

Dear Colleague

UNIVERSAL ACCESS LATERAL FLOW DEVICE TEST KITS – COMMUNITY PHARMACY COVID-19 TEST KIT DISTRIBUTION SERVICE – AMENDMENTS TO STANDARD OPERATING PROCEDURE REGARDING BATCH RECALLS

Purpose

1. [Circular PCA \(P\)\(2021\) 08](#) set out arrangements for a pharmacy distribution service for members of the public to access lateral flow test kits. Following the successful launch of the service, this circular informs community pharmacy contractors of changes made to the Standard Operating Procedure (SOP) regarding recall mitigations.

Detail

2. Following discussions with the Department for Health and Social Care and the wholesaler Alliance Healthcare, instructions have been added to the SOP for the LFD collection service in order to meet Medicines and Healthcare products Regulatory Agency (MHRA) batch traceability requirements for the distribution of LFD Self Tests.
3. In the event of a recall, Alliance will communicate with community pharmacies in up to four different ways and pharmacy teams are required to acknowledge these communications, check stock to identify if they have a recalled batch, isolate any recalled stock and act on all return/destruction instructions that follow.
4. To comply with these requirements, contractors must continue to adhere to the MHRA recording instructions as set out in the SOP, including retention of this data for six months from the date on which the stock was delivered:
 - LOT Number (e.g. A1234567)
 - Quantity of cartons (xx Cartons)
 - Supplying wholesaler (variable)
 - Date of receipt (DD/MM/YY)

25 November 2021

Addresses

For action
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5. Community contractors must ensure that members of the pharmacy team review the updated SOP for the *Pharmacy Collect* offer.

Action

6. **NHS Boards and community pharmacy contractors are asked to:**

- **note the contents of this Circular**
- **Adhere to the revised Standard Operating Procedures set out in Annex A.**

Yours sincerely,



Alison Strath

Chief Pharmaceutical Officer
Pharmacy and Medicines Division



Scottish Government
Riaghaltas na h-Alba
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Department
of Health &
Social Care

Scottish Government and Department of Health and Social Care (DHSC) COVID-19 Response

National Testing Programme

Standard Operating Procedures and Guidance for – NHS community pharmacy COVID-19 lateral flow device distribution service for people without symptoms.

Version 1.3

Date of publication: 25/11/2021

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1 Introduction

This document is part of the framework provided by the Scottish Government and the Department of Health and Social Care (DHSC) for asymptomatic testing for SARS-CoV-2 using lateral flow technology.

The objective of the document is for service providers to provide a description of the testing services and associated clinical protocols, and to ensure the service is provided safely and effectively by contractors. It is very important for service providers to adhere to any updates on this document based on learnings and policies within Test and Protect. Failure to do so will lead to a service being considered delivered 'at risk' as it will not be following the latest framework as part of Test and Protect.

The document describes how this element of testing services can be delivered safely, efficiently, with quality output and uniformity of performance.

A. Pharmacy procedures for collection of self-test kits

The target for this service is asymptomatic testing. The tests described in this document are more likely to detect infectious levels of virus than lower virus levels.

B. Scope of this document

This document includes the delivery model for the use of Lateral Flow Devices (LFD) self-test collect: LFD self-test kits are delivered to community pharmacy sites to be collected by asymptomatic individuals who use the kit to self test..

The LFD self-test product is the operational model that allows a person to conduct a full self-test, currently using the COVID-19 Self-Test (Rapid Antigen Test) and also referred to as LFD self-test kits. This product includes the capability to self-swab, process the test, interpret and submit test results themselves, away from pharmacy premises.

C. Audience

This clinical SOP is designed for safe implementation of approved processes for pharmacies in Scotland. **Major changes or innovations to this SOP must pass through the Scottish Governments Clinical Governance Group before implementation.**

D. Responsibilities / accountabilities

It is expected that this clinical SOP may need to be modified in light of local delivery aims and circumstances. Where the Scottish Government and DHSC are responsible for, or have oversight of, delivery, if clinical SOPs deviate substantially it is expected these deviations will be flagged to national clinical and public health leads for additional sign off. Where there is local responsibility or oversight of delivery sign off for tailored clinical SOP is local.

2 Background and service aims

Background

COVID-19 lateral flow antigen tests allow the detection of people with high levels of the COVID-19 virus, and are used in Scotland to support case finding among people who do not have COVID symptoms. With up to a third of infected individuals not displaying symptoms, broadening asymptomatic testing enables us to find more cases. Increased use of lateral flow devices (LFD) can help identify more people who are highly likely to spread the virus, and therefore break the chain of transmission.

NHS Test and Protect is making available through this service lateral flow devices (LFD) for self use for collection from a community pharmacy.

Service Aims

1. The purpose of the NHS Community Pharmacy COVID-19 Lateral Flow Device Distribution Service is to improve access to testing by making LFD test kits readily available at community pharmacies for asymptomatic people to collect for self-testing, to identify positive cases in the community and break the chain of transmission.
2. This service will work alongside existing NHS Test and Protect COVID-19 testing routes.
3. Tests will be administered away from the pharmacy. The pharmacy will not be involved in the generation or communication of results. Pharmacy teams will not be required to support the communication of results or next steps to the person taking the test.
4. The NHS Community Pharmacy COVID-19 Lateral Flow Device Distribution Service will be evaluated.

3 Service sign-up

Prior to provision of the service, the pharmacy contractor must:

- a. be compliant with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of Essential Services and an acceptable system of clinical governance
- b. be listed on the NHS Boards Pharmaceutical List for the provision of pharmaceutical services as noted in the NHS (Pharmaceutical Services) (Scotland) Regulations 2009, Schedule 1
- c. Sign up by completing the registration form in Circular PCA(P) 2021 8 and returning this to Practitioner and Counter Fraud Services.
- d. be satisfied that all pharmacy staff involved in the provision of the service are competent to do so
- e. have a suitable place away from members of the public to store test kits ordered from the wholesaler

Furthermore:

- f. All contractors will be automatically uploaded onto the NHS Test and Trace Site Finder map <https://maps.test-and-trace.nhs.uk/> as a participating pharmacy for the LFD collect service once they sign up to deliver the service.
- g. The pharmacy contractor will be hidden from public view on the map until the service is live. If a pharmacy contractor registers after that date they will be automatically displayed on the map.
- h. If a pharmacy contractor wishes to amend/update any details they see displayed on the map they can do so by emailing the request to nss.nctcscotland@nhs.scot with the following subject line "Pharmacies sitefinder". Requests made with a different subject line may not get to the right team and risk not being completed. The pharmacies details will be updated within a week.
- i. Pharmacy contractors who sign up to provide the service will qualify for a single sign-up payment of £450.
- j. This service will be reviewed at the end of August 2021. This will allow the specification to be updated in light of possible insight from user engagement with this testing route.

See appendix for the end to end service model.

A. Supply of tests kits to the pharmacy

- a. Pharmacy contractors will need to place the first order of test kits after sign-up via a participating wholesaler in the normal way. A list of participating wholesalers can be found on the NHSBSA website [Dispensing Contractors - information | NHSBSA](#). Test kits will be supplied free of charge to pharmacies providing the service as part of their standard deliveries from the wholesaler. Pharmacy contractors will need to be aware stock ordered may not arrive with your next delivery and plan accordingly
- b. Until Monday 27 September 2021, the test kits are supplied in cartons containing 54 boxes, with each box (for an individual person) containing seven test kits. The carton dimensions are 50 x 29 x 40.5 cm. These dimensions and numbers refer to the COVID-19 Self-Test (Rapid Antigen Test) (7 pack V1). From Monday 27 September 2021, the test kits are going to be supplied in cartons containing 80 boxes, with each box (for an individual person) containing seven test kits. The carton dimensions are 58 x 50 x 28 cm. These dimensions and numbers refer to the Orient Gene Rapid Covid-19 (Antigen) Self-test only.
- c. Initial demand for test kits will be difficult to predict and pharmacy contractors will be able to order and re-order appropriate quantities of kits in line with the demand of the population they serve, up to an initial weekly order limit of 12 cartons (two cartons per day, assuming a six-day working week). This equates to a maximum of 648 boxes of seven tests handed out in a six-day week. The weekly order limit is subject to review.
- d. To comply with MHRA product recall requirements, in the event of a recall notice for LFD kits being issued, pharmacy contractors must:
 - Respond in line with all instructions in the recall notice, particularly the requirement to respond and confirm that they have received and acted upon the recall notice (this could be via but not limited to email or an automated telephone system), while noting that the recall will include other instructions (e.g. the display of information regarding the recall to the public).
 - Quarantine any affected stock immediately and comply with follow-up instructions which could include returning or destroying affected stock.
- e. In the event of a recall, contractors must display information on any safety recalls/concerns using posters. Where a pharmacy can share this information using social media channels, that communication route to the public can also be used.
- f. On receipt of cartons from wholesalers, contractors must make a record of the following, which is retained for 6 months from the date on which the stock was delivered:
 - LOT Number (e.g. A1234567)

- Quantity of cartons (xx Cartons)
 - Supplying wholesaler (variable)
 - Date of receipt (DD/MM/YY)
- g. Pharmacy teams should ensure local storage of data should it be requested by any relevant authority such as Scottish Government or MHRA. The quantities of test kit boxes ordered and supplied to the public will be monitored and reviewed as part of the post-payment verification process.

B. Storage

- a. Test kits need to be stored in conditions that will preserve the integrity of the swab. When storing for prolonged periods, test kits should be stored in a designated area away from direct sunlight, between 2°C and 30°C.

C. Distribution service

- a. The test kits will be provided free of charge to people requesting them.
- b. Contractors can supply one box of test kits per individual. If the person is also collecting on behalf of a household, contractors can hand out the required number of boxes per transaction. Pharmacy teams may provide one box for each household member.
- c. Each box contains seven LFDs. This allows the person to test themselves twice weekly over a three-week timeframe. This number of tests in the box factors in the potential for a void test.
- d. There is no minimum age for use of LFD test kits.
- e. The Test and Protect minimum recommended age for a person to collect LFD test kits is 18 years, reflecting that the instructions for use require under 18s to test and self-report with adult supervision, or having an adult perform and report the test if the child is under 12, but where necessary professional judgement can be applied by pharmacy contractors. Pharmacies are not expected to ask for proof of age.
- f. Tests must be conducted and results registered away from the pharmacy, as explained in the instructions inside the test kit. People undertaking a test can contact 119 for assistance with using the kit or to register their result.
- g. If the pharmacy temporarily runs out of test kits or experiences a demand for test kits it cannot meet at that time, contractors have the option to change their information on the online. To do this they should email PharmacyCollect@dhsc.gov.uk to setup the two factor authentication that is required.

D. Service pathway

- a. The pharmacy must make every effort to obtain the person collecting the kits CHI number for payment and MHRA traceability requirements. This can be done by asking the person to supply their CHI number and if they do not have their CHI number it can be looked up using the PMR system if the person can supply their name and date of birth. If a person has collected a kit before and CHI has been recorded, a record should be held of the previous supply. Kit batch numbers should be recorded on Patient Management Records (PMR records). If multiple kits have been supplied, each kit batch number should be recorded against the record of the person collecting.
- b. Community Pharmacy teams will use the Universal Claim Form (UCF) functionality in the same way as they currently do for supplying any medication to enter the relevant information and submit a claim to indicate the collection of LFD kits.
 - Select patient and UCF service (Covid-19 LFD Supply).
 - Select the supply item (Lateral Flow Device Kit) and quantity number of boxes then select the dispensed item (Lateral Flow Device Kit (7 tests)) and quantity of packs dispensed.
- c. Where no CHI can be recorded, e.g. visitor to Scotland, pharmacy team members should record the batch number and contact details within the PMR and the batch number recorded in the 'Supporting Document Reference' text box to be included in the electronic claim.
- d. The data entered into the UCF will be used for evaluation and service improvement purposes and it will also populate the end of month payment.
- e. Pharmacy staff must ensure the person collecting the test kits understands the following **key points**:
 - i. The tests help identify people who are positive for COVID-19 but do not have symptoms.
 - ii. Pharmacy teams should advise that if anyone tests positive on their LFD they should self-isolate immediately along with everyone in their household, report their result, and book a follow-up confirmatory PCR test using this link <https://www.nhsinform.scot/testing..> Once they have reported their positive LFD result a contact tracer from NHS Test and Protect will be in touch to provide them and their contacts with further advice.
 - iii. **A negative result does not guarantee someone does not have COVID-19. It is important to continue following Scottish Government guidelines**

and restrictions.

- iv. Instructions on how to use the test and report your results are inside the box. Information including a video of how to use the test is also available on NHS Inform: [Coronavirus \(COVID-19\): How to do a rapid lateral flow device \(LFD\) test at home | NHS inform](#)
- v. **It is important to report your results, whether positive, negative or void.** This is because reporting results helps the NHS identify areas where asymptomatic cases of COVID-19 are rising and declining, so we can all keep each other safe. When you report your result, you will be provided with information on the next steps you need to take.
If a person indicates that they have not previously reported their results, it is particularly important to reiterate the importance of doing so for the new tests being supplied.
- vi. The person collecting or using the tests must make a note of the lot number of the test kit used, in case you need to report any incidents related to the device, test instructions, harm or injury. The instructions inside the box give details on how you can report any incidents.
- vii. People with COVID symptoms should not use the LFD test, instead they should self-isolate and book a PCR test - see: <https://www.nhsinform.scot/testing>.
- f. If a pharmacy is contacted by a person with a query about the device, test instructions, harm, injury or results, it should direct them to 119, and report any incidents as described in Section 6.
- g. In the event of a recall, contractors must contact the person from the recorded data entered into the PMR system. In addition they may wish to display information on any safety recalls/concerns using posters provided by NHS Test and Protect. Where a pharmacy can share this information using social media channels, that communication route to the public can also be used.

4 Service availability

- a. The contractor must seek to ensure that the service is available throughout the pharmacy's core and supplementary opening hours.
- b. The contractor must ensure the service is accessible, appropriate and sensitive to the needs of all service users. No eligible person should be excluded or experience difficulty

in accessing and effectively using this service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.

- c. If there is a problem with the service, the contractor should contact the NHS Test and Trace support team by calling 119.
- d. If the contractor wishes to stop providing the service, this can be done via the withdrawal form attached in the annex and returned by email to NHS Practitioner and Counter Fraud Services.

5 Clinical governance

- a. The pharmacy Superintendent must provide feedback about any incidents relating to patient safety, the referral process or operational issues with respect to the service by contacting the local Health Board through existing standard channels.
- b. To comply with MHRA governance requirements, in the event of any incidents with respect to the test kits, the contractor must provide feedback to NHS Test and Trace via email (integrator@dhsc.gov.uk). Feedback must be submitted by 11am on Monday mornings for incidents that occurred in the preceding week.
- c. The pharmacy contractor should also make Yellow Card reports to MHRA, as necessary (see guidance at <https://coronavirus-yellowcard.mhra.gov.uk/>).
- d. Any information supplied must be anonymised and not contain any patient identifiable information.

6 Information governance

The pharmacy must comply with all Data Protection legislation in delivering this service. Specific information relating to the delivery of this service can be found in the DPIA embedded here:

7 Policy and operations queries

If a pharmacy has a policy question on this service they should contact PharmacyTeam@gov.scot

If a pharmacy has an operational question on this service they should contact enquiries@cps.scot

8 Risk and incident management

Each pharmacy site is responsible for ensuring:

- a. Premises meet all relevant legislative, certification and validation inspections and requirements including health & safety.
 - i. Premises must be accessible, clean, secure, suitable for purpose, properly used, physical distancing measures in place, properly maintained and appropriately located for the purposes for which they are being used
 - ii. Risk assessments are undertaken
- b. Sufficient numbers of suitably trained, competent, skilled and experienced persons must be deployed in order to meet the requirements of the service and persons employed by the service must:
 - i. Receive such appropriate support, training, professional development including update training, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,
 - ii. Be enabled where appropriate to obtain further qualifications appropriate to the work they perform
 - iii. Where such persons are health care professionals or other professionals, they will be registered with a health care or social care regulator
- c. Clear escalation and decision mechanisms in place to support the Responsible Pharmacist and ensure staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally where appropriate.
- d. Process in place to ensure lessons are learned and systemic problems and themes are identified so that an action is taken as a result of investigations when things go wrong.
- e. Pharmacy should define their risk management and accountabilities.

9 Face coverings

Individuals are required to arrive at the pharmacy wearing a face covering, unless they are exempt or have a reasonable excuse . If an individual arrives without a face covering and indicates they are exempt in accordance to latest Scottish Government guidance, they should be permitted to enter the pharmacy.

Each pharmacy should have traffic flow systems in place to mitigate the risk of individuals coming within close proximity of each other.

Children under the age of 5 years will not be required to wear a face covering while attending.

Each pharmacy may consider supplying a face covering to individuals who arrive without one, to enable them to enter the pharmacy and return home safely (decreasing the risk of onward transmission if the individual is asymptomatic).

10 PPE

Staff required to distribute LFDs on the pharmacy site are required to wear the appropriate PPE as detailed below. PPE will be provided to staff by the pharmacy

	Gloves	Apron	Fluid Resistant Surgical Mask (FRSM)	Eye/face protection
Collection Point Assistant	Not required. Perform hand hygiene after contact with person.	Not required	Wear FRSM at all times <u>Sessional use</u>	Not required

Only FRSMs may be worn sessionally. This means that FRSMs may be worn for a period of time between interactions with multiple people. Some FRSMs will have a 'maximum wear time' which should be adhered to if stipulated by manufacturer otherwise it would be reasonable to change an FRSM after 4 hours of wear for comfort purposes. FRSMs should be changed if protective properties are compromised, contaminated or damaged. If an FRSM is removed to eat or drink, hand hygiene should be performed and a new FRSM donned..

Other than FRSMs, PPE should be changed between tasks and contact with an individual service user.

All staff need to be reminded of the importance of IPC guidance. Regular hand hygiene and consistent physical distancing are key to ensuring safety for all roles.

This is enabled and supported by frequent cleaning of the Collection Point and high touchpoint areas.

11 Physical Distancing

There should be clear requirements for 2m physical distancing, throughout the end to end process. There should be a robust process for assurance of these measures. There should be a designated individual with the responsibility to ensure these measures are being adhered to.

Where space is limited, queues will be managed safely to avoid disruption and must allow for appropriate physical distancing.

12 Appendix

A. Infection Prevention and Control (IPC)

No additional IPC guidance is necessary for distribution over and above that used throughout the COVID-19 response. It is essential that all staff follow the general guidance contained within the PHS Guidance for Primary Care settings to prevent potential transmission of SARS-CoV-2 to themselves and others. Any non-compliance will be escalated through existing organisation incident management protocols.

A summary of the key elements to support IPC can be seen below, and all pharmacies will display appropriate signage:

1. Hand hygiene, including hand washing with soap and water, and the use of alcohol-based hand rub
2. Respiratory hygiene - 'Catch it, bin it, kill it'
3. Personal Protective Equipment (PPE) (Donning and Doffing)
4. Physical distancing: All workers should always remain 2 metres apart where possible, in accordance with government guidance in the working and welfare settings. Car sharing should be avoided where possible
5. Decontamination of reusable non-invasive care equipment
6. Effective segregation and disposal of waste

B. Common Clinical and Public Health Issues

The purpose of this section is to provide an answer to commonly asked clinical and public health issues related to testing. This section aims to be used as a reference.

Common pharmacy specific questions and answers and some general questions and answers can be found in this document (please see Annex B) .



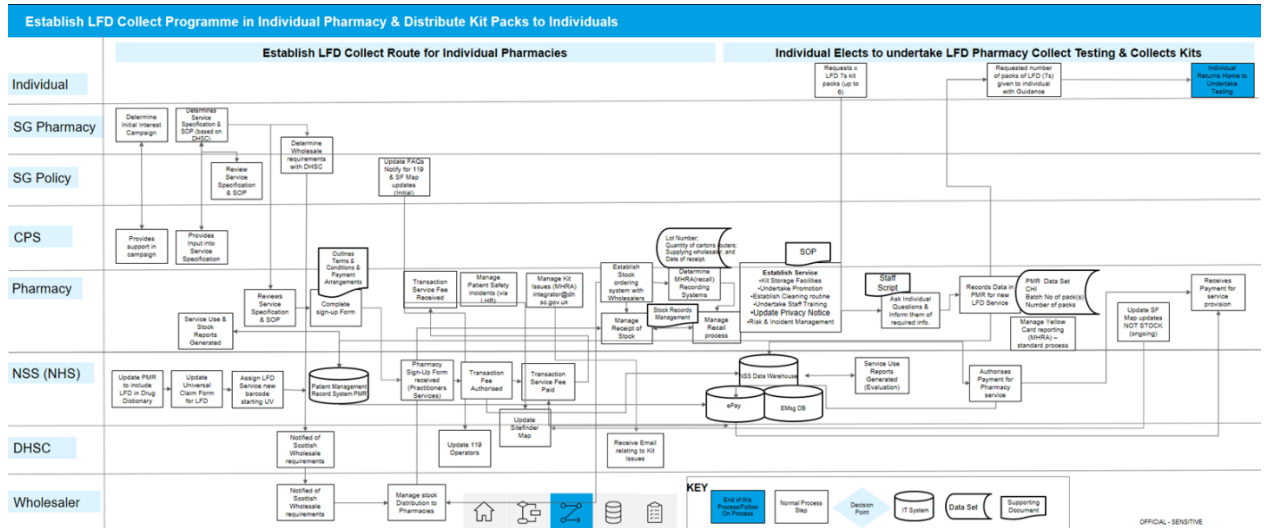
Universally Accessible
Testing - Q&A.docx

Further general questions and answers can be found in this document (please see Annex C).



Master FAQ for LFD
Asymptomatic Testing

C. End to end process map



Universally Accessible LFD Testing Programme – Q&A

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1. Overview of the Universally Accessible Testing programme

1.1 What is the offer?

We will enable people in Scotland who do not have symptoms but want to test regularly to access up to 2 LFDs per week to do so. This offer will be reviewed in June.

1.2 When will this be available?

From 26 April, there will be a variety of options to access tests. It will be possible to pick up tests from a designated test site location in your local area. There will also be an option to order tests online. From 9 June it will be possible to also collect LFD test kits from pharmacies in your local area.

1.3 How long will this last?

The universal testing offer will last at least until the end of June, and will be reviewed prior to then.

1.4 What is the purpose of this testing?

This is part of our Test and Protect programme. The purpose of regular LFD testing is to find cases among people who do not have symptoms. This enables us to interrupt chains of transmission, as those who test positive are asked to isolate along with their households and close contacts, to reduce the risk of further transmission. Broadening out our offer of regular testing will allow access to testing for individuals who are not part of an existing regular testing programme in Scotland.

1.5 Who can participate?

You can get rapid lateral flow devices (LFDs), for twice-weekly testing, if:

- you do not have [COVID-19 symptoms](#)
- you live in Scotland
- you have not been told to self-isolate

You need to be aged 18 or over to collect or order the test kits. Anyone aged 12 to 17 should ask an adult to collect or order a test kit for them and should self-test and report their result under adult supervision. We do not recommend regular testing for children who go to primary school, or who are younger than primary school age.

Do not use a rapid LFD test if you have COVID-19 symptoms. If you have symptoms you must self-isolate immediately and book a PCR test through [NHS Inform](#).

You should not access a test in this way if:

- you have tested positive for COVID-19 in the previous 90 days
- you can get tested through your workplace or education setting (ask them for rapid LFD tests)
- you need to take a test for [international travel](#)

1.6 How will people be able to access tests?

From 26 April, there will be a variety of options to access tests. It will be possible to pick up tests from a designated test site location in your local area. There will also be an option to order tests online. From 7 June it will be possible to also collect LFD test kits from pharmacies in your local area.

1.6.1 Collect a LFD test kit from your nearest local test site

You can collect a pack of LFD tests from most COVID-19 test sites.

- Find your [nearest COVID-19 test site](#) where LFD tests can be collected

A pack of tests contains seven test kits which you can complete at home. Up to two LFD test kits can be collected per household. If you are collecting for multiple people, up to four LFD test kits can be collected.

You can collect your LFD test kit from a COVID-19 test site between 8am - 8pm. You do not need to book an appointment.

1.6.2 Order an LFD test kit online, to be delivered to your home

You can order LFD tests online for [home delivery](#). Your order will contain one pack with seven LFD tests inside, and it will be delivered to your home in one to two days. You can order one pack per household each day.

If you're ordering for another household in addition to your own household, you should:

- complete a separate order
- use their personal details including name, address, date of birth and email address

If you cannot place an order online, you can order by calling 119.

1.6.3 Collect a LFD test kit from your nearest pharmacy

You can collect a pack of LFD tests from several pharmacies in Scotland.

- find your [nearest participating pharmacy](#) where LFD tests can be collected

One box of seven LFD tests can be collected per person. If you are collecting on behalf of a household, you may receive one box for each household member.

Please check the opening times of your local pharmacy to collect your packs of LFD tests. You do not need to book an appointment.

1.7 Is there an age limit?

You need to be aged 18 or over to collect or order the test kits. Anyone aged 12 to 17 should ask an adult to collect or order a test kit for them and should self-test and report their result under adult supervision. We do not recommend regular testing for children who go to primary school, or who are younger than primary school age.

1.8 Who should take part in regular testing?

Anyone who wishes to access regular testing can choose to do so. Testing may be of most benefit for those living or working in areas with higher prevalence, working, caring for or living with people who are particularly vulnerable or those who have regular

contact with other people through employment or other interactions (and are not already accessing testing via their employer).

1.9 Can I access information about the LFD test kits in a language other than English?

Yes – You can access a translated version of the instructions for use online. The instructions for use differ depending on the type of test kit you are using. Please access the COVID-19 Self-Test (Rapid Antigen Test) (3s and 7s) instructions for use [via this link](#) and the Orient Gene Rapid Covid-19 (Antigen) Self-test only instructions for use [via this link](#). Alternatively, you can call the 119 COVID Testing Helpline and ask for a translator to assist you.

1.10 How will test sites and pharmacies provide a safe environment for picking up LFDs?

Test sites will continue to provide PCR testing until early afternoon. They will then close and undergo a deep clean before reopening for LFD collection. If you have symptoms, you must book a slot for testing and only attend at that time.

Pharmacies have mitigations in place to guide symptomatic individuals against entering their premises and informing the public to continue following COVID-19 [protective measures](#). If you have [COVID-19 symptoms](#) you must self-isolate immediately and [book a PCR test](#) through NHS Inform.

1.11 Should people who have been vaccinated consider taking part in asymptomatic testing?

Yes. While vaccines reduce the risk the risk of infection after 14-21 days, people who have been vaccinated can still become infected. The Scottish Government is keeping the evidence about the impact of vaccination on transmission under review.

1.12 If I test positive, is there any support available?

Support to help people to self-isolate is available. In the first instance, people should call the Coronavirus National Assistance Helpline on 0800 111 4000, open from Monday to Friday, 9am to 5pm.

People who have been asked to self-isolate are also able to either contact their local authority directly, or, depending on their mode of being traced, are able to consent to sharing their information with their local authority, who will contact them throughout their isolation period to provide any support.

Local Authorities can help with food and essential medicine deliveries and other support you may require. Employees who are unable to work from home are also able to request [a notification letter from the NHS](#), which they can share with their employer.

If you earn less than the real living wage and satisfy the other eligibility criteria, you might be able to claim for the Self-Isolation Support Grant, a one-off payment of £500 to help you through your isolation. To find out more, [visit the Self-Isolation pages on Gov.Scot](#) or contact the Coronavirus National Assistance Helpline on 0800 111 4000.

1.13 Can I access the Self-Isolation Support Grant if I test positive?

If you earn less than the real living wage, test positive and satisfy the eligibility criteria, you may be eligible to claim the Self-Isolation Support Grant, a one-off payment of

£500 to help people self-isolate. You should contact the National Assistance Helpline for Coronavirus, on 0800 111 4000, open from Monday to Friday 9am – 5pm, to find out more.

2. Testing process and Test Technology

2.1 How do I take an LFD test?

The test usually involves taking a sample from either your: a) throat and nose or b) nose only, depending on the test kit you get. Detailed instructions, including videos, on how to do a rapid lateral flow test at home can be found here: [Report your coronavirus \(COVID-19\) test result | NHS inform](#)

It is very important that you use the right instructions for the respective test kit. You should check which test kit you have so you know which instructions to use. Test kits may be different to those that you may have used before.

You should take an LFD test twice a week (every 3 or 4 days).

2.2 What do I do once I have my test result?

Report your result.

You should report your LFD test results at [GOV.UK](#) the day you or someone in your household takes the test.

2.3 What should I do if I get a positive LFD test result?

If you or anyone in your household tests positive, everyone in the household must:

- self-isolate immediately. Financial and practical support is available at [Coronavirus \(COVID-19\): self-isolation factsheet - gov.scot \(www.gov.scot\)](#)
- book a PCR test at [NHS inform](#) to confirm the result (a PCR test is a different type of coronavirus test, and is regularly used for those with symptoms)

2.4 What should I do if I get a negative LFD test result?

If your test result is negative, it is important to continue to follow physical distancing and other COVID-19 mitigation measures including COVID-19 [protective measures](#).

A negative result only reflects a specific point in time. If you develop coronavirus symptoms you must book a PCR test at [NHS inform](#).

2.5 What should I do if I get a void LFD test result?

This means your test has not run correctly. You should:

- [report the result online](#) and take another LFD test.
- you should use a new test kit, and not reuse anything from the first kit.

If your LFD test fails for a second time, you should:

- report the result and book a PCR test through [NHS inform](#)
- you do not need to self-isolate after two void results, but you must continue to follow COVID-19 [protective measures](#).

2.6 I recently tested positive with a PCR test, should I access LFD testing?

People who have tested positive by PCR in the last 90 days should not participate in asymptomatic testing. Once 90 days have passed, you can participate in asymptomatic testing.

2.7 Can I order LFDs for delivery if I don't have internet access?

Yes. Test kits can be ordered by calling 119.

3. Interaction with existing testing routes/arrangements

3.1 Interaction with community asymptomatic testing arrangements

3.1.1 Will community Asymptomatic Testing Sites stay open?

Yes. Targeted Community Testing through our NHS Board and Local Authority partnerships will focus on maximising participation in those communities where the benefit would be greatest. For example, where transmission is stubbornly high; rapidly rising; or communities have specific transmission risks they wish to address. This would be achieved through the provision of additional local testing sites and targeted community engagement. You can access more information on asymptomatic testing sites in targeted communities via this [link](#).

3.2 Interaction with employer-based testing

3.2.1 I am an NHS worker and currently get testing via my employer. Will arrangements for testing change?

No – you will continue to be provided with LFD tests through your employer.

3.2.2 I get regular testing through the LFD collect model at work. Will arrangements for testing change?

No – we are asking all employers currently using LFD collect to continue to provide testing to staff.

3.2.3 Will employers who are eligible for workplace testing continue to be eligible for workplace testing?

Yes. Our approach to workplace testing is risk-based and employer who are already providing testing should continue to do so.

3.2.4 I am an employer providing testing to my staff through an Asymptomatic Test Site or LFD collect model. I would like my employees to use the universal offer instead, can I switch?

The universal offer will enable anyone in Scotland to access testing if they wish. Although this approach places less burden on employers, testing via the workplace provides more opportunities for employers to support and encourage employees to participate, as well as providing valuable data. We therefore recommend you continue to provide on-site testing which the Scottish Government is committed to support over the medium term.

3.2.5 What are the advantages for employers of using the employer testing approach?

Employer based testing enables employers to offer testing to employees in the context of wider range of workplace COVID mitigations, and to support and encourage employees to take up testing. It gives employers more visibility of the scale of workforce take up and opportunities to address any issues and concerns.

Providing on-site testing in the workplace has a number of benefits over the other at home routes:

- Strengthens the workplace culture of investing in the health and safety of staff and those who you work with
- Supports the uptake of testing by individuals who may not be motivated to test at home
- Enables the monitoring of staff uptake and the ability to strengthen communications or messaging around the purpose of testing when required
- Provides regular data on the results of tests by site or workplace locations
- Provides an opportunity to highlight the support that can be offered for those who have to isolate

3.3 Interaction with university testing

3.3.1 Can I access regular asymptomatic testing through the LFD collect model at my university?

Yes, all eligible staff and students can continue to access testing via their university

3.3.2 Can I use LFD testing before travel to university instead of PCR testing?

Yes. If you are using LFD tests twice a week, you do not need to undergo additional tests before travel. If you wish to use LFD tests prior to travel, you should take 2 tests before travel, 3 days apart. You can also choose to have one PCR test before travel.

3.4 Interaction with colleges testing

3.4.1 Can I access regular asymptomatic testing through the LFD collect model at my college?

Yes, all eligible staff and students can access twice weekly testing via their college from 23 April.

3.4.2 I am part of the University of the Highlands and Islands (UHI), can I access asymptomatic testing via the LFD collect model?

Yes, all eligible staff and students can access twice weekly testing via their UHI campus.

3.5 Interaction with schools, nursery and childcare testing

3.5.1 I get regular testing through the LFD collect model at my school, nursery or childcare setting. Will arrangements for testing change?

No, schools and ELC settings will still provide testing for staff and secondary pupils. You are encouraged to continue to access testing through this route.

3.5.2 I am a childminder and do not participate in the regular ELC settings testing programme, does this now mean that I can access regular testing?

Yes, universally accessible testing will enable you carry out twice weekly asymptomatic testing for you and your household.

3.6 Interaction with close contact testing

3.6.1 I am a close contact should I participate in LFD testing?

All close contacts of someone who tested positive for COVID are offered a PCR test to help us identify cases. Testing negative does not mean that you can leave self-isolation, and all close contacts need to complete their self-isolation period. During your self-isolation period you can continue regular LFD testing, but this does not exempt you from self-isolation.

Frequently Asked Questions Asymptomatic LFD Testing Programmes

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1. Overview of the LFD Asymptomatic Testing Programmes

1.1 Does this replace existing testing arrangements?

The asymptomatic testing programme does not replace the current testing policy for those with symptoms (new continuous cough, fever or loss of, or change in, sense of smell or taste). Individuals who experience symptoms of coronavirus must self-isolate immediately and arrange a PCR test at www.gov.uk/get-coronavirus-test. People with symptoms must not rely on a negative LFD result as a reason to continue to attend the workplace.

1.2 Do participants have to pay?

No. Tests are free of charge.

1.3 Are the tests safe and accurate?

Lateral Flow Device (LFD) tests have been widely and successfully used to detect coronavirus in asymptomatic individuals. No test is perfect, but the speed and convenience of LFD tests supports detection of the virus in asymptomatic individuals who would not otherwise be tested. They are clinically approved and are crucial in the fight against the virus.

If you test positive using an LFD, it is likely that you are infectious at that moment. This means that by using the LFD, we can identify people with a high viral load who are the most likely to spread the virus further. Only a very small proportion of people who do not have coronavirus will receive a positive result (false positive).

There is a risk of returning a false negative result when viral loads are low (e.g. in the early stages of infection). This is why the Scottish Government recommend two LFD tests 3 to 4 days apart, or regular testing, to enhance detection by picking up any cases which were not detected during the first test and to catch any new infections. This is also why it is important to continue to follow COVID-19 [protective measures](#) even if you have had a negative test result.

1.4 How should results be reported?

All individuals doing home testing must register the test kits at www.gov.uk/report-covid19-result, and report the results whether positive, negative or void/invalid. Alternatively, you can report by telephone by calling 119 in Scotland.

1.5 What happens if an individual tests positive?

If a participant receives a positive result on their Lateral Flow Device at home, they must report the result online at www.gov.uk/report-covid19-result (or by calling 119 in Scotland), self-isolate and book a confirmatory PCR test. This can be done at www.gov.uk/get-coronavirus-test or by calling 119. We advise visiting a drive through or walk-through test site as this is the quickest way to get tested, or participants can order a home test kit.

It is important that individuals who test positive, and anyone else who lives in the same household, begin self-isolation immediately after they receive the positive result from the LFD test, and do not wait until the result of their PCR test.

A positive test result via Lateral Flow Device will feed into the Test and Protect contact tracing system and commence contact tracing for the positive case. The person who has tested positive will then be offered a confirmatory PCR test. If this reports a negative result, contact tracers will consider via risk assessment whether to rescind self-isolation advice issued to close contacts, and whether the positive case can leave self-isolation. More details on this can be found under the section 'Testing and self-isolation'.

Further advice and guidance on self-isolation, and the support available to enable people to self-isolate and cut off chains of transmission, is here: <https://www.gov.scot/publications/coronavirus-covid-19-test-and-protect/pages/summary/>

1.6 If someone tests positive from an LFD test should they seek a PCR test to confirm the result?

Yes. The Scottish Government is providing confirmatory PCR testing for everyone testing positive using an LFD test.

1.7 What happens if the test result is "void"?

This means the test has not run correctly. Participants should report the result online at www.gov.uk/report-covid19-result. They need to take another LFD test. They should use a new test kit, and not reuse anything from the first kit.

If this fails for a second time, they should report the result and book a PCR test through NHS inform (www.nhsinform.scot/self-help-guides/self-help-guide-access-to-testing-for-coronavirus). Participants do not need to self-isolate due to 2 void results.

1.8 What if an individual has had a positive PCR test recently?

Anyone who has had a positive PCR test in the past 90 days should not participate in this programme until the 90 day period has elapsed. Once the 90 day period has elapsed the person should start this routine testing programme as soon as possible.

1.9 How is regular asymptomatic testing using LFDs affected by the PCR testing of close contacts?

When close contacts are identified through Test and Protect, they are now asked to get tested as soon as possible. Close contacts will book a PCR test through the UK booking portal, but can get help booking their test via NHS24.

The test can be taken at test sites or through a home test kit. The PCR test is taken as soon as possible after exposure to ensure we capture any already infectious close contacts. This will enable us to trace any people they might have transmitted the virus to before self-isolating.

If a close contact tests negative they are asked to complete their 10 day self-isolation period. Contact Testing does NOT mean that a person is able to leave self-isolation after a negative test result.

If a close contact tests positive they become an index case, and will have to self-isolate for a further 10 days from their test date. Test and Protect will contact this person and

perform a risk assessment to determine who has been exposed to the virus and needs to self-isolate.

If you are participating in weekly LFD testing and you are identified as a close contact of someone who has coronavirus you will need to get a PCR test as instructed and self-isolate for 10 days (even if you have tested negative in your weekly LFD testing).

If you receive a negative PCR result you may continue with your weekly at-home LFD testing if you have LFD at home test kits in your home to continue testing with. Otherwise, you will have to complete your 10 days isolation before picking up further kits.

If you receive a positive PCR result then you and your household will have to start isolating for 10 days from the date of your PCR test. You will not be able to participate in weekly LFD testing for 90 days.

1.10 Does testing replace the need for other mitigations (e.g. distancing, wearing of masks etc.)?

No. A negative LFD result must not be taken as leave to relax or ignore physical distancing or other measures intended to reduce transmission – LFD testing is an additional intervention that contributes to reducing risk.

Individuals should ensure they observe physical distancing and wear face coverings when attending the workplace to collect test kits.

1.11 What happens if someone has a problem with the tests?

Any incidents that could potentially impact the quality or safety of testing should be reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

Incidents occurring in a home setting (for example: something damaged, or missing or difficult to use in the kit, unable to log result) should be reported to **119**.

If there is a clinical incident which led to, or has the potential for, harm (e.g. swab breaks in the mouth, bleeding, allergic reaction on using the kit etc.) this should be reported on <https://coronavirusyellowcard.mhra.gov.uk>.

This is not for seeking immediate medical care. Medical care should be sought through the usual route of contacting 111 or 999

1.12 Can I access information about the LFD test kits in a language other than English?

Yes – You can access a translated version of the instructions for use online. The instructions for use differ depending on the type of test kit you are using. Please access the COVID-19 Self-Test (Rapid Antigen Test) (3s and 7s) instructions for use [via this link](#) and the Orient Gene Rapid Covid-19 (Antigen) Self-test only instructions for use [via this link](#). Alternatively, you can call the 119 COVID Testing Helpline and ask for a translator to assist you.

2. Testing and self-isolation

2.1 Why should individuals get tested if they have no symptoms (i.e. asymptomatic)?

Lateral flow tests detect the level of virus in individuals who do not experience or show any symptoms, but who could still be infectious and pass the virus to others. By taking a test and isolating if the result is positive, individuals will help to stop the spread of the virus, protect other people, and save lives.

2.2 Should someone who has been vaccinated take a LFD test?

Yes, we do not yet know whether vaccines prevent individuals transmitting the virus.

2.3 What happens if individuals have a positive LFD test at home but the follow up PCR is then negative?

If the confirmatory PCR test is negative, individuals will be contacted by Test and Protect who will advise them on what to do next.

In most cases this will involve ending self-isolation, provided the individual continues to have no symptoms. In some limited circumstances the individual may be advised by Test and Protect to continue self-isolation if a risk assessment determines this to be appropriate.

2.4 What should happen to contacts of individuals who have a positive LFD test and a positive confirmatory PCR test?

Test and Protect will contact individuals who were in close contact with a positive LFD case to inform them that they need to self-isolate and book a test through <https://www.gov.uk/get-coronavirus-test>.

If a close contact tests negative they are asked to continue to complete their 10 day self-isolation period. However, if they continue to show no symptoms, other people living in the same household do not need to self-isolate.

If a close contact starts showing symptoms, everyone in their household needs to self-isolate immediately and another test needs to be arranged to determine whether the close contact has coronavirus.

If a close contact tests positive then they become an index case, and they and their household will have to self-isolate for a further 10 days from their test date. Test and Protect will contact this person and perform a risk assessment to determine who has been exposed to the virus and needs to get tested and self-isolate.

2.5 From when should self-isolation of an asymptomatic case commence?

If individuals are asymptomatic, the self-isolation should start as soon as the LFD test taken at home shows a positive result, in line with the Scottish Government stay at home guidance. They should arrange a confirmatory PCR test as soon as possible,

ideally the same or next day.

2.6 Should I still take part in the asymptomatic testing programme if I have recently had a positive PCR test for coronavirus?

No. If individuals have recently (within 90 days) tested positive for coronavirus by PCR, they should not take part in the regular testing. They must complete their period of self-isolation before returning to school or setting.

This applies to both regular asymptomatic testing using LFD tests, and the existing offer of asymptomatic PCR testing.

However, if a person develops symptoms (at any point) they and their household must self-isolate and the individual should book a PCR test.

2.7 I have previously tested positive for coronavirus antibodies, should I still take part?

Yes, you should still take part in LFD testing as this is measuring something very different. An antibody test is a blood test to check if you've had COVID-19 before, it does not tell us if you are immune to infection. It may still be possible for you to become infected and transmit COVID-19 to other people.

2.8 I have been vaccinated, should I still take part?

People who have been vaccinated should continue to participate in regular asymptomatic testing. The vaccines used in Scotland do not increase the risk of false positive results.

3. Information about LFD tests

3.1 I'm confused: how many different types of tests are out there and what's the difference between them?

In addition to the COVID-19 Antibody Test, which is a blood test to check if you've had COVID-19 before, there are two main types of test used to check if people currently have coronavirus.

The first type of test is known as a PCR test, and looks for the virus's genetic material. They require a laboratory to be processed. Those with symptoms (new continuous cough, fever or loss of, or change in, sense of smell or taste) must self-isolate immediately and arrange a PCR test at <https://www.gov.uk/get-coronavirus-test>.

The second is called a Lateral Flow Test or Lateral Flow Device. This detects the coronavirus antigen that is produced when a person is infected with coronavirus by applying a swab from either the nose and throat or just the nose (depending on the type of the test kit you are using) to a special test kit. These are quicker tests that produce a result within 15-30 minutes and do not require a laboratory to be processed.

It is extremely important that you do not let a negative test result affect the way you follow and stick to the COVID-19 [protective measures](#) in place.

3.2 Why are you using Lateral Flow Devices to test asymptomatic people?

By testing a higher proportion of asymptomatic people, we can identify positive cases and isolate more people who are at high likelihood of spreading virus, and break the chain of transmission. Lateral Flow Devices enable the asymptomatic testing of more people.

3.3 Will the Lateral Flow Devices work to detect the new COVID-19 variants

Yes. Scientists have tested using LFDs against the new variants.

We will continue to monitor the new variants and are keeping our response to it under constant review.

3.4 Does the LFD test contain any harmful substances and are there any precautions for dealing with spillages?

Extraction solution which comes with the LFD test kit contains the following components: Na_2HPO_4 (disodium hydrogen phosphate), NaH_2PO_4 (sodium phosphate monobasic), NaCl (Sodium Chloride). These components do not have any hazard labels associated with them, and the manufacturer states that there are no hazards anticipated if individuals follow the instructions for use.

Any spillages should be wiped with a paper towel and if the solution included the throat and nose sample, the area should be appropriately disinfected using household disinfectant.

3.5 Do the LFD tests contain animal products or have they been tested on animals?

While we do not test any of these products on animals, nor are animals harmed in the development process, the antibodies used for the test reaction are derived using an animal cell in the laboratory. The T line for a positive test is derived by reaction between the sample as it flows to the membrane (thin paper like material inside the device) which is coated with these antibodies. It is therefore highly unlikely for there to be any direct contact between the person being tested and the animal material itself.

However, we want to make sure that the people undertaking the test make an informed choice about this.

3.6 Are the LFD tests vegan?

The monoclonal antibody technology present in our lateral flow devices are generated from animal cells. During development, at no time have any component parts been tested on animals.

3.7 Are the LFD tests halal?

No animal products have been used in the production of the swabs. The swab is the only material with which the individual will come into direct contact. The individual using the test will not come into direct contact with any materials made from animal products.

The thin paper like material inside the LFD is coated with antibodies from animal cells. No direct contact will be made between the person and this material. The monoclonal antibody technology present in our lateral flow devices are generated from animal cells. This is in common with other tests of this kind, including commercially available pregnancy tests.

3.8 Is the LFD test safe for those that are pregnant?

Yes, the tests are safe to use by those who are pregnant.