

LATERAL FLOW DEVICE COMMUNITY TESTING

'ON PREMISES' TESTING FOR BUSINESS STAFF FOR THOSE WHO CANNOT WORK FROM HOME

Important to note before going further:

- **Businesses with over 50 staff should register on the government website: <https://www.gov.uk/get-workplace-coronavirus-tests>**
- **We are not able to provide 'at home' testing kits**

Business On Premises Testing

Before you do any testing

Complete and return your business checklist and risk assessment to the Cornwall Council Community Testing Team: mary.dawe@cornwall.gov.uk

Ensure that all necessary staff have undertaken the appropriate online training – you can refer back to the training at any time

Ensure that your business has been registered on the Government portal via the Community Testing Team and your named site Lead and Deputy Lead have access to the portal

Ensure you have arranged your order – including test kits and PPE from DHSC – via the Community Testing Team by pre-arranged appointment

Ensure you have all other equipment you may need that is not provided by Cornwall Council

Steps to Test and Report



Training

This is the link to the training <https://go.tessello.co.uk/TestDeviceTraining/> This link will take you to the training portal to access training for both test operatives, site operatives, team leaders and trainers. Depending on the role within the business there may be a need to undertake more than one of the training modules:

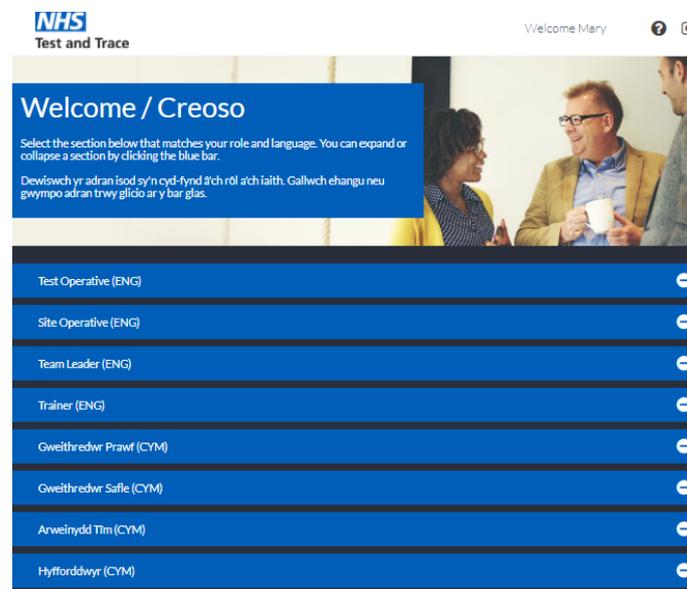
Once you have accessed the site from the link above, initial registration is via 'Need to register?' link (the 'blue login button') which will take you to the registration page where you enter the site registration token: **3wkcVi4UTX**

You'll then be prompted to set up an individual account and password (which is very quick and easy to do).

If you experience any technical issues associated with access, using the training platform, or completing the training assessment, please call the helpdesk on **0161 903 10321032**.



Once signed in you should see this page and can proceed with the appropriate training:



You will notice during the training that there are a number of items that you may feel that you need in order to make your site workable and safe. These items are not provided by Cornwall Council. The ordering/purchase of these must be covered by your own business.

Please ignore the 'Orient Gene' training modules and just completed the 'Innova modules' within the training.

Test Operative (ENG)

 <p>Infection prevention and control</p> <p>Completed ✓</p>	 <p>How to give guidance on self-swabbing for the Innova LFD test</p> <p>Completed ✓</p>	 <p>How to process COVID-19 tests using the Innova Lateral Flow Device</p> <p>Completed ✓</p>	 <p>How to log results for COVID-19 tests using the Innova Lateral Flow Device</p> <p>Completed ✓</p>
 <p>How to give guidance on self-swabbing for the Orient Gene LFD test</p> <p>Not Started</p>	 <p>How to process COVID-19 tests using the Orient Gene LFD</p> <p>Not Started</p>	 <p>How to log results for COVID-19 tests using the Orient Gene LFD</p> <p>Not Started</p>	 <p>Test Operative - using the Log Results website</p> <p>Completed ✓</p>

Registration of your Business on the NHS Test and Trace Portal
Roles and Responsibilities within the Portal

Important: Cornwall Council Public Health Community Testing Team will act as Organisation Manager

ROLES AND DIGITAL RESPONSIBILITIES

Different workforce members will have different responsibilities within the digital ecosystem and will need to create different accounts.

ROLE	DIGITAL RESPONSIBILITIES
Organisation Manager (Organisation member in charge of the testing programme and decides where test sites are set up)	<ul style="list-style-type: none"> Requests access to use the Log Results Website for their Organisation or multiple Organisations Adds test sites to each Organisation they manage Adds team leaders to each test site
Team Leader (Test site staff)	<ul style="list-style-type: none"> Approves or denies Log Results Website access for Testing Operatives (Results recorders) to their test sites
Testing Operative (Results Recorder) (Test site staff)	<ul style="list-style-type: none"> Uses the Log Results Website to scan and upload LFD barcodes and test results
Testing Participant (Individual being tested)	<ul style="list-style-type: none"> Registers their unique test barcode each time they test at the test site

Important - Please note that this is an authentication login so you will need appropriate work mobile numbers. An authentication code will be sent via text every time an operative logs in.

The Community Testing Team will register your business on the portal test site once you have sent them all the requirements which are:

- Business suitability Checklist (emailed previously)
- Your business risk assessment for each site (templates at the end of this document to aid)
- Company Name, full address including postcode - for each site that you are using to carry out tests
- Names, email addresses and mobile phone numbers for each allocated testing Lead and Deputy Lead within your organisation.

Once your business is registered the Community Team will send you your Unique Site Code which you will need at all stages of the test process.

Businesses will be registered under: "business name LFD test site – town"

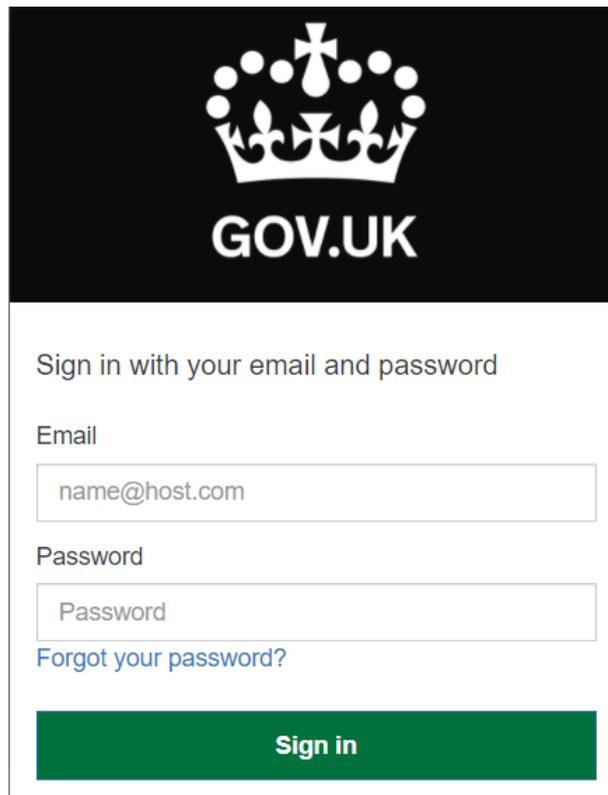
If you have more than one test site, then each site needs a separate site code.

As well as registering the business name we will also register two team leaders per site – we will require a business email and work mobile telephone number for each of these leaders as access to the site is via a two-process authentication e.g. password and access code which is sent direct to the team leaders via text message at each session login.

After your business is initially registered by Cornwall Council, Team leaders will then be responsible and able to approve or deny additional test site staff access for Testing Operatives. Any misuse of the site could result in access to your business being withdrawn from both the site and the LFD test programme.

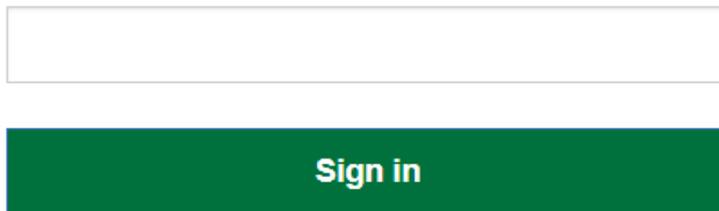
Team Leaders

Once registered by the Community Testing Team, the Team Leaders will be sent a text message with a temporary password. First time users will need to change their password to complete set up. A code will then be sent to the mobile registered under that user for authentication



The screenshot shows the GOV.UK sign-in interface. At the top is the GOV.UK logo (a crown) on a black background. Below the logo, the text "Sign in with your email and password" is displayed. There are two input fields: "Email" with the placeholder "name@host.com" and "Password" with the placeholder "Password". A blue link "Forgot your password?" is located below the password field. A green "Sign in" button is at the bottom of the form.

We have delivered the authentication code by SMS to +*****6358. Please enter the code to complete authentication.

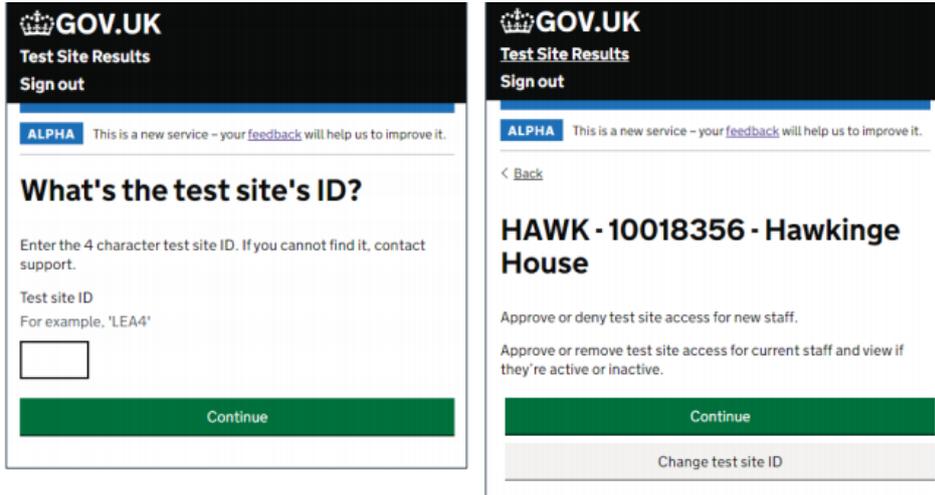


The screenshot shows a single text input field for entering the authentication code. Below the input field is a green "Sign in" button.

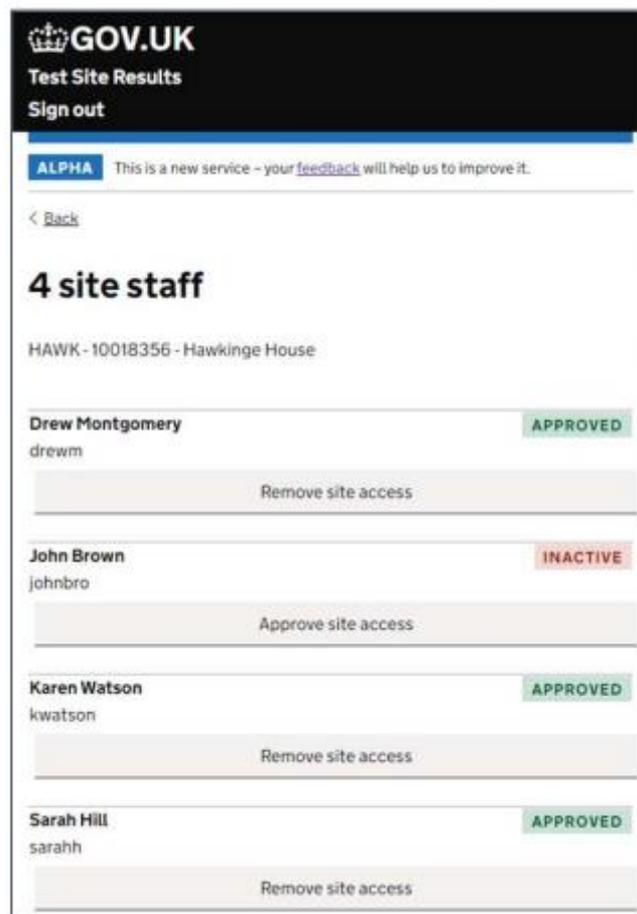
Once Team leaders have logged in for the first time and updated their password their status will become 'active' and they can then manage testing operatives at their test sites within the organisation:

Test site Selection

Enter your site Unique ID and select **continue**



Team Leaders have the option to manage new Testing Operative access requests for the site, as well as to view and manage the Testing Operatives who currently have access to the test site. Team Leaders can view, remove and re-approve site access for current Testing Operatives, with the current status of each operative shown via inline 'Approved' or 'Inactive' status. **Test operatives should register in order for Team Leaders to approve them – Team Leaders are not able to Add Site Operatives.**



Kit and PPE Collection

Collection of LFD test kits and PPE needs to be arranged by appointment so please contact Mary.Dawe@Cornwall.Gov.Uk. Two weeks of PPE and kits will be issued at one time, though this may alter depending on frequency of stock delivery. You will need to ensure that you have someone available to drive to New County Hall on the day of your agreed appointment to collect the items.

Cornwall Council will provide the following items:

Aprons, visors, gloves (small, medium, large, ex large) masks, LFD barcodes, registration cards, LFD kits which contain the following:



Important: LFD test kits can be stored in temperatures between 2-30°C - It is important to note that to reagent (develop) the device the temperature must be between 15-30°C

Personal Protective Equipment (PPE)

Appropriate PPE should be used dependant on which role is being undertaken. Instructions for donning and doffing and disposing of PPE is given in the training videos relevant to each site staff role but this is a quick reference guide.

Role	Disposable gloves	Disposable plastic apron	Fluid-resistant (Type IIR) surgical mask (FRSM)	Eye protection
Processing Operative				
Cleaning Staff				
Test Assistant				
Site Coordinator / Team Leader				
Registration Assistant				
Results Recorder				
Supplies Coordinator				
Queue Coordinator				
Indicates single or sessional use*	Single use	Sessional use	Sessional use	Sessional use

* See instructions.

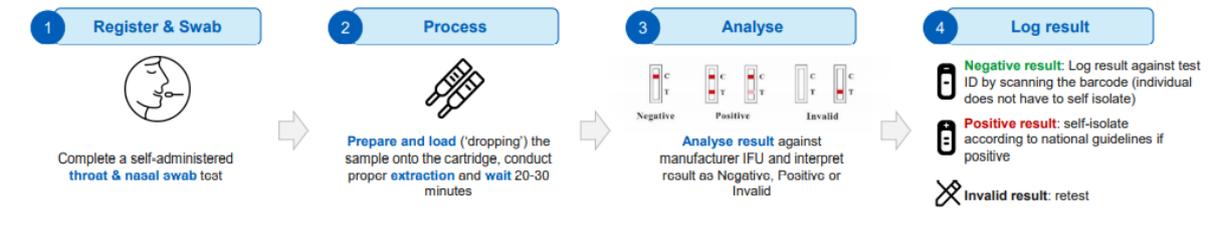
Prepare Staff

The business should prepare their staff for the introduction of twice weekly testing and gain their consent to take part. Make your expectations clear as an employer and communicate the process to staff. Discuss implications of a positive test with staff members and put together a plan for their safe route home to isolate.

Important note: The subject should be asked to avoid eating or drinking for at least 30 minutes before taking the test to reduce the risk of spoiling the test.

Staff should be encouraged to use their own mobile devices to register their own tests, however, you may wish to have a device available as a contingency.

Test Overview



Welcome, Registration and Check in Process

Subjects (person being tested) should be welcomed and checks made that they do not have symptoms of COVID 19. If the subject does have symptoms, they should be politely asked to leave and book an alternative test at a nearby test centre or order an at home test kit.

Assuming the subject has no symptoms and is happy to continue the test, the subject will collect their registration form and unique barcodes. The registration form will have a QR Code to take them to the registration site where they 'Register a test'.

They will need to give their full name, email address, mobile phone number and home address ideally by themselves on their own mobile phone device but some people who do not have their own phone may need some help.

Access to the registration site: www.gov.uk/enter-lateral-flow-test or by scanning:



Any business device used to support the registration process will have to be operated in 'incognito' mode (this is to protect the privacy of the participants, as it will prevent users going back to previous form entries or seeing form auto-fills with personal information).

The device browser should also have form auto-fill disabled, to prevent past Participants' data showing up in forms if the incognito windows isn't closed. Devices should have antivirus software installed if possible.

It is useful to have a large printed laminated/cleanable sheet giving your Unique Test Site ID, the website address and QR code.

Register a coronavirus test

Use this service to register a coronavirus test for you or someone else.

You need to register each coronavirus test to get the results.

To complete this form, you'll need:

- the test kit barcode for the test you're registering
- a mobile number (for you or the person you're registering it for)
- the Royal Mail barcode on the return box (only if you are registering a home test kit)

If you are taking a test before your hospital visit, you need to [register your kit here](#).

Start now >

How we use your data

To find out how we use your personal data when you register for a coronavirus test, [read the coronavirus privacy note](#).

[Help](#) [Privacy](#) [Cookies Statement](#) [Accessibility statement](#) [Terms and conditions](#)



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You will have the option to register for 'Myself' or 'Someone Else'

Who are you registering a test for?

Myself

Someone else

Continue

Then you either enter the unique test kit barcode or scan – if you manually enter you will be asked to do this twice to reduce the risk of an error inputting.

Enter the unique test kit barcode

If you have a home test kit, use the camera on your phone or computer to scan one of the identical barcodes on the plastic tube, plastic bag and return box.

Or you can manually enter the 11 character reference below the barcode.

If you're using a home test kit, you'll find the identical barcodes inside the home test kit, either attached to the plastic vial, biohazard bag and return box or loose for you to stick on yourself (please read instructions).

These are different from your pre-paid Royal Mail return package barcode on your box.

▶ [What does the barcode look like?](#)

Test kit barcode reference

Confirm test kit barcode reference

Issue with Test Site Registration for Subject

If the site for subjects to register their test kit is down:

- Give the Participant a registration card with their **barcode** on it to take away
- Instruct the Participant to **follow the instructions** on the card and **attempt to register** as frequently as possible **until successful**

Please note:

- You can continue to record results on-site using the Log Results system
- Participants can register their test retrospectively, even after the result is submitted by the test site
- The system will hold unmatched test results for up to 7 days while waiting for the subject to register

Unique Bar Code

Once registered and logged into their own account, subjects can scan or manually enter their unique test barcode for that day's test, this will link to the participants test sample and their personal details – this should be handed over with their test sample to the test operative.

Subjects will be issued with a unique barcode at each test which will link their test sample to their contact records details.

Sample collection

Once relevant staff are wearing appropriate PPE and all checks have been made the testing can commence.

The Test Assistant will explain the process to the subject. The subject will also be informed that the swab may sometimes make them gag and they should use a sick bowl if necessary. Subjects complete a self-administered throat and mid-turbinate nasal swab test as per instructions. The process is as follows:

Test and Trace

- 1** Participants will gently blow their nose into a tissue. Throw the tissue into the clinical waste bin provided.

This is so that they get rid of excess mucus.


- 2** Participants will use hand sanitiser to clean their hands


- 3** They will look inside their mouth, and find their tonsils at the back of the throat. They can use the mirror to help.

Their tonsils, or where they would have been, (if they are removed) are where they will swab their sample.

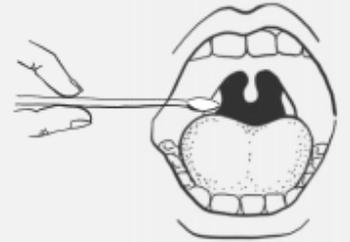

- 4** The Participant should identify the soft, fabric tip of the swab its sealed, sterile packaging, peel open the packaging and gently remove the swab whilst taking care to not touch the soft, fabric tip of the swab



5

Holding the swab between fingers, they will open their mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been) at the back of their throat, **at least 4 times on each site** (they can use a mirror to help them do this). If the Participant is unable to take a throat swab, they can swab both nostrils instead.

Carefully remove the swab stick from the back of their throat.



6

Put the same end of the same swab gently into one nostril until they feel a slight resistance (about 2.5cm up the nose). Rotate the swab 10 times and slowly remove it.

They only need to sample one nostril. If the Participant has a nose piercing, swab the other nostril. If pierced on both sides, remove the piercing on one side before swabbing. If nasal swabbing is not possible because the Participant has unhealed wounds or fresh piercings on both nostrils, throat only swabbing can be used.



Sample Analysis

The Processing Operative receives the barcode directly from the subject.

The Processing Operative then removes the LFD device from the pouch and applies a barcode to the underside of the LFD cartridge.

LFD cartridges should be used without a long delay after opening the pouches in which they are supplied.

The Processing Operative sets up the extraction tube by following these steps:

- Place the extraction tube in the tube rack (or other receptacle) with the opening facing up
- Press the extraction solution bottle to drip 6 drops of extraction solution into the extraction tube without touching the edge of the tube. **Do not let the buffer bottle touch the edge of the tube.** The extraction solution bottle should be decontaminated with an appropriate wipe between samples to prevent cross-contamination.
- The extraction tube will be left in the tube rack on the processing bench ready for the subject to place the swab
- The Subject will place the swab sample into the prepared extraction tube

The Processing Operative then takes the swab and commences the following steps:

- a. Extract: Hold and press the swab head against the wall of the tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head



- b. Remove swab: Squeeze the swab head by squeezing the lower end of the tube while removing the swab in order to remove as much liquid as possible from the swab as shown in Figure 2
- c. On withdrawal, immediately dispose of the swab into healthcare waste bin.
- d. Install a nozzle cap onto the extraction tube
- e. Load: drip 2 drops of the sample inside the extraction tube into the sample well of the LFD cartridge

Manufacturer's note: guidance should be followed for the 2 drops of extraction solution to be loaded on the cartridge. However, results with 2 to 4 drops have been validated and accepted.

Record the time of test (Drop @ XX:XX) in marker on the LFD and make sure you have set a timer to read the results at 30 minutes.

- f. Re-check that the liquid can be seen seeping through the cartridge (to ensure the drop was not an air bubble)
- g. If the cartridge appears dry, the subject will need to be recalled for a further sample to be taken.
- h. If needed, move the cartridge to a defined processing space for reading and leave for between 20-30 minutes.

Important Note: Please note the LFD movement should be kept to a minimum and where it is required to be moved, keep horizontal using a tray.

Clean the sample preparation area and equipment thoroughly with disinfectant (e.g. appropriate wipe)

Reading and Interpreting LFD Result

Important Note: Result must be read between 20 and 30 minutes
The temperature required to develop the device must be between 15-30°C -

Strong positive results can be reported at 20 minutes, however, negative results must be reported at 30 minutes.

If a positive signal appears after 30 minutes, it should not be reported as positive.

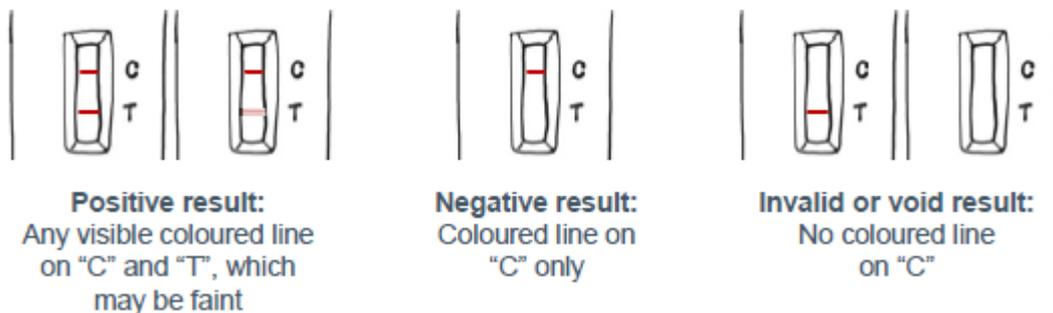
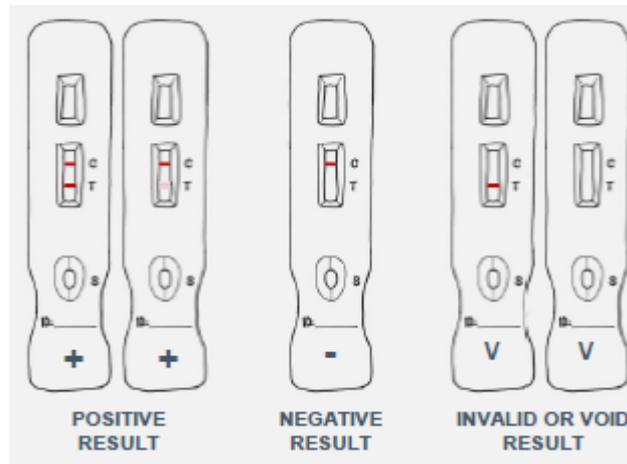
Line C must be coloured to have a valid test result.

Valid results:

Negative result: There is coloration on line C only, suggesting that there is no SARS-CoV-2 antigen in the specimen.

Positive result: There is coloration, even if faint, on both line C and line T indicating that there is SARS-CoV-2 antigen in the specimen.

Invalid results: There is no coloration on line C, the test is invalid or an error in operation occurred.



Tests should be marked with a black **permanent** pen and removed from the desk. A symbol system should be used to avoid confusion:

1. '+' mark for positives – removed any time before 30min
2. 'V' mark for invalid – removed 30min after "drop"
3. '-' mark for negatives – removed 30min after "drop"

The LFD can then be moved to the next station for data logging/result recording
The area where the device was situated is then cleaned after it has been removed

Recording of Results

Sign into your account - ***you will need your registered mobile phone to receive authentication code***

Select your site location

Scan the LFD barcode as per digital results recording process with the web-based application and digitally record the applicable result. Alternatively, manually enter the barcode details.

The area where the device was situated and equipment (i.e. pen, tray, etc.) are then cleaned after each batch with an appropriate wipe.

Once result has been logged, the LFD are disposed of as per the requirements outlined in your *waste management plan*.

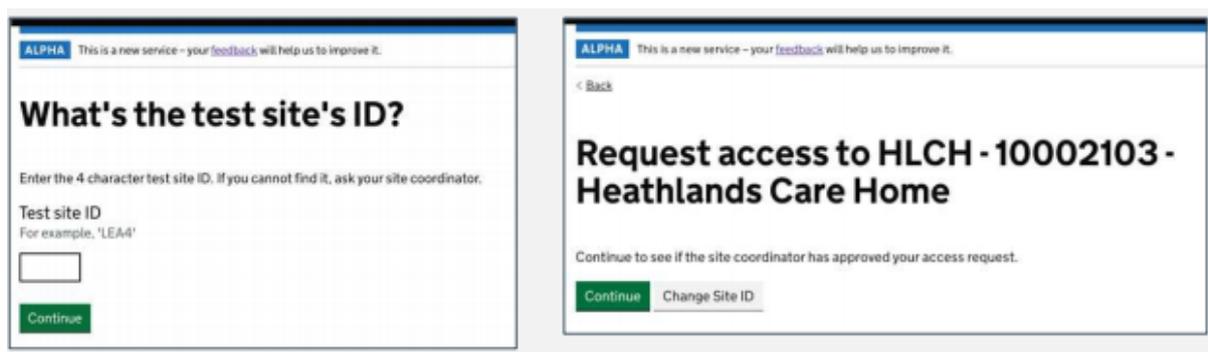
Logging Results on the Portal

The Test Site Operative must choose 'I'm a test site operative' on the starting page (<http://log-coronavirus-test-site-results.service.gov.uk/>) and proceed to 'Sign in' using their username and password. If it is their first time accessing the website, they will need to select "Sign up" to create their username and password.

Note: It is very important that the Testing Operative account belongs to an individual and is not shared between several people at an organisation

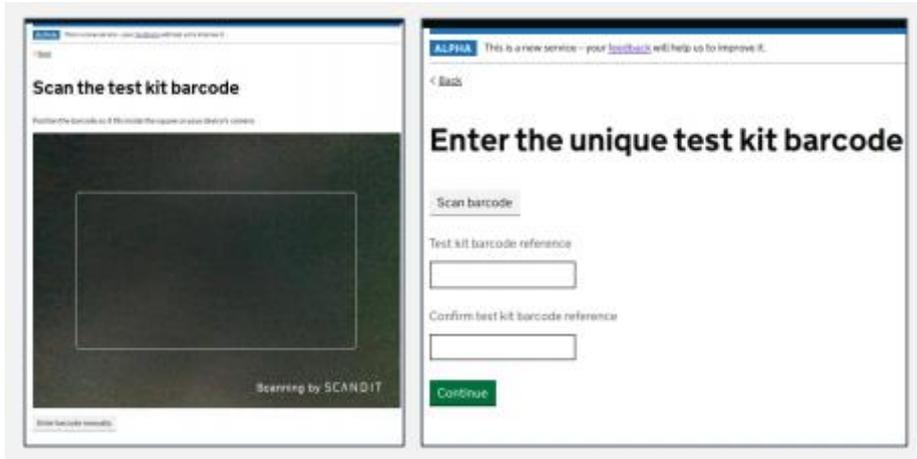


The Test Site Operative then selects the business site location using the site ID (provided their your Team Leader). Confirming this will send a request through to the Team Leader to approve.



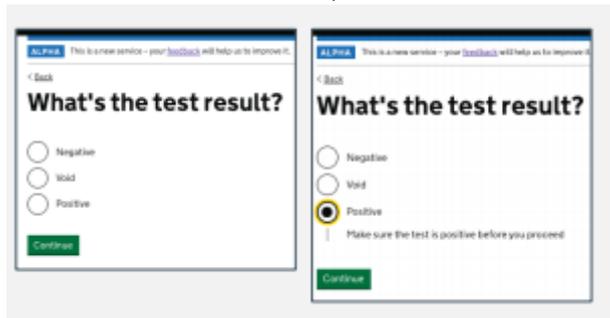
The 'Awaiting approval' page will be updated automatically when the user has been given access by their Team Leader. It will then allow them to start logging test results.

In order to log results the Test Site Operative positions the device scanner so that the barcode sits within the box. When the barcode is scanned successfully, they will be directed to the next page to log result. There is an option to enter the barcode manually if the scanner is unable to capture the barcode. The user will have to enter the barcode twice to ensure data accuracy



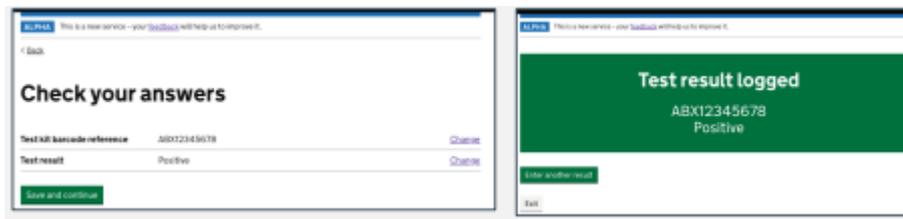
Enter Results:

The Test Site Operative selects the result of the test, and selects **continue**



Review and Submit Results

A summary of the test result is shown to the Test Site Operator before they can submit the result. The Test Site Operative can change both the barcode and the Test result using the 'change' buttons. Once they are confident with the result they can 'Save and continue' and will be shown a successful 'Test result logged' page if the result was successfully submitted.



Sign Out

When the test operative finishes their shift or hands over to another operative they must sign out at the top left of the screen.



Issue with Test Result Site

Short term outage – Majority of operational processes remain the same with registration and results uploaded retrospectively once access is regained to the digital system.

Record results manually offline

Operational process changes are required to deliver results directly to subjects in person or record registration details offline to deliver results manually.

Longer term outage – (Multiple days of no access)

All positive tests must be reported within 24 hours

For outages longer than 24 hours, positive results must also be reported to Public Health England via the Laboratory Reporting Process -when using the contingency process test results will be recorded at the time of retrospective entry rather than the actual date of test. This impacts on national test results and should not be used as a 'business as usual' process.

Data Management

The results are uploaded as linked to the barcode. Hence, there is no visibility or access to linking the results with the subject's identity.

Communication of Results

N.B. It is assumed that every employee who participates in this programme to be tested will have either a mobile telephone number or an e-mail address.

Results will be sent to the subjects via text message and/or an e-mail using contact details recorded at the registration or check-in process. The results will be communicated within a day of the test.

In most cases it is envisaged that the person being tested will leave the test site as soon as they have completed the test. If the result is also to be given in person-if the person is in a waiting area-, this needs to be delivered using a prepared script including:

- Detail of the result (negative, invalid, positive)
- Instructions on what to do for invalid results (retest LFD)
- Instructions on what to do for positive results (go home immediately and follow self-isolation guidelines)
- Travel advice for subjects
-

Verbal results must be given confidentially.

Invalid Results

Subjects who return an invalid (or could not read sample) LFD result should be offered a follow-up test:

- If the subject is within close proximity of the testing site where they took the first test and it is operationally feasible, it is recommended that they return to the site and take a second LFD test. If the LFD result is invalid a second time, they should be retested with a PCR test. Where this is operational, guidance will need to be provided to the Subject while they are at the test site.
- If the subject has left the testing site and it is operationally more feasible, it is acceptable to retest with a PCR test after the first invalid result. Subjects should be directed to go to www.gov.uk/get-coronavirus-test and choose 'home testing' (do not choose a test site).

While awaiting a follow-up test they'll only need to self-isolate if a) they are symptomatic (they'll need to book a different test), b) someone they live with tests positive (or has symptoms and has not been tested yet) or c) they've been traced as a contact or someone who tested positive.

Positive Results

People who return a positive LFD result and everyone in their household must self-isolate immediately for 10 days. The 10 days begin the day after your test date.

If the subject or anyone in their household get symptoms, they must self-isolate from the day symptoms started and for the next 10 full days.

Care home residents must self-isolate for 14 days.

For a child or staff at school or nursery, tell the school/nursery.

3 days after the LFD positive result the subject will receive a follow-up text message to ensure they and everyone in their household continue to self-isolate for 10 days. If they or anyone in their household get symptoms, they should self-isolate from the day symptoms started and for the next 10 full days.

Weekly Reporting to Cornwall Council

By 3pm each Monday, please report back the following details to Cornwall Council by email to: Amy.Glover@cornwall.gov.uk

This data should include the **previous week's** testing data from Monday to Sunday inclusive:

- Number of tests booked
- Number of tests delivered
- Number of void tests
- Number of positive tests
- Projected number of tests for the following week

Return to Work

Your business may have a return to work policy but the subject can return to work the day after they finish self-isolating if they have not had a high temperature in 48 hours, even if you still have a cough.

Travel Advice for Positive Results

Subjects should try to have arrangements in place to travel home safely in the event they test positive. They should be advised to:

- Travel home immediately, wearing a face covering
- Wherever possible they should travel home in their own vehicle or by walking or cycling
- If it is not possible to do so, they should arrange for a member of their household to pick them up
- Positive cases should follow national guidance provided by the Department for Transport when travelling home
- Asymptomatic contacts of positives cases should go home as they would normally do. If the contact becomes symptomatic, they should follow same travel advice as positive cases.
- **It is especially important that people follow Government guidance on hygiene, including hand washing before leaving, throughout the process of attending a testing site.**

Post Covid Testing

Subjects that have tested positive by PCR for COVID-19 are exempt from routine re-testing by PCR or LFD tests within a period of 90 days from their initial illness onset or test (if asymptomatic) unless they develop new COVID-19 symptoms.

If a subject decides to take part in testing within the 90-day period, they should follow the latest government guidance:

For management of staff and exposed patients or residents in health and social care settings: <https://www.gov.uk/government/publications/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings/covid-19-management-of-exposed-healthcare-workers-and-patients-in-hospital-settings>

For household settings: <https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance/stay-at-home-guidance-for-households-with-possible-coronavirus-covid-19-infection>.

Cleaning and Waste Disposal

For guidance on cleaning please refer to the Infection Prevention and Control (IPC guidance)



InfectionPrevention
AndControl.docx

Prior to commencement you should discuss the management of waste from the lateral flow tests with your waste collection contractor. We are waiting for updated guidance on waste disposal from Defra and we will circulate that when it is published.



WasteManagement
.docx



Business Checklist and FAQ



BusinessInHouseTe
stingChecklist.docx



FAQonRapidComm
unityAsymptomaticT

Example Risk Assessment



Example_Risk_Asses
sment.docx

PPE and Additional Items



PuttingOnPPE.docx



RemovingPPE.docx



PPEAdditionalInfor
mation.docx

Testing



TakingaSwabSampl
e.docx



SelfSwabbing.docx

Printable Poster Pack



ATS_Asymptomatic_
Testing_Site_Signag

It is vital that your business supports staff to follow all covid protocols whilst testing and if a positive test result is given to follow the self-isolation guidance.

The Department of Health Clinical Standard Operating Procedure (SOP) for mass testing with lateral flow devices document may also contain some useful information:



Workplace_Asymptomatic_Test_Site_SOP_2.5 (1).pdf



If you have any problems opening any of these documents then please let us know and we can forward them to you under separate cover.

Useful Sites:

Self-Isolation guidance:

[When to self-isolate and what to do - Coronavirus \(COVID-19\) - NHS \(www.nhs.uk\)](https://www.nhs.uk/when-to-self-isolate-and-what-to-do)

Registration page to order tests for businesses with over 50 staff who can't work from home:

<https://www.gov.uk/get-workplace-coronavirus-tests>