the Testing;
 - 5.1.3 provide access to an online training and assessment tool for use by the individuals selected by the Institution to carry out the Testing; 5.1.4 provide a reasonable level of advice and support to the Institution on matters relating to the Testing; and
 - 5.1.5 provide such items as are listed as to be provided by DHSC in the Guidance and in such quantities as are agreed between the parties, including Managed Devices, LFD antigen testing kits and PCR testing kits (as more fully described in the Guidance).
- 5.2 DHSC shall be responsible for ensuring that:
- 5.2.1 save where the Guidance expressly states otherwise, the Guidance is appropriate for Testing in accordance with the T&Cs and applicable law and regulation (provided that the Institution acknowledges that the implementation of the Guidance by the Institution needs to take account of the particular circumstances of the Institution and accordingly the Guidance can not include a comprehensive list of all actions that will be required to carry out the Testing at the Institution);

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5.2.2 the DHSC Supplies (defined below) are appropriate for use by the Institution to carry out the Testing in accordance with the Guidance and the T&Cs; and

5.2.3 the DHSC Supplies are of the necessary quality and standard to enable the Institution to carry out the Testing and free from material defects. Subject to clause 5.3.1, if the Institution notifies DHSC that any DHSC Supplies have material defects, DHSC shall endeavour to provide replacements in accordance with clause 1.

5.3 Unless otherwise agreed by the Parties in writing, any testing kits and Managed Devices (“DHSC Supplies”) provided by DHSC for use by the Institution:

5.3.1 shall be provided at DHSC’s sole discretion (save that DHSC will use reasonable endeavours to meet any volumes agreed with the Institution);

5.3.2 shall be inspected by the Institution after receipt in order that the Institution can confirm that the DHSC Supplies that have been delivered include the expected quantity and type of DHSC Supplies;

5.3.3 must be returned to DHSC within any agreed timescales for such return or otherwise upon DHSC’s request; and

5.3.4 subject to clauses 5.3.2 and 5.3.3 above, shall be used by the Institution at the Institution’s risk and the Institution shall upon written request by DHSC reimburse DHSC for any loss or damage relating to Managed Devices caused by the Institution (fair wear and tear exempted).

Clause 6: Data Protection

6.1 Each party will process personal data under or in connection with this T&Cs. Each party will be a controller in respect of the information that it processes under or connection with this T&Cs. Without limitation to the foregoing, the parties intend that:

6.1.1 the Institution shall be the controller in respect of any personal data it collects from Test Subjects (including in arranging the attendance of Test Subjects at the Institution); and

6.1.2 DHSC shall be the controller in respect of any personal data it collects from the Institution and/or Testing personnel for the purposes of procuring the provision of training under clause 5.1.3 and in respect of any personal data processed through the NHS Test and Trace digital system.

6.2 The parties do not intend to disclose any personal data to each other under or in connection with this T&Cs (including without limitation in relation to the Test Subjects). To the extent that the parties each process personal data relating to the Test Subjects, each will do so as a separate controller. 6.3 Without prejudice to clause 6.2, the Authority does not intend to disclose any results obtained during Testing directly to DHSC under these terms & conditions. Any notification of the results of the Testing to Test Subjects and/or to the Authority will be carried out in accordance with the applicable Wales Test Trace Protect Service processes.

6.4 In carrying out its obligations under this T&Cs, each party shall comply with its obligations under the Data Protection Act 2018, or, for the period it remains in force in the UK, the General Data Protection Regulation (EU) 2016/679 (as applicable) and any other applicable laws relating to the protection of personal data and the privacy of individuals (all as amended, updated or re-enacted from time to time).

6.5 In particular, the Institution shall in accordance with the Guidance obtain and keep a written record of each Test Subject’s (or where applicable a Test Subject’s parent or legal guardian) consent to participate in the Testing.

Clause 7: Confidential information

7.1 For the purposes of this T&Cs, “Confidential Information” shall mean information, data and material of any nature, which either party may receive or obtain in connection with the conclusion and/or operation of the T&Cs which is designated as confidential by either party or that ought reasonably to be considered as confidential.

7.2 Each party shall take all proper steps to keep confidential all Confidential Information of the other party which is disclosed to or obtained by it under or as a result of the T&Cs, and shall not disclose the same to any third party and shall allow access to the same to its own employees only on a need-to-know basis, except to the extent that any such Confidential Information becomes public through no fault of that party and except for use reasonably necessary for the performance of the T&Cs.

7.3 Notwithstanding clause 7.2:

7.3.1 either party may disclose Confidential Information received from the other to its contractors to the extent necessary to enable them to comply with their obligations under the T&Cs; and

7.3.2 DHSC may use and disclose the Confidential Information for the purpose of improving the process and operations involved in the Testing, which may include DHSC sharing information relating to the experiences and insights gained as a result of the Testing

7.4 Upon termination of this T&Cs, each party shall return to the other party or destroy any written data (without retaining copies) provided for the purposes of the T&Cs.

7.5 Notwithstanding the termination or expiry of the T&Cs, this clause shall be valid for a further period of seven years from the date of termination or expiry.

Clause 8: Freedom of Information Act

8.1 The Institution acknowledges that DHSC is subject to the Freedom of Information Act 2000 and the Environmental Information Regulations 2004 (together “FOIA”) and shall assist and co-operate with DHSC to enable it to comply with the requirements of FOIA in relation to the T&Cs.

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8.2 The Institution further acknowledges that DHSC may be obliged to disclose any information (including Confidential Information) which it holds in response to a request received under FOIA, and that the extent, content and format of the disclosure is DHSC's decision.

8.3 The Institution shall ensure that all Information (as defined in section 84 of Freedom of Information Act 2000) produced in the course of the T&Cs or relating to the T&Cs is retained for disclosure for a period of seven (7) years from the date of expiry or termination of the T&Cs and shall permit DHSC to inspect such records as requested from time to time during the Term of the T&Cs.

8.4 In no event shall the Institution respond directly to a Request For Information (as defined in the Freedom of Information Act 2000, and such term shall include its equivalent under the Environmental Information Regulations 2004) related or otherwise connected to DHSC or this T&Cs unless expressly authorised to do so by DHSC.

Clause 9: Liability

9.1 The parties expressly exclude liability for loss of data, profits, business, goodwill or anticipated savings, and all other indirect or consequential loss or damages suffered or incurred by a party under or in connection with the T&Cs.

9.2 Nothing in the T&Cs shall limit or exclude either party's liability for:

9.2.1 death or personal injury or damage to property caused by negligence on the part of that party or its employees, contractors or agents; or

9.2.2 any matter in respect of which it would be unlawful for that party to exclude or restrict liability.

Clause 10: Costs

10.1 Each party shall bear its own costs in relation to the Testing and carrying out its responsibilities under the T&Cs.

Clause 11: Termination

11.1 Either party may terminate the T&Cs on fourteen (14) days written notice to the other party.

11.2 Either party may immediately terminate the T&Cs by issuing a notice in writing to the other party if the other party is in material breach of any obligation in the T&Cs which is either incapable or remedy or, where capable of remedy, that breach is not remedied within seven (7) days of receiving notice specifying the breach and requiring it to be remedied.

11.3 On termination or expiry of the T&Cs, the Institution shall promptly return to DHSC:

11.3.1 all Managed Devices that DHSC has supplied to the Institution; and

11.3.2 at DHSC's request, all other equipment, materials and property that DHSC has supplied to the Institution in connection with the Testing, including the testing kits which the Institution has not used or applied to the provision of the Testing.

11.4 The termination of the T&Cs shall be without prejudice to the rights and remedies of a party which may have accrued at the date of termination.

Clause 12: Change in applicable law or guidance

12.1 Neither party shall be liable to the other party for any delay or failure to perform, its obligations under the T&Cs (other than a payment of money) to the extent that such delay or failure is a result of changes in applicable law and/or government guidance which mean that the Testing cannot be carried out (in all material respects) without such laws and/or government guidance being breached, or if either party can reasonably demonstrate that despite all reasonable endeavours it is unable to secure the supply of non-Covid-19 infected personnel to the Testing due to the levels of Covid-19 infections in the population of the United Kingdom.

12.2 Notwithstanding clause 12.1, each party shall use all reasonable endeavours to continue to perform its obligations under the T&Cs to the extent possible (in accordance with applicable laws and guidance), which may include only providing part of the Testing.

12.3 However, if either party is prevented from performing its material obligations under the T&Cs and the parties are unable to agree a way to facilitate the continued performance of the T&Cs, either party may terminate the T&Cs with immediate effect by notice in writing.

Clause 13: Publicity

13.1 Save for the publicity carried out by the parties in promoting the Testing to potential Test Subjects in accordance with the T&Cs, neither party shall make any press announcement in relation to, or publicise, the T&Cs or any part of it in any way, without the prior written consent of the other party.

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Clause 14: General

14.1 The parties irrevocably agree that the T&Cs shall be subject to the laws of England and Wales and that the courts of England and Wales shall have exclusive jurisdiction to hear and settle any dispute in connection with the T&Cs.

14.2 In the event of the transfer of all or a substantial part of DHSC's activities to one or more government bodies, DHSC's rights and obligations shall, notwithstanding any provision to the contrary in the T&Cs, automatically transfer to such other government body.

14.3 Except as provided elsewhere in the T&Cs, a person who is not a party to the T&Cs shall not have any rights under or in connection with it.

14.4 If any part of the T&Cs is prohibited by law or judged by a court to be unlawful, void or unenforceable, it must be read as if that part was removed from the T&Cs as much as required and rendered ineffective as far as possible without affecting the rest of the T&Cs, whether its valid or enforceable.

14.5 No purported alteration or variation of the T&Cs shall be effective unless it is in writing and is signed by each of the parties to the T&Cs.

14.6 Notices shall be sent to such address as the relevant party may give notice to the other party for the purpose of service of notices under the T&Cs.

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.