Department of Health & Social Care

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

Test and Trace

Clinical Standard Operating Procedure (SOP) for Pharmacy Testing with Lateral Flow Antigen Testing Devices

Base on DHSC Version 4.6

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SOP Framework authorised by: Dr Tom Fowler and Dr Peter Marks, Test and Trace Programme Health Protection and Public Health Leads

This Community Testing SOP is based on a variation of the Clinical Framework Standard Operating Procedures (SOP) for LFD asymptomatic testing. The Community Testing Programme is accountable for obtaining approval for all clinical changes

NHS Test and Trace is making rapid lateral flow antigen testing available alongside standard lab-based PCR tests. These tests play a different, but crucial role in the fight against COVID-19.

Lateral flow device (LFD) testing is a fast and simple way to test people who do not have symptoms of COVID-19, but who may still be spreading the virus. The tests are easy to use and give results in 30 minutes. Those who test positive must immediately self-isolate to avoid passing the virus on to others.

Around 1 in 3 people with COVID-19 do not have symptoms, so a test that rapidly detects these otherwise hidden cases is a very useful additional tool for tackling the virus.

Lateral flow tests are practical, easy to interpret and can be used in a wide range of settings. This makes them ideal for widespread repeat use in the community.

By taking part in deployment of LFDs your organisation is playing an important role in the response against the virus. Each positive case identified can help prevent many additional people becoming infected over time.

What is the clinical standard operating procedure?

The clinical SOP document is part of the DHSC's testing framework describing how testing services can be delivered safely, efficiently, with quality output and uniformity of performance.

Why is it important for you to read the document?

As a testing provider, you will be responsible for delivering key elements of the testing service, so the framework is intended to help you carry out those activities. Unlike many operational decisions, the clinical procedures are not negotiable. Without a thorough understanding of the framework, it is not possible for organisations to deliver and operate these services safely.

Common terms used in the LFD framework as defined by gov.uk

The MHRA has provided definitions for terms relevant to testing during the COVID-19 pandemic (available at this link). The terminology used in this LFD framework is aligned to the interpretation of the terminology provided by the MHRA:

Professional Use Test

MHRA's definition of a professional use test is: *"A test which is intended to be used by a professional user*. The test must be UKCA marked or CE marked as a "general IVD" in accordance with UK MDR 2002 (as amended). The manufacturer of the test must demonstrate that they hold evidence to support the intended use as stated in their Instructions for Use (IFU) e.g. If the manufacturer of a professional use COVID-19 test intends the test to be used in an assisted or supervised testing situation, then the IFU should make this clear and there should also be evidence of performance data to support their use in these situations."*

In this LFD clinical framework, products used in the ATS delivery model are for professional use only.

*Please see the definition of Professional Use and Professional User for further information.

Supervised testing for COVID-19

MHRA's definition of supervised testing is: *"A lay person is supervised by a professional user whilst the lay person performs the sample collection and operation of the COVID-19 professional use rapid lateral flow test.*

The manufacturer of the professional use rapid lateral flow test being used under supervision must have supporting evidence demonstrating the test may be used in this way documented in the IFU.

The supervisor is a professional user (see below). The supervisor must be in the same location as the person taking the test. If required, the supervisor may conduct all or some of the steps to obtain a result.

The supervision may not be via video link or other telehealth approach unless the test being used is regulated as a self-test."

In this LFD clinical framework, the Supported Self-Test at an ATS section is relevant for the definition provided for Supervised Testing for COVID-19. In a supported self-test, subjects will use a self-test with the supervision provided by trained personnel to give advice on how to complete the self-test if required.

Professional Use and Professional User

MHRA's definition of professional use and professional user is as follows: "*Use by personnel who have received specialised education and training with regard to procedures utilising in-vitro diagnostic medical devices (Source ISO 18113-1 section 3.56).*

Examples:

- *Qualified healthcare professionals or laboratory personnel who in addition to their medical or laboratory qualifications have also received training and assessed for competency on the use of a specific in vitro diagnostic assay/test*
- *An individual who has received comprehensive training and assessed for competency on the use of a specific point of care in vitro diagnostic assay/test such as the rapid lateral flow tests used by NHS Test and Trace at Assisted Testing Sites to detect cases of COVID-19 in asymptomatic individuals"*

In this LFD clinical framework, the workforce referenced has undergone training and regular competency assessments in alignment with MHRA guidance (see below)

Training and competency assessment

MHRA's guidance for training and competency assessment is as follows: *"For information on what an appropriate training programme and competency assessment for professional users of COVID-19 tests should include, manufacturers and testing service providers should refer to the BSI Standards Publication PD ISO/TS 22583:2019 "Guidance for supervisors and operators of point of care testing (POCT) devices". The MHRA recommends that there shall be an appointed person(s) (supervisor) who has the authority and takes responsibility for the quality of the service and is competent to supervise the testing and training of other professional users.*

After completing the training programme professional users should:

- *have demonstrated ability to apply knowledge and skills to produce an accurate POCT result*
- *have an understanding of the testing requirements and be able to assess the appropriateness and suitability of the person to be tested*
- *be able to perform tests following the manufacturers' instructions for use, including quality control checks, operating environment and reagent storage*
- *have an understanding of interference factors. For example, a substance or process which falsely alters a test result*
- *be able to demonstrate safe and accurate results reporting and interpretation*
- *have an understanding of quality assurance activities and be able to detect erroneous results and take appropriate action*

The training should include a competency assessment to check for understanding and correct performance of the test."

The training programme referenced in this LFD clinical framework meets the criteria set out by MHRA. All staff are required to undergo the required training for their role and also complete updates to training when updates are released. This framework also references the requirement for sites and Use Cases to appoint a Quality Lead. The Quality Leads will be responsible for ensuring compliance to training requirements and will also ensure that staff demonstrate their ability to perform their role. The Quality Lead will also ensure that competency assessments are performed for staff members and, if required due to staff not adhering to the SOP, ensure that training is retaken.

Contents

Document Control and Approval

Version Control

The table below contains a summary of changes contained per version.

This document is based on version 4.4 of the LFD Clinical Framework – adapted for Community Testing.

MASTER LFD Clinical SOP Template (ATS C

Version	Author	Summary of Changes	Reviewed By	Date
V.01	**Emma Paisley**	Tailor to Hertfordshire County Council Pharmacy Testing		

Testing service end-to-end process and accountable organisation

Area	Processes	Accountable Organisation	Authorised Signature	Date
Governance	Clinical accountability	Pharmacy		
Evaluation	Evaluation framework creation	Public health		
	Evaluation data collection	Public health		
	Evaluation data analysis and write up	Public heatlh		
Workforce	Training	Pharmacy		
	Set-up	Pharmacy		
	Delivery (swabbing)	Pharmacy		
	Delivery (LFD Processing)	Pharmacy		
Operations and Logistics	Supplies: consumables	Public health		
	Supplies: test kits	Public health		
	Site set-up (general testing and analysis)	Pharmacy		
	Waste management	Pharmacy		
Testing process	Identification and recruitment of people to test	Pharmacy		
	Registration of participants	Pharmacy		
	Sample collection	Pharmacy		
	Sample processing	Pharmacy		
	Results analysis	Pharmacy		
Incidents and Queries	Results notification	Pharmacy		
	Response to queries from people tested	Pharmacy		
	Risk and incidence management	Pharmacy		
	Media queries	Communications		
Quality assurance	Quality assurance: operational delivery	Public health		
	Quality assurance: data analysis and reporting	Public health		

CORE SECTIONS

2 Clinical Governance

2.1 What is clinical governance and why is it important?

Clinical governance is the system through which healthcare services are accountable for monitoring and continuously improving the quality of their services and safeguarding high standards of care. Clinical governance encompasses quality assurance, quality improvement and risk and incident management. Within the Test and Trace programme it is essential that DHSC receives assurance from service providers that services are being delivered safely to the required standard.

The Public Health and Clinical Advice Oversight team (PHCO) within Test and Trace has responsibility for clinical oversight of the programme; including ownership of the testing framework (Clinical SOP) and monitoring implementation across service areas within the quality assurance framework which would enable an overview of the testing service in meeting programme aims and objectives and identify any systemic issues or risks to delivery across the whole programme and also identify emerging themes and areas for improvement.

2.2 Accountabilities and quality lead role

Each testing site will be required to designate a member of the team to oversee the quality and clinical governance processes on site. This can be the Team Leader or a specific role. They will have the accountability for quality and risk management of the service within the context of a non-laboratory environment.

It is not essential for this person to have clinical background but they should have appropriate training for the role and have sufficient experience in service quality improvement. In smaller settings, it may be optimal for the site team leader to take on the role of quality lead.

2.3 Clinical governance processes needed prior to starting testing

Each testing site is responsible for ensuring:

- Premises meet all relevant legislative, certification and validation inspections and requirements including health & safety.
    - Premises must be accessible, clean, secure, suitable for purpose, properly used, social distancing measures in place, properly maintained and appropriately located for the purposes for which they are being used
    - Risk assessments are undertaken if the premises used mean that hygiene standards are more difficult to maintain (e.g. carpeted flooring)
- 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:
    - 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,
    - Be enabled where appropriate to obtain further qualifications appropriate to the work they perform
    - Where such persons are health care professionals or other professionals, they will be registered with a health care or social care regulator

- Clear escalation and decision mechanisms in 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.
- 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.
- Creating clear clinical governance processes prior to the start of the testing, which should include the following:

1. Training:
    - Knowledge assessment at the end of on-line training- this is done as part of online training
    - A dry run as a team during mobilisation or on first day
2. Observing testing process:
    - Clinical quality audits by site supervisor. A sample quality checklist template is provided below

Sample Quality Checklist.docx

    - Staff competence checks. Competency checklists templates for key roles are provided below:

Competency Assessments.docx

3. Monitoring
    - Void rates and invalid tests rates by day and by operator
    - Recording errors
    - Serious incident rates and escalation
4. Risk assessment

2.4 Risk assessment

Community testing roll outs should define their risk management and accountabilities. To prevent or minimize harm, the following simple three-step clinical risk management process is commonly used: Identify the risk, assess the frequency and severity of the risk and mitigate the risk.

A risk assessment template is provided below. All sites should have a risk assessment completed prior to sign off for launch.

Risk Assessment Template.xlsx

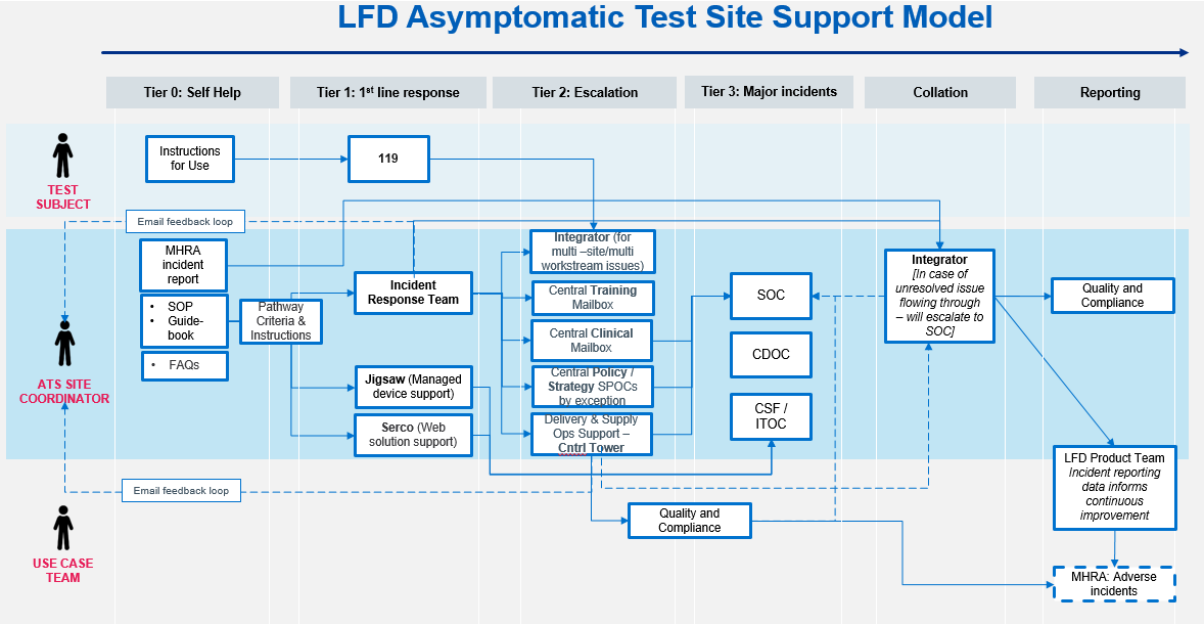
2.5 Incident management and reporting

The service provider should have a robust system in place to capture all incidents from identification, investigation, review and closure. A clinical governance record should be used to document that the checks have been undertaken and that, if any actions are necessary, they are documented and followed up in a timely manner.

Clinical or serious incidents are managed through local service delivery governance processes, and programme channel leads should still be notified to ensure local, programme and national implications are understood and required action is taken.

In order to meet the required quality assurance, PHCO will require two levels of reporting which is of particular value in service evaluation; a rapid response where PHCO would be informed if any immediate action is required with regard to programme delivery risk mitigation and a monthly management report which would enable an overview of the testing service in meeting programme aims and objectives and identify any systemic issues or risks to delivery of the service. The Use Case Quality Lead will be responsible for engaging in this process.

In addition to the internal incident management by the testing sites, all incidents that could potentially impact quality or safety of testing should be reported DHSC through the clinical governance process for mass testing. Relevant incidents will be reported to the MHRA yellow card scheme (https://coronavirus-yellowcard.mhra.gov.uk/) in consultation with the DHSC incident response team.



2.6 Clinical effectiveness

An essential element of the programme is that we deliver clinically accurate testing – there is an increased risk if the testing procedure is not carried out effectively, that an individual who has SARS-CoV-2 may incorrectly receive a negative result and not self-isolate. In addition, to protect staff and guests it is essential that PPE provided is worn appropriately and when required hand sanitising techniques are used.

If the testing service site is asked by the Test and Trace programme to engage with the internal quality assurance process, and/or the quality assurance on-going evaluation, they must follow the instructions given and report as required. Detailed work instructions will be provided to test sites in scope for these processes.

2.6.1 Internal Quality Assurance

Internal Quality Assurance (IQA) forms part of the wider Quality Assurance process. The IQA process ensures that the processes documented in the quality management system can deliver repeatable results.

As part of their IQA, sites should also monitor results and key performance indicators (KPIs):

- Void rates and invalid tests
- Rates of discordant results where confirmatory testing is in place
- Studies evaluating false negative and false positive results
- Void and positive rates comparison with other sites to detect anomalies or trends
- Quality control checks of the test-kit (conducted at a central laboratory on batches of test kits before dispatch)

2.7 LFD results reporting and confirmatory testing uptake

Use Cases and Service Areas should wherever possible:

• Explain the requirement to register LFD results

• Remind subjects the importance of getting a follow-up PCR test following a positive LFD result

Use Case and Service Areas will be responsible for monitoring performance of confirmatory PCR uptake and taking action where necessary.

2.8 MHRA reporting and lessons learned

Sites will have a 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.

Adverse incident reporting is a Medicines and Healthcare Products Regulatory Agency (MHRA) regulatory requirement, and all sites using LFD's are expected record and report this as part of their day to day running of the testing service. Should any adverse incidents related to the testing process be resolved locally i.e. the packaging is damaged or a component is missing, the quality lead / site coordinator will need to capture these within the agreed process, incidents which require escalation sites should provide as much information as possible about the issue or incident; site ID, details of the test kit (e.g. brand name/model, Lot/batch, barcode number). The test site should have clear and agreed recording and reporting processes for both locally resolved and incidents requiring escalation prior to commencement.

In addition, routine reports to DHSC from each site will include weekly lessons learned report required by MHRA. Refer to the Guidebook for more information on this.

2.9 Care Quality Commission

The law has now changed which makes COVID-19 testing an activity that falls outside the scope of registration with the Care Quality Commission (CQC). It is therefore not a requirement for Use Cases to register with the CQC to provide COVID-19 diagnostic and screening services. Commercial providers of Covid-19 testing services have to comply with the requirements in relation to accreditation with UKAS in the Health Protection (Coronavirus, Testing Requirements and Standards) Regulations 2020. Providers of antibody testing, and organisations which provide testing services on a non-commercial basis can choose to apply for accreditation with UKAS, and are recommended to do so.

3 Testing Rationale

3.1 Public health purposes

Through the identification of positive cases and subsequent self-isolation, Lateral flow devices (LFD) help to drive down the spread of COVID-19. LFD testing is a fast and simple way to test people who do not have symptoms of COVID-19, but who may still be spreading the virus.

Overall objectives

To identify asymptomatic infection to reduce and sustain low levels of COVID transmission, supporting the recovery and reducing inequalities.

- To identify positive asymptomatic cases of COVID-19 and advise to self-isolate.
- To reduce COVID-19 transmission to other people.
- To support those who struggle or are unconfident to test themselves at home to access testing.
- To ensure that supervised testing remains accessible to disproportionately impacted and underrepresented groups (Appendix A).
- To improve awareness of key COVID-19 messages and mitigating health harm in higher risk residents.

3.2 Broader setting rationale and benefits

Pharmacy testing is likely to have the following benefits:

1. **Maximise scale** of local delivery of asymptomatic testing in every part of Hertfordshire
2. **Maximise the impact** of community testing in reducing prevalence and transmission, particularly for disproportionately impacted groups.
3. **Deliver testing efficiently and effectively**, and demonstrate good value for money
4. **Contribute to wider strategic objectives** as set out in the road map and beyond
5. **Allow Hertfordshire to add value by using local community knowledge** to target testing where it is most needed and most effective, particularly by focusing on groups that are hard to reach, providing societal benefit.

3.2.1 Rationale for test type & frequency

The aim of the community testing programme is test twice weekly, as the use of frequent lateral flow testing has been shown through modelling to detect a comparable number of infections to frequent PCR, and can avert more transmission than PCR if they can be used more frequently. Frequent lateral flow testing may also present a viable strategy to detect infections, avert transmission and prevent mortality in defined populations*. Rapid antigen tests can also help reduce further transmission through early detection of highly infectious cases, enabling a rapid start of contact tracing.

*Repeated mass testing with rapid antigen tests.pdf (adss.cymru)

4 Lateral Flow Antigen Test Devices (LFD)

Lateral flow is an established technology, adapted to detect proteins (antigens) that are present when a person has SARS-CoV-2. The best-known example of a lateral flow test is the home pregnancy test kit.

The test kit is a hand-held device with an absorbent pad at one end and a reading window at the other. Inside the device is a strip of test paper that changes colour in the presence of SARS-CoV-2 proteins (antigens). The device detects a viral protein (antigen) produced in greatest quantity at its most infectious stage.

Lateral Flow Antigen testing involves the processing of human nasal swabs, throat swabs, or sputum samples with a Lateral Flow device.

The swab sample is added to a fluid in the test kit. This fluid acts as an extraction buffer and is optimised to release viral antigens from the specimen if they are present. During the test analysis, these antigens migrate along the strip in the lateral flow device, binding to anti-SARS-CoV-2 antibodies located in the strip. The antibodies are linked to coloured particles. The presence of a coloured band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result.

The test cartridge and extraction solution should be stored at ambient temperature (2-30 degrees Centigrade). The reagents and devices must be at room temperature (15-30 degrees centigrade) when used for testing.

There are several Lateral Flow Device products which have undergone, or are in the process of undergoing, independent validation for NHS Test & Trace. These Lateral Flow Devices are CE certified or have exceptional use authorisation.

Lateral flow tests deliver a rapid result. If the result of LFD is positive, the person will be asked to self-isolate for 10 days in line with normal NHS T&T procedures.

It should be noted that a negative result does not rule out SARS-CoV-2 infection and there can be false negative results. If negative and clinically indicated, a repeat test should be undertaken using PCR to detect presence of SARS-CoV-2 RNA.

5 Supply & Equipment

Unless otherwise agreed:

Hertfordshire County Council will provide and distribute to the pharmacies:

- Sample collection kits (all types)
- Lateral flow devices (different devices will be supplied depending on the delivery model)
- PPE (including gloves, aprons, masks, goggles/visors) based on Authority quantities of LFD devices ordered through the LFD order form
  Signage

5.1 Workforce Training

Pharmacy staff will need to complete the below training:

- Infection prevention and control
- How to give guidance on self-swabbing LFD test
- How to process LFD test
- How to log results
- Clinical Governance

The face to face training and competence/training checks is provided by staff identified by the local authorities.

Hertfordshire County Council may undertake an informed observation exercise:

- clinical governance audit by site supervisor checking:
  - Subjects understand self-swab procedures and are performing correctly
  - All testing staff have appropriate training
  - Onsite testing supervision: Observing the end-to-end testing process of a sample of tests to ensure that knowledge and skills are appropriate
  - Taking off and putting on PPE and hand washing is within guidelines
  - Supplies and equipment are being stored and handled correctly
  - Waste is segregated and managed correctly
- A clinical governance record should be used to document that the checks have been undertaken and that if any actions are necessary that they are documented and followed up in a timely manner
- Where interventions do not improve with further training/guidance, the staff should be removed from performing clinical tasks

Sites will have a process in place to 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.

Please contact testertraining@dhsc.gov.uk for more information.

5.2 PPE

PPE requirements are sourced by DHSC. Quantities are automatically calculated on the basis of the number of LFDs required and ordered by Hertfordshire County Council.

5.3 Digital & Tech

The tech hardware requirements have been simplified by the use of online test result recording and bar code reading. The tech to be used should be sourced using existing owned laptops and phones with Wi-Fi connectivity.

5.4 Furniture

The furniture used to set up testing stations e.g. desks and chairs should be existing furniture owned by the Pharmacy.

6 Data Management

6.1 Data control

Within the scope of the process outlined in Testing process section, employers and host institutions are not regarded as Data Controllers or Processors.

The Department of Health and Social Care (DHSC) is the data controller for all sites. All other partners will be classified as data processors acting under the instruction of DHSC if they are required to store personally identifiable information on their subjects. As processors of data, the site must have a process in place for ensuring that data protection legislation is complied with. Controls include (not an exhaustive list):

a) A single point of accountability for subject data
b) Processes to ensure subject data is not lost (security)
c) Processes to ensure subject data is destroyed when it is no longer needed by the site (storage limitation)
d) Processes to ensure that subject data is only used for its intended purpose (purpose limitation)
e) Processes to ensure that data collected is limited to that needed for its intended purpose (data minimisation)

6.2 Consent from the data subject

The local authority is responsible for communicating the purpose of the testing to develop an understanding of the service. Participation by the subject is voluntary.

If an employer or host institution is classified as a data processor or controller, they must issue a data privacy notice that informs the subject of how their data will be used. If the subject wishes to participate, having now received this information, the subject will issue their consent. The local authority is responsible for capturing consent.

How subject data is captured and shared with DHSC

The following data elements are captured by the Registration process, a service that is operated by DHSC and NHS Digital:

1. Whether the test is being taken at a test site or at home
2. [If at a test site] The postcode of where the test is being taken
3. [If at a test site] The test site the test will be taken at
4. Test kit URN (barcode of test kit)
5. The date and time that test will be taken
6. Subject date of birth
7. Subject name
8. Subject gender
9. Subject ethnic group

10. Subject ethnic background
11. Whether the subject is displaying any coronavirus symptoms
12. The country the subject lives in (Member of the UK)
13. Subject home postcode
14. Subject address line 1
15. Work OR Study Status – plus Industry, Occupation, Employer OR Study Grade, Institution, Institution Town
16. Whether the subject has an email address and, if so, what that address is
17. Whether the subject has a mobile phone number and, if so, what that number is
18. Whether the subject has a landline phone number and, if so, what that number is
19. Whether the subject knows their NHS number and, if so, what it is

7 Infection Prevention and Control (IPC)

7.1 General guidance

It is essential that all staff follow this SOP to prevent potential transmission of SARS-CoV-2 to themselves and others. Any non-compliance will be escalated through existing incident management protocols. Those on-boarding operatives who may be exposed to these individuals will be provided with IPC advice based on government guidance for managing a subject with possible SARS-CoV-2 infection.

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

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. Social distancing: All workers should always remain 2 metres apart where possible and subjects should remain 2 metres apart from workers and other subjects, 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

6.3 Cleaning policy

Regular cleaning plays a vital role in limiting the transmission of SARS-CoV-2. It is important to reduce the clutter and remove difficult items to clean, the frequency of cleaning should be increased paying particular attention to surfaces that have been touch frequently such as telephones, door handles, chair arms etc. As a minimum frequently touched surfaces should be cleaned twice a day, and one of these should be at the beginning or the end of the working day.

Public areas where a symptomatic subject has passed through and spent minimal time but which are not visibly contaminated with body fluids can be cleaned thoroughly as normal.

Cleaning staff must follow the PPE guidance as listed. They should only enter sampling areas when the activity is no longer being conducted. In case of a spillage when they need to enter an active test area, cleaners should ensure that they have appropriate PPE, and equipment i.e. spillage kit required for safe management of the spillage, and remain 2 metres from the subject and change their PPE after cleaning and perform hand hygiene.

The following cleaning guidelines must be followed:

1. All surfaces that the subject has come into contact with must be cleaned and disinfected, including all potentially contaminated and frequently touched areas such as handles, light switches, telephones, and the surfaces that the subject may have had contact in between each individual that is tested

2. Use disposable cloths or paper roll and disposable mop heads, to clean all hard surfaces, floors, chairs, door handles and sanitary fittings – think one site, one wipe, in one direction
3. Any cloth and mop heads used for cleaning must be disposed of as healthcare waste (offensive waste/tiger bag)
4. Surfaces will require to be cleaned at the end of the session before the next session starts
5. Surfaces will require to be cleaned at the end of the session before the next session starts i.e. in between test group batches of subjects
6. Before the inspection, maintenance or repair of equipment, the returning of or placing of equipment in storage and the disposal of equipment, it must be decontaminated with the appropriate cleaning product by a competent person, and the decontamination certificate completed. An example Certificate of Decontamination of Equipment can be found here.

Use one of the options below:

- A combined detergent and disinfectant at a dilution of 1000 parts per million (ppm) available chlorine (ppm av.cl). Referred to as a stage one process, as the area is cleaned and disinfected at the same time. The area must be left to air dry, to enable the disinfectant to have the required contact time.

- A household detergent followed by disinfection (1000 ppm av.cl). Follow manufacturer's instructions for dilution, application and contract times for all detergents and disinfectants. This is referred to as a two-stage process, the area needs to be cleaned with a detergent, rinsed and dry, then the disinfectant can be applied and left to air dry, to achieve the correct contact time required.

- If an alternative disinfectant is used ensure that it is effective against enveloped viruses, be this a combined product or a stand-alone disinfectant.

Avoid mixing cleaning products together as this can create toxic fumes. Avoid creating splashes and spray when cleaning.

Disinfectant wipes **must** be effective against enveloped viruses. It is recommended were possible that combined detergent and disinfectant wipes is used, as they will both clean and sanitise the surface at the same time.

If a disinfectant wipe is used, it is important to **note that they do not contain a detergent**. If this method is used, it is important that the area is cleaned properly with a detergent, rinse before a disinfectant wipe is used.

For all wipes it is important that the manufacturers' instructions are followed in relation to the contact time required. It is advisable where possible to purchase packets that have a reliable closure mechanism to ensure the wipes do not dry out between uses, as this will affect their ability to be effective against the virus.

6.4 Hand hygiene guidance

It is critical for Test Sites to ensure that staff, subjects and visitors are maintaining regularly hand hygiene. Testing booths or sample areas should be equipped with alcohol-based hand rub dispensers for use throughout the testing process.

To aid hand hygiene staff must:

- Follow the principles of bare below the elbow, while in the testing zone. Ensuring wrists and forearms are exposed, removing any items that may hinder the process for hand hygiene including wrist watches, rings with stones in (a single, plain metal finger ring is permitted but should be removed (or moved up) during hand hygiene, bracelets, friendship bands, long sleeved clothing.
- If the exposure of arms is not acceptable due to religious reasons, disposable thumb looped long sleeve aprons, or thumb looped long sleeve fluid repellent gowns can be used to cover the forearms, when supporting a subject with an assisted test or processing a test. Note this is limited to members of staff who cannot expose their arms and require their arms to be covered while assisting a subject with an assisted test or are processing tests.
- Sleeves must not be loose or dangling. Sleeves must be able to be rolled or pulled back and kept securely in place during hand washing and direct patient/subject activity.
- Ensure fingernails are clean and short, and do not wear artificial nails or nail products
- Any cuts and abrasion on the hands or arms must be covered with a waterproof dressing
- Any skin condition such as boils, abscesses, eczema or psoriasis must be reported to the organisational Occupation Health

How to perform hand hygiene?

Wash hands with non-antimicrobial liquid soap and water if hands are visibly soiled or dirty, interaction with a subject who has vomited. In all other circumstances use an alcohol-based hand rub. Where running water is unavailable or hand hygiene facilities are lacking, staff may use hand wipes followed by alcohol-based hand rub, and must wash their hands at the first opportunity (NHSE/I 2019)

Preparation: wet hands under warm running water prior to applying one dose of liquid soap.

Washing: hands must be vigorously rubbed together following the hand washing technique. Rinse off the liquid soap under running water

Drying: effective hand drying is essential to prevent damage to skin integrity, use good quality disposable absorbent paper towels

Moisturisers: intact skin is a natural barrier to infection; staff should protect and maintain skin integrity through regular use of moisturiser (do not use or provide communal tubs of hand cream due to the high risk of contamination and cross transmission).

Alcohol based hand rub: It is critical for Test Sites to ensure that guests and staff are maintaining regular hand sanitisation as prescribed in this document and the testing procedures. Testing booths or sample collection areas should be equipped with hand sanitiser dispensers for use throughout the testing process. In accordance with guidance from the WHO 2020 – effective alcohol-based hand rub products should contain between 60% - 80% of alcohol and its efficacy should be proven according to EN1500.

Won't frequent use of alcohol-based hand rubs dry out my skin?
No, there are several studies that have proven healthcare staff who routinely perform hand hygiene between patients using an alcohol-based hand rub had less skin irritation and dryness than healthcare staff who washed their hands with soap and water. Many alcohol-based hand rubs contain moisturisers (emollients) that help prevent dryness of the hands

How many times can I use alcohol-based hand rubs before I need to wash my hands with soap and water?
Some people have advocated that you should wash your hands after every four or five uses of an alcohol-based hand rub. But, there is no reason to do this. If your hands feel 'grubby' or are visibly dirty, then yes you need to wash them with soap and water.

When should I wash with soap and water?
Wash with soap and water when your hands are visibly soiled and when you feel like there is something on your hands. You can use an alcohol-based hand rub at all other times.

Best practices techniques for hand rub and hand wash can be found in Appendix C.

6.5 Body fluid spillage guidance

Spillage of blood and other body fluids must be decontaminated immediately by staff trained to undertake this safely.

There are several types of spill kits available specifically developed to deal with body fluid spills. If you have access to a body fluid spillage kit, follow the manufacturer's instructions, and ensure you are wearing appropriate PPE and the area has been cordoned off. Staff who deal with a spillage must report to their line manager to ensure that the spillage kit is replaced after it is used.

A local CoSHH risk assessment must be undertaken, and staff must be aware of the implications of these assessments for storage and use of the product and first aid in the event of exposure.

If you do not have one of these, use the flowing process:

- Cordoned off the affected areas
- Don appropriate PPE, where there is risk of splash, wear eye protection
- Using disposable paper towels remove all traces of visible spillage, dispose of as healthcare waste
- Once the residual waste has been removed the area must be cleaned thoroughly using a general purpose detergent solution in warm water, using disposable cloths, rinse and dry
- Using appropriate disinfection i.e. available chlorine at 1.000ppm, disinfect the area using disposable cloths, and allow to air dry
- Clean the bucket in fresh water and general purpose detergent, rinse and dry
- Dispose of all disposable towels, gloves and disposable apron carefully as healthcare waste (offensive)
- Dispose of cleaning equipment i.e. cloths, mop heads carefully as healthcare waste (offensive)
- Decontaminate hands thoroughly

6.6 Site staff testing

As part of the local testing service and in accordance with national policy, test sites can offer LFD testing to their staff twice per week. Tested staff should be treated the same way as regular participants and follow the protocols outlined in this document (i.e. reporting results, etc). If staff testing is provided and the frequency differs from national policy, the rationale should be reviewed and agreed with PHCO prior to offering the service.

6.6.1 Site staff outbreak management

As part of providing regular staff testing it is important for the site to monitor positive case rates and work with local health protection teams to manage outbreaks. According to national guidance an outbreak is defined as two or more test-confirmed cases of COVID-19 among individuals associated with a specific non-residential setting with illness onset dates within a 14-day period. For residential settings (e.g. care homes), this also includes clinically suspected cases. If this is the case, an outbreak needs to be reported to the local authority and appropriate local guidance should be followed for outbreak management.

DELIVERY MODEL SPECIFIC SECTIONS

ATS Testing

This section includes clinical guidance for:

Delivery model	ATS
Population tested	Asymptomatic
Test	Innova SARS-CoV-2 Antigen Test
Sample type	Throat and nasal swab
Sample collection method	Self-swab (i.e. subject takes the swab sample)
Sample processing method	Assisted (i.e. processing operative processes the swab sample)

. Testing frequency	
Frequency of Testing ***(per individual within population)***	_**2**__ tests per week

Product specifics and Instructions for Use

8.1 Innova: Innova SARS-CoV-2 Antigen Test

The manufacturer's instructions for use (IFU) can be found here or embedded below

SARS-CoV-2 IFU.pdf

Some community testing services' operational implementation may be outside the manufacturer's IFU. Specific elements described in this document that are considered outside of the manufacturer's IFU are: a) use on asymptomatic patients, b) patient self-swab under supervision and c) administered by individuals trained specifically in processing the test, not an individual trained more generically in point of care testing. Risk assessments have been conducted at the request of MHRA for these areas. MHRA has provided advice to mitigate risks as far as possible and the DHSC have agreed to supply key information to MHRA to allow them to monitor risks closely. These have also been validated by Public Health England Porton Down and Oxford advisory group.

9 Workforce

The key roles outlined in the blueprint in order to operate a Pharmacy Testing site are as follows:

Site Roles	Staff Positions	Key Responsibilities

Team Leader	**Pharmacy Manager**	Responsible for managing the training, performance and wider activities of the Pharmacy Testing Site to ensure that community testing operations are safe, efficient and effective and reflect positively on Hertfordshire County Council 1. Ensure Pharmoutcomes is completed with the required data 2. Provision of appropriate protective equipment for all team members 3. Lead on the maintenance of clinical governance, engaging Public Health staffs as necessary 4. Investigate and take action to mitigate any increase in the number of void tests 5. Management of all clinical waste with appropriate records maintained 6. Troubleshooting issues that arise and attend any incidents to assist the Pharmacy staff 7. Motivate teams to promote a smooth end to end process with positive / supportive interaction with visiting members of the community 8. Check all sites are set up within a safe environment with a Health and Safety check before opened to the public 9. Report all incidents of aggressive, verbal/physical behaviour towards staff 10. Investigate any complaints from the public with regards to the testing process and/or conduct of any staff members 11. Ensure the adherence of social distancing and strict application of PPE rules 12. Provide regular management information and reports as requested
Testing Operative	**Pharmacy staff**	1. Highlighting any shortages of supplies and equipment such as test kits, PPE etc 2. Supporting the smooth running of the test site following standard operating procedures 3. Setting up the testing workspace 4. Meet and Greet members of the public (considering safety as per training) and help to manage the flow of people on site whilst ensuring social distancing measures are adhered to 5. Greets subject at arrival, asks them to sanitise hands and ensures the subject is eligible for asymptomatic testing 6. Provide the subject with key messages for testing including definition of the test, that no test is perfect and a negative result does not guarantee that they don't have coronavirus 7. Provide support registering for the test on mobile phones / devices 8. Provides assistance for people who might not have the relevant digital information such as phone number and email address 9. Communicate to test subjects the purpose of participating in testing at your site and the testing journey. 10. Advise those presenting for a test how to self-administer the test in a manner suitable for different groups of people including those who may have specific /additional needs such as the elderly 11. Administration tasks such as completing paperwork/records/test results 12. Maintaining infection, prevention and control as noted in the clinical governance programme by ensuring the testing site is cleaned meticulously, to a very high standard, in line with the Standard Operating Procedure and clinical guidelines **Prepares test sample for analysis and interprets result.** 1. Sets up sample for analysis, and pipettes reagent to sample 2. Times the sample analysis 3. Await and read result displayed, and mark it on device 4.Enters result into the results logging web app 5. Complete details in Pharmaoutcomes

10 Points to note for use of Community Pharmacy for ATS

The following information lays out the minimum viable service (MVS) requirements for self-swab, assisted processing of LFDs in community pharmacies. The test can be carried out in the pharmacy's consultation room providing it meets the criteria outlined below. Larger pharmacies may choose to set up testing in a dedicated area away from the consultation room, in which case the standard open plan or privacy booth models may be more appropriate (See the Guidebook for further information on these layouts)

The information given below should be used in conjunction with the general ATS set up information below. Each site will need to conduct a local risk assessment for full set up;

Consultation room minimum set up requirements:

1. **Minimum consultation room size; length: 3m and width: 1.2m.**

1. Suitable lighting, power, temperature control, airflow/ventilation
2. Table (minimum 1mx1m)
    1. Table should not block the sink, which most consultations rooms will already have
3. Chair (optional - most consultation rooms will have two)
4. Cleanable, intact surfaces and flooring
5. Internet connection
6. Accessible e.g. for wheelchair
7. Storage space
8. Clutter-free
9. Protective clear screen across the table (strongly recommended)
    1. Screen should have a hatch to allow subject to pass their sample (upright) to the Processing Operative

    Additional considerations:
    2. The welcome desk should be separate to the pharmacy counter (or a separate part of the counter) i.e. separate queue for testing vs BAU pharmacy services. If using a separate part of the same counter, additional considerations and protective measures may be required e.g. plastic partition to keep queues separate, queue management to allow for appropriate social distancing.
    3. If subjects are waiting for their results on-site, subjects should be instructed to wait in a dedicated waiting area. The waiting area must have measures in place to allow for social distancing and must be in a designated area separate to the waiting area for customers of BAU pharmacy services.

1.1.1 General Testing Site Set-up

The following information lays out the minimum viable service (MVS) requirements for self-swab, assisted processing of Lateral Flow Devices (LFDs) in community pharmacies. The test will likely be carried out in the pharmacy's consultation room, given it meets the following criteria. Larger pharmacies may choose to set up testing in a dedicated area away from the consultation room, in which case the standard open plan or privacy booth models may be more appropriate.

Adobe Acrobat Document

Please refer to the LFD ATS Setting up your site for layout considerations.

The specific configuration of a site will depend on infrastructure and environmental constraints.

We recognise that a pharmacy may run business-as-usual (BAU) activities near or at close proximity to the test site. While each site setup will be unique to each pharmacy, it is expected that pharmacies will understand the following site considerations:

1. The test Site should be try to be separate from the main area of business operations for privacy, safe queue management, and to limit disruption to both testing and BAU activity
2. If possible, Test Site location should be close to the main area of business operations to make it easier for subjects to locate and access the service
3. Where space is limited, test queues will be managed safely to avoid disruption – for example, a waiting room may be separate and adjacent to a testing room and must allow for appropriate social distancing
4. Fire, health and safety, and evacuation routes should be clearly marked in line with the rest of the building

5. No one associated with BAU activity should be permitted access to the test site unless they are involved in the day-to-day running of test site operations
6. On non-testing days, ATS can be used for BAU activities given appropriate cleaning has taken place to make the site/location clean and ready for the ATS sites to be used for those activities (in line with the cleaning guidance in the SOP).
7. Clinical test site and non-healthcare Business-As-Usual waste should be segregated in accordance with the waste management section. Waste should be securely managed and stored prior to collection.
8. The LFD devices and reagents need to be stored between 15 and 30°C during use. Appropriate temperature monitoring and control will be necessary to ensure this

Courier and waste collection service should be easy to access from your Test Site location.

For a serious medical emergency, sites will follow the protocols for making the area safe, it is the local authority's responsibility to ensure any individual who requires medical support receives it. If a subject or staff member is in distress, personnel will alert the nominated First Aider on site.

For a fire evacuation, after the alert is raised, everyone on site will need to leave by the nearest emergency exit to the organisation's existing local assembly point. The management will be responsible for coordinating the response and ensuring that all site personnel have been accounted for. They will also be responsible for coordinating the Blue Light Responders. In the event of an emergency, all samples that have been placed into the extraction buffer or have not been marked by pen with a result will be abandoned, and later recorded as invalid. subjects who receive an invalid result will need to be retested.

Any member of test site staff who feels unwell for any reason, including displaying potential COVID-19 symptoms should alert their relevant team leader and site lead or colleagues and, arrange to travel home and follow the latest government guidance on treatment (this may involve contacting the prescribed emergency number where necessary). After the individual has departed, site management should immediately assess based on that individual's role on the site, with whom they have been working, whether there are other individuals from the overall site team that they have been in close contact with, in which areas of the site, what equipment they have been using and follow the relevant policy. This may involve areas being immediately locked down and cleaned.

10.1.1 Ventilation requirements for sites

In poorly ventilated areas the amount of virus in the air can build up, increasing the risk of spreading the virus, the more fresh air is brought into the site, the quicker any airborne virus will be removed from the room. Each site should do a risk assessment to identify any poorly ventilated areas, reviewing areas where staff work with no mechanical or natural ventilation i.e. opening windows, doors or vents. For more information, please refer to: ***Ventilation of indoor spaces to stop the spread of coronavirus (COVID-19) - GOV.UK (www.gov.uk)***11 Testing Process

All subjects will be required to wear appropriate face covering or face mask at arrival and must endeavour to maintain social distancing of at least 2 metres from each other and the staff apart from when being tested.

Upon arrival on-site, subjects may have their eligibility and identity checked by greeting personnel.

To ensure accessibility support, the onsite staff can be requested for help with registration if the subject faces any difficulty in self-registration. This will be done while maintaining social distancing.

Rate of Testing

There is no formal limit on number of individuals tested through an ATS regardless of number of booths. However, individuals must be allowed to conduct the swabbing process at their own pace and must not be hurried.

11.1 Eligibility

- The subject will be over 16
- The subject will be asymptomatic
- The subject will consent to participation in community testing
- The subject will consent to sharing their data with the National T&T programme

A subject is considered to be symptomatic if they are experiencing any of the symptoms listed in the latest government guidance . If they are not experiencing any of these symptoms they are eligible for testing at an ATS. If they are experiencing any of these symptoms, they should go to the gov.uk site and register for a test offered for symptomatic patients.

While different models may be implemented, for generic ATS settings it is expected that the approach below will be the followed for children under 18.

- Young people aged 16-17 can self-swab at a testing site
- If the subject refuses to take the test, their wishes should be respected
- If a young person under 16 years old shows up at an ATS without a parent or a guardian and wishes to get a test, the site should refuse the service

11.2.1 Need for consent

Local authorities need to be aware of requirements for informed consent for conducting the test and have a process for people who do not have capacity to give informed consent. Local authorities must make sure that they seek the appropriate consent from a consultee, in line with the Mental Capacity Act 2005. A consultee may be a parent or guardian, or a carer, and the individual must be fully informed to make the decision.

People with additional needs (this could arise from a physical or cognitive disability) might not be able to self-swab. If the person has the capacity to consent, they should be asked if they will allow someone to help them do the test, or to allow someone to do the test for them. If the person does not have the capacity to consent, a consultee (e.g. a parent, guardian or a carer) can consent on their behalf. Carers or other accompanying individuals should only be asked to assist or test the person if this falls into their normal responsibilities and they feel comfortable and confident on doing so.

11.2.2 Information about testing

At registration, the registration assistant should provide key messages to the testing subject and ensure they understand them, including:

- The test involves taking a swab of the inside of your nose and the tonsils area. There will be instructions to show you what to do.
- No test is perfect. Sometimes they can give an incorrect result.
- A negative result means that it's likely you were not infectious when the test was done. There is still a chance you may be infectious, so you need to keep following guidelines to reduce the risk of spreading the virus to others – including social distancing, avoiding mixing, regular handwashing, and wearing a face covering where recommended.
- A positive result means it's likely you had the Coronavirus when the test was done. You and anyone in your home must self-isolate immediately and you may be asked to get a follow-up test to help us make sure you are infectious. Though this is less likely, false positive results may occur

  To assist the dissemination of this information a poster has been developed (see Appendix G). It is a requirement for sites to post this information near the registration point to help communicate key information about testing to subjects.

11.3 Face coverings

Children under the age of 3 years will not be required to wear a face covering while attending an ATS.

Individuals are required to arrive at the test site wearing a face covering, unless they are exempt or have a reasonable excuse in accordance with the latest government guidelines. If an individual arrives at an ATS without a face covering and indicates they are exempt in accordance to latest government guidance, they should be permitted to enter the test site and perform the test.

Each test site should consider implementing traffic flow or sample collection areas for those who are exempted from wearing a face covering in order to mitigate the risk to other subjects coming in close proximity of those individuals i.e. highlight an area that can be used safely, that maintain 2 metres social distancing from others.

Sites may consider supplying a face covering to a subject who arrives without one, to enable them to enter the site, complete the test and return home safely (decreasing the risk of onward transmission).

11.4 Testing people with additional needs

People with additional needs (this could be physical or mental disability) might not be able to self-swab. If the person has the capacity to consent, they should be asked if they will allow someone to help them do the test, or to allow someone to do the test for them. If the person does not have the capacity to consent, a parent or guardian can consent on their behalf. Carers or other accompanying individuals should only be asked to assist or test the person if this falls into their normal responsibilities and they feel comfortable and confident on doing so.

Each case should be assessed on a case-by-case basis and if required, the carer or family member can consult their physician in case specific care is required to swab the person.

Appropriate hand sanitisation is needed before and after the swabbing process for both, the test subject and the accompanying person.

Each test site should consider implementing traffic flow or sample collection areas for those who require assisted swabbing by a carer or family member to mitigate the risk to other subjects coming in close proximity of those individuals i.e. highlight an area that can be used safely, that maintain 2 metres social distancing from others.

If assisted swabbing is performed by a family member and they are considered part of the person's support bubble, no extra PPE is required apart from a face covering. Appropriate hand sanitisation is needed before and after the swabbing process. If a pair of gloves is requested, they should be issued with gloves to perform the swabbing.

If assisted swabbing is performed by a carer who is paid to provide care, they need to follow their organisational policy. They may have their own PPE or may need to be issued with gloves to perform the swabbing.

The IFU must be followed at all times.

This section covers swabbing performed by an accompanying person and does not include assisted swabbing as an ATS service.

11.5 Sample collection and analysis overview

Here is a high-level summary of the process as follows:

1. Staff must be wearing appropriate PPE
2. Subjects will be invited to register for a test and consent to participate in testing at the site.
3. Carrying out the swabbing process

a) Subjects are welcomed and issued test-kits (and peripherals* and relevant instructions
b) Subjects will give their barcode to the Processing Operative
c) Subjects complete a self-administered swab test
d) Subject will be required to place their swab directly into the prepared extraction tube on the processing area.
e) Subjects respect all hygiene and social distancing rules
f) Subjects exit the facility OR, if subjects are waiting for their results on-site, subjects are instructed to wait in waiting area (waiting area must have measures in place to ensure social distancing).
g) If the test procedure was incorrectly administered, it would be repeated with consent.

4. Samples will be analysed
   a) Analysis conducted on-site by the Testing Operative
   b) Multiple LFD may be moved with a tray grouped by time cohort from the area where sample applied, to an area where test result read. Movement must be kept to a minimum and the tray must be kept horizontal.
5. Sample matching and results notification
   a) Results will be captured by the Testing Operative
   b) Results of LFD will be shared with the national Test and Trace programme
   c) Results matching will be completed and notifications issued to the subject directly – results will only be issued to the subject, not to the employer or host institution
   d) If subjects are waiting for their results on-site, results are given verbally to subject in a confidential manner, maintaining social distancing and PPE measures throughout
6. Follow up of results
   a) The pharmacy and subject will follow Public Health guidelines and procedure on follow up

11.6 Self-swabbing sample collection procedure - Innova

Subjects will be given a sealed sterile swab at the welcoming desk and will be directed to a sample collection booth from the check-in zone. A crowd control system should be in place to ensure the subject is only sent into a booth when the Processing Operative is ready to process the swab.

Before commencing swabbing, 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 for any expectoration or vomit and guidance will be given regarding what to do with this if used.

1. Once at the sample collection station, the barcode should be handed immediately to the Processing Operative. The subject will then be required to remove face covering and complete hand hygiene
2. The subject should blow their nose into a tissue and dispose of it in the waste bin provided
3. The subject should complete hand hygiene using the alcohol-based hand rub provided in the booth
4. The subject will be required to open their mouth and visually identify the left and right tonsils (or tonsillar pits for subjects with the previous tonsillectomy). A mirror should be provided in each booth for this. If the subject cannot take a throat swab, they should instead swab both nostrils.

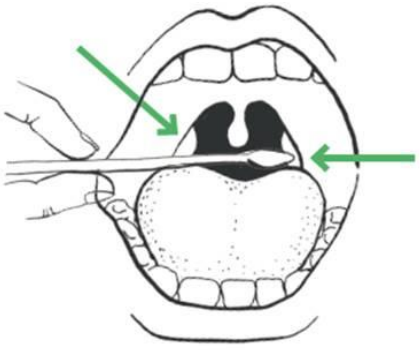


Figure 1 Swab rubbing the tonsil

5. The subject should identify the soft, fabric tip of the swab in 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
    a. The swab must be kept dry before taking a sample from the back of the throat and therefore it must not touch any surfaces including the teeth, gums, tongue, cheek or any other surfaces when conducting the test.

       Please note: The swab will be invalid if it touches these parts during or after sampling and it must be put in healthcare waste container and a fresh swab selected. The swab will also be invalid if the soft, fabric tip is touched by the subject's hands.

6. Holding the swab between fingers, the subject should 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 the throat with good contact at least 4 times on each side (a mirror can be used to ensure the tonsils are being swabbed). If the subject cannot take a throat swab, this step should not be taken and the subject should swab both nostrils (see point 7). Carefully remove the swab stick from the back of the throat taking care to ensure that it does not come into contact with any other structure or surface.
7. The subject should then insert the same swab into one nostril. The swab tip should be inserted until there is a slight resistance up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab firmly around the inside of the nostril, making 10 complete circles along the mucosa to ensure that both mucus and cells are collected.
8. If the subject has a nose piercing, swab the other nostril. If pierced on both sides, remove the piercing on one side before swabbing.
9. Note: If nasal swabbing is not possible because the subject has unhealed wounds or fresh piercings on both nostrils, throat only swabbing can be used. Note this is only to be used in assisted testing if nasal swab is not possible (by exception only) and there is currently no independent data for throat swab only.

10. Note: In children, adults and the very elderly where throat swabbing is more difficult or they have a very sensitive gag reflex that prohibits the throat swab from being completed successfully, double nasal swabbing can be used (by exception only).
11. The subject will be required to place their swab directly into the prepared extraction tube on the bench at the window with the cotton bud end facing down.
    a. The subject will not grasp the cotton bud end, which has been in contact with the tonsils and nostril.
12. The subject will complete hand hygiene using alcohol-based hand rub in the booth. If the operational model includes the subject handling any equipment (e.g. hand mirror) they should disinfect the surfaces with the wipes provided (Refer to Infection Prevention and Control Section)
13. The subject will put back on their face covering and leave the booth.

In the event that a subject vomits, operations at the testing bay shall be ceased and the site personnel should follow the spillage guidelines until the area has been cleaned adequately to allow resumption.

11.7 Sample processing and analysis procedure – Innova

The Processing Operative should prepare the area in advance of receiving the sample and barcode from the subject.

The Processing Operative should only process one sample at a time.

The following steps will be followed in line with manufacturer's IFU and with equipment available:

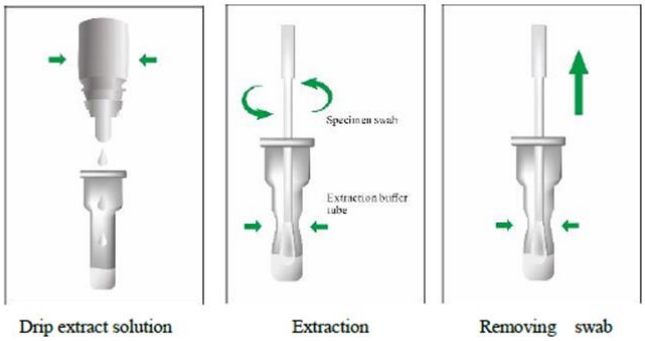
1. The Processing Operative receives barcode directly from the subject (as described in self-swab section above)
2. The Processing Operative then removes the LFD device from the pouch and applies a barcode to the underside of the LFD cartridge.
    a) LFD cartridges should be used without a long delay after opening the pouches in which they are supplied.

3. The Processing Operative sets up the extraction tube by following these steps:
    a) Place the extraction tube in the tube rack with the opening facing up
    b) Open the extraction solution bottle and hold the cap with the free hand. Do not put the cap down on the table while adding extraction solution to the tube as this would increase the risk of contamination.
    c) 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 Processing Operative should check the label and, if breached, they should dispose of the buffer bottle.
        i. Manufacturer's note: guidance should be followed for the 6 drops of extraction solution to be added to the tube. However, results with 4 to 7 drops have been validated and accepted.
    d) The extraction tube will be left in the tube rack on the processing bench next to the window for the subject to place the swab
4. The subject will place the swab sample into the prepared extraction tube (as described in self-swab section above) located on the table at the window (to potentially prevent the swab from drying out)
5. 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 (below)
    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
        i. 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). Refer to the section below on interpreting LFD results for details on the control C line to ensure the test is valid.
    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 as below. Please note the LFD movement should be kept to a minimum and where it is required to be moved, keep horizontal using a tray.
6. Clean the sample preparation area and equipment thoroughly with disinfectant (e.g. appropriate wipe)

Figure 2 Extraction buffer preparation



The Processing Operative is responsible for preparing and loading ('dropping') the sample onto the cartridge after receiving the subject's swab.

The subject can leave the test centre and await results communication after loading. The testing site is entitled to set up a waiting area for subject to wait for the results. The waiting area should follow the physical requirements outlined earlier in this document.

The Processing Operative may move the LFD to a different area to read results, keeping movement to a minimum and always keeping it horizontal with a tray. The LFD can be grouped by time cohort.

11.8 Reading LFD results – Innova

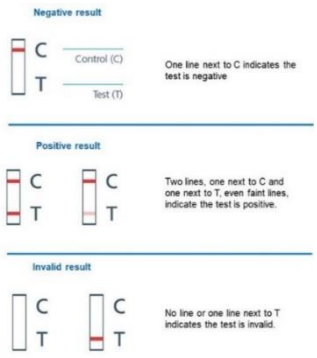
The result is read by staff according to the manufacturer IFU between 20 and 30 minutes.

- 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.

11.9 Interpreting LFD results

1. Results should be interpreted as follows:

Figure 3. Result interpretation



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.
- The operator cannot differentiate whether a T line is discernible or not.

The control C line is designed to indicate that the test strip does not have a mechanical fault. It is not designed to confirm if the sample applied to the test strip is a valid sample. Therefore, it is vital that the instructions for collection and preparation of the subject's sample are followed precisely.

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

- **'+'** mark for positives
- **'V'** mark for invalid
- **'-'** mark for negatives

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

11.10 Recording of results

Results logging web app (for locally provided devices)

1. Sign-up for an account
2. Select the test site location
3. Scan the LFD barcode as per digital results recording process with the web based application and digitally record the applicable result
4. The area where the device was situated and equipment (i.e. pen, tray, etc.) are then cleaned after each batch with an appropriate wipe (Refer to the Infection Prevention and Control Section)
5. Once result has been logged, the LFD are disposed of as per the requirements outlined in the waste management section.

Results logging using iOS app (for DHSC provided managed devices)

1. Login to the results application
2. Select the test site location
3. Scan the LFD barcode as per digital results recording process with the iOS mobile application and digitally record the applicable result
4. After entering the result of the test, take a phone of the LFD device
5. The area where the device was situated and equipment (i.e. pen, tray, etc.) are then cleaned after each batch with an appropriate wipe (Refer to the Infection Prevention and Control Section)
6. Once result has been logged, the LFD are disposed of as per the requirements outlined in the waste management section.

Please refer to the Guidebook for further information on recording on results.

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.

11.11 Communication of results

If subjects need to have another test, and the test is not going to be delivered immediately, a paper copy of the instructions of how to access the test (either accessing on-site or online from www.gov.uk/get-coronavirus-test) should be provided.

The ATS will analyse the sample and upload the test results linked to the barcode to NHS Test and Trace digital system. The Test and Trace systems will link the registration record with the test result.

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. The wording of the result text will reflect the national guidance published by the NHS.

11.12 Reporting

The reporting data flow for antigen testing is as follows:

1) NHS BSA (for subject result notification)
2) Keystone* (to update GP records)
3) NHS Digital
4) Public Health Agencies in line with mandatory notifiable disease reporting regulations:
    a) Public Health England (PHE)
    b) NSS Scotland (on behalf of Public Health Scotland)
    c) BSO Northern Ireland (on behalf of Public Health Agency)
    d) NWIS (on behalf of Public Health Wales)
5) NHS Arden and GEM CSU (on behalf of NHS E/I)
6) DHSC Edge (for NHS Test and Trace/Joint Biosecurity Centre)

*Please note that for lateral flow tests at ATS only positive results will be updated into GP records (not negative or invalid). GP records will only be updated if the correct demographic information has been provided. This has been agreed with Joint GP IT Committee. **Note: Participants who are self-testing will need to report their results**

As per the latest amendments to the Health Protection Regulations relating to notifiable diseases reporting, these results need to be reported into the public health bodies in the UK. NHS Test and Trace will undertake this notification through the above data flows for any testing that uses our digital systems, so additional notification is not required unless there are existing relationships between you and your local Health Protection Team.

11.13 Negative results

Subjects who return a negative test result do not need to self-isolate unless: 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),c) they've been traced as a contact of someone who tested positive.

Individuals who have a negative test result must continue to follow all national guidance including social distancing, regular handwashing and the use of face coverings.

11.14 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), c) they've been traced as a contact or someone who tested positive.

11.15 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.

11.16 Confirmatory testing

Following a decrease on the national COVID-19 prevalence (the proportion of false positives compared to all cases increases as prevalence decreases), the temporary suspension of the requirement for routine confirmatory PCR for positive LFD results has been lifted.

- If your LFD test result is positive, you must self-isolate immediately. You could be fined if you do not do this.
- You may be entitled to a one-off payment through the NHS Test and Trace Support Payment scheme if you are required to self-isolate.
- Contact tracing will commence on confirmation of a positive LFD test
- The subject should go to www.gov.uk/get-coronavirus-test to book a follow-up test on the same day or as soon as possible. They should choose to visit a test site (e.g. RTS/MTU/LTS) if possible, as it is faster than requesting a Home test.
- While waiting for your follow-up PCR test result you and your household members should isolate and follow this guidance. If you receive a negative follow-up PCR test result, and this PCR test was taken within 2 days of the positive LFD test, you and your household will be told by NHS Test and Trace that you can stop self-isolating. However, you and your household must continue to self-isolate if:
  - this PCR test result is positive or void
  - you choose not to take a follow-up PCR test
  - your follow-up PCR test was taken more than 2 days after the positive LFD test result
- It is important to book your follow-up PCR test as soon as you can following your positive LFD test result.
- If the follow-up test is positive, the subject and everyone in their household will need to self-isolate for 10 full days, this is from the date of the LFD test and the next 10 days
- If the subject is isolating because of a positive test result but did not have any symptoms, and they develop COVID-19 symptoms within the isolation period, they must start a new 10 day isolation period by counting 10 full days from the day following the symptom onset.

If the subject develops COVID-19 symptoms at any point after ending the first period of isolation they and everyone in their household should follow the steps in the national guidance again

11.17 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 and should strictly observe social distancing measures keeping at least 2m away from other passengers, keep windows open, wear a face covering, face away from other passengers avoid touch points, wash their hands before and after the journey, and use hand sanitiser at regular intervals during the journey. We expect people to plan for this scenario and, where possible, walk, cycle or drive.

- 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.

11.18 Repeat testing

Subjects that have tested positive by PCR for SARS-CoV-2 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.

Subjects participating in specific authorised programmes may be tested within this 90-day period (e.g. daily contact testing).

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 all other 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

12 PPE

Staff on sites are required to wear the appropriate PPE for their role as detailed below (refer to Section on Workforce for the definition of roles):

	Gloves[2]	**Apron**	**Fluid Resistant Surgical Mask (FRSM)**	**Eye/face protection[4]**
Testing operative	During Sample analysis Single use	During Sample analysis Check notes for use[3]	Wear FRSM at all times Extended use - Check notes for use[4]	During Sample analysis Extended use - Check notes for use[4]
Cleaning staff	During cleaning Change between cleaning tasks[2] /if cleaning a spillage, and if visibly contaminated	During cleaning Change between cleaning tasks and if cleaning a spillage	Wear FRSM at all times Extended use - Check notes for use[4]	During cleaning Extended use - Check notes for use[4]

From National Guidance

Notes:

1) Use of gloves:
    - Gloves are not required when undertaking administrative tasks for example using the telephone, using a computer or tablet, handing out test kits

- Gloves must be worn when exposure to blood and/or body fluids, non-intact skin or mucous membranes is anticipated or likely
- Gloves, when worn correctly, protect the wearer
- Gloves must be put on immediately before performing the task
- Gloves are single use items that are disposed of immediately after completion of a task and after interaction with each subject
- Gloves **must not** be decontaminated between tasks either by soap and water or alcohol based hand rubs
- Gloves must be changed if a perforation or puncture is suspected or identified
- Gloves must be changed after contact with cleaning chemicals which may compromise the barrier integrity of the gloves
- **The use of gloves does not replace the need for staff to perform hand hygiene**

2) Use of aprons for processing operatives:
    - Aprons to be put on just prior to processing
    - Once PPE is put on, individuals must not move around the testing site
    - Once PPE is put on, if the individual needs to move to another area, the apron is removed and hand hygiene is performed
    - A local assessment is undertaken to review the flow through the testing site. Change of aprons will fluctuate depending on the flow of individuals for testing
    - If the flow is performed, and a fresh apron is put on when the new cartridge is being processed
    - If the flow is high, i.e. several tests being process either in batches or one after the other with no movement of staff, the apron is to be removed once the task is completed, and hand hygiene to be performed
    - When leaving the testing area for a break/comfort break apron is removed, and hand hygiene is performed
3) A local risk assessment should be undertaken for the use of eye and face protections (visor and goggles), which need to be worn when there is a risk from;
    - splashing of secretions (including respiratory secretions) (Gov.UK 2020)
    - when there is a risk of contamination of the eyes from splashing such as cleaning activity or during aerosol generating procedures (HSE 2020)
    - when there is a perceived risk that blood and/or body fluids or chemicals may splash into the eyes.

Eye or face protection can be achieved using any of the following items:

- A surgical face mask with an integrated visor
- A full face visor or shield
- Goggles
- Please note eye protection spectacles are not recommended, as they do not meet the required EN 166 standard when interacting with suspected or confirmed SARS-CoV-2 cases.

PPE should be changed between sessions for all staff except those who assist an individual in taking a test; Test Assistant staff must change their PPE in-between individuals whom they assist / intervention is required.

Extended use of face mask refers to a period of time when a member of staff is undertaking a duty who is not involved in assisted testing of a subject. The extended use ends when the member of staff finishes their task and leaves the area or takes a break. The maximum time a face mask must be worn is 4 hours.

The maximum period of time for extended wearing of a Type IIR face mask is 4 hours. The Type IIR face mask must be changed if it becomes visibly soiled, damaged, moist, wet or uncomfortable to wear.

The extended use of a face mask does not remove the need for other key bundles of measures to reduce the risk of transmission of SARS-CoV-2, including social distancing, optimal hand hygiene,

frequent surface decontamination, ventilation and other measures where appropriate. Reliance on individuals as opposed to bundles of measures to reduce the risk of virus transmission is not sufficient.

PPE should be changed if protective properties are compromised or if contaminated, or if suspected to be contaminated.

Reusable goggles or visors can be cleaned and reused. Please check the packaging for the goggles or visors to see if the product is reusable. Staff should follow manufacturer's instructions on how to clean, disinfect and store them. As a minimum, between uses goggles or visors should be:

- Cleaned with a neutral detergent wipe, allowed to dry, disinfected with a 70% alcohol wipe and allowed to dry
- Or cleaned with single step detergent and disinfectant wipe, allowing the item to dry afterwards

Reusable goggles or visors should be then stored in a bag or lidded box to avoid possible contamination after cleaning and disinfection is complete. Eye protection must NOT be put on until it is completely dry. Cleaning of reusable PPE items that have been provided to a member of staff is their responsibility. If they are single use, they need to be disposed of after use.

Staff should not smoke and should avoid contact with flames while wearing eye protection.

Sites need to do a local risk assessment for the extended use of face mask and eye protection depending on the ability to maintain social distancing at all times (i.e. face masks and eye protections need to be changed if social distancing is not maintained).

Staff who are required to top up supplies within test areas should do so at the beginning of each testing group and when no subjects are present.

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

This is enabled and supported by frequent cleaning of test booths and high touchpoint areas.

Protocols for putting on and taking off PPE can be found in the PPE Instructions Section.

13 Waste Management

This section is based on the national testing policy from the Waste Management SOP v1.0 and is subject to change.

13.1 Classification

The legislative framework that applies to waste duty of care requires that waste is coded based on the source of that waste. This is why waste from healthcare settings are coded differently from schools and workplaces where testing is not the primary activity

While the testing sites are regarded as healthcare settings in England and Wales, in Scotland they are viewed as municipal sites. In either scenario the waste that is generated should be segregated at source and should not be over classified as clinical waste. With the increased testing availability in

the National Test and Trace Programme, there is a requirement to fully understand the responsibilities of healthcare waste management at a local level. *Investigation is on-going in Northern Ireland.*

All areas have a waste management 'Duty of Care' and are responsible for undertaking a local WM3 assessment for the classification of the waste that they will generate (if not identified in the table below), this assessment must be documented. A Duty of Care Waste Transfer Note must be completed before waste is removed from site and records kept for minimum of 2 years were applicable.

13.2 Regulatory Position Statement (RPSs) and Local Enforcement Positions (LEPs)

The Environment Agency publishes time-limited COVID-19 regulatory position statements (RPSs) in relation to certain regulatory requirements. This is to avoid increasing risks to the environment or human health during the particular circumstances of the coronavirus pandemic. Local Enforcement Positions (LEPs) have also been provided to a number of waste transfer sites to facilitate collection prior to disposal and a number of municipal waste incinerators have been allowed to accept Lateral Flow Device (LFD) testing wastes without appropriate waste codes on the permit.

13.3 Prior to a new site being set up

Prior to setting up any new testing site, the waste management chain including the final of disposal should be identified in advance with the Waste Contractor who is involved in the collection of the waste from the testing site. This will ensure that a plan is in place for the transfer of the waste to final disposal in the safest and most effective manner.

For testing sites where the testing kit waste is classified as 18 01 04 and 18 01 07, the Operational Teams need to consider the following:

- What waste disposal facilities are available in the location that will accept 18 01 04 and 18 01 07 waste or if there is available capacity outside of the location how will the waste be transported in order to be safely received?
- Where there is no facility already permitted to transfer, incinerate or landfill 18 01 04 and 18 01 047 wastes and reliance on a Local Enforcement Position or Regulatory Position Statement may be required, contact the waste contractor to confirm that they will accept the waste, understand in what form it needs to be delivered and that regulatory requirements are in place.
- Where incinerator or landfill operators are willing to accept the waste, ensure that they obtain, or have already obtained permission from the local Environmental Agency Officer and demonstrate that they can meet the conditions set out in Regulatory Position Statements and corresponding Local Enforcement Position Statements.
- Once they have confirmed that permission is in place, arrange a disposal collection schedule

13.4 Waste produced from testing sites

- General waste, including takeaway food packaging
- Packaging, including cardboard boxes, plastic bags, information leaflets
- Personal protective equipment, including face masks, visor/goggles, gloves, plastic aprons and gowns
- Testing kits, including testing swabs and packaging, cartridge, pipette, buffer solution, testing strip packaging

Waste is disposed of according to agreed protocol with respect to the respective waste stream described in the following tables (differentiating healthcare and non-healthcare waste).

13.5 Transportation category

The waste generated (healthcare waste/offensive) from the testing sites fall outside the scope of Carriage of Dangerous Goods Regulations, ADR, RID and IMDG for road and rail, as well as sea if using ferry routes and would not require an ADR driver (waste is classified or transported as clinical waste, UN3291).

13.6 Appropriate waste bags

Supplies of appropriate healthcare disposal bags and/or containers need to be available to ensure that wastes are not confused at the point of collection, it is therefore suggested:

- Clear or white without biohazard markings
- Yellow, ensuring no hazardous waste (infectious/biohazard) markings
- Yellow bag with a black strip (tiger bag)

Please note the exceptions to these listed in the Waste Streams pertaining to testing sites where testing is not the primary function of the site (e.g. schools and workplaces).

13.7 Storage: 72 hours storage and reclassification is not acceptable

There are two models for the correct removal of healthcare waste which can be followed:

a) Local Authorities (LA) have the option to use pre-existing waste contracts that may utilise the COVID-19 RPS C23 regulatory position. The regulatory position and any RPS that allows for this waste to be landfilled allows waste management companies to dispose of SARS-CoV-2 Lateral Flow Devices (LFD) testing waste in a municipal waste incinerator without having to make permanent changes to their environmental permits, however, there will need to be a Local Enforcement Position issued by the local Environment Agency Office.

b) Using Crown Commercial Services, contracts can be established with Speedy, who are a national company and can provide healthcare waste management products, including safe and compliant disposal. Due to the number of demands on the company throughout this time, this should be the last viable option. Speedy can be contacted direct on 01332850004 or at covidsupplies@speedyservices.com

13.8 Waste streams for Asymptomatic Testing Site – Lateral Flow Testing

The information leaflets (IFU) for some Lateral Flow Test kits that test for SARS-CoV-2, the cause of COVID-19, state that the used test should be discarded as biohazardous waste. Using WM3 (Guidance on the classification and assessment of waste) the used test kits have been assessed as non-hazardous waste.

Used LFDs are required to be disposed on in line with waste duty of care regulations which mean that they need to be segregated as non-infectious healthcare waste from dedicated test centres and universities. They may be discarded in the residual/municipal waste stream from household, employer and workplace environments.

The table below is applicable to England. Devolved Administrations will need to seek local consultation for waste streams.

Item	Sample	Waste categorisation	European Waste Code (EWC)	Likely Management Route / Waste Hierarchy	Health Technical Memoranda (HTM) 07.01 Packaging
General Waste	Sandwich wrapper	Domestic/ Recycling	20 03 01	1st Option: Materials Recovery Facility	Not applicable

				2nd Option: Energy from waste 3rd Option: Landfill	
All packaging	Outer packaging on equipment	Domestic / recycling	15 01 01 15 01 02 15 01 05 15 01 06	1st Option: Materials Recovery Facility 2nd Option: Energy From Waste 3rd Option: Landfill	Use existing municipal route
Swabs	Absorbent pads Vials Tissues	Chemical	18 01 07 Plus 18 01 04	1st Option: Energy from Waste 2nd Option: Municipal Incineration 3rd Option: Clinical Waste Incinerator 4th Option: Landfill (last resort)	1st Option: Unmarked yellow neutral container/bag 2nd Option: White / clear container/bag 3rd Option: Tiger bag **Do not use hazardous waste packaging**
Cartridges / Devices **(i.e. Innova, Orient Gene, Surescreen)**	LFT cartridge	Chemical	18 01 07 Plus 18 01 04	1st Option: Energy from Waste 2nd Option: Municipal Incineration 3rd Option: Clinical Waste Incinerator 4th Option: Landfill (last resort)	1st Option: Unmarked yellow neutral container/bag 2nd Option: White / clear container/bag 3rd Option: Tiger bag **Do not use hazardous waste packaging**
Personal Protective Equipment	Apron Face mask Gloves	Offensive	18 01 04	1st Option: Energy for waste 2nd Option: Municipal Incineration 3rd Option: Landfill (last resort)	1st Option: Tiger bag

N.B. The information leaflets (IFU) for some Lateral Flow Test kits that test for SARS-CoV-2, the cause of COVID-19, state that the used test should be discarded as biohazardous waste. Using WM3 (Guidance on the classification and assessment of waste) the used test kits have been assessed as non-hazardous waste.

Used LFDs are required to be disposed of in line with waste duty of care regulations which mean that they need to be segregated as non-infectious healthcare waste from registered healthcare facilities, dedicated test centres and universities. They may be discarded in the residual/municipal waste stream from household, employer and workplace environments.

Appendix A: Community assisted-testing scripts

Introduction and overview of process

What does testing involve?

You will be asked to take a test using a Lateral Flow Device to check if you are currently infectious with Covid-19.

Please do a throat and nose swab and then we will let you know your result in 20-30 minutes. We ask you to complete the swabbing yourself, supervised by a trained staff member who can assist if needed.

Full instructions will be provided to you upon your visit along with the test kit.

You will be asked to give consent to take the test and share personal information with us and register your details, so we can record and tell you your result.

You will then be asked to register for your test on line with help from a staff member if needed
This is how NHS Test & Trace can link you to your test sample and collect contact details to send you your result.

Take your test:

- After you check in, you will be given a swab.
- You will then need to take your own throat and nose swab, supervised by one of our trained staff members. We will walk you through how to swab yourself which will only take about 30 seconds to do.
- [IF SUBJECT WILL BE WAITING FOR RESULT ON-SITE: Once you have handed over the swab, you will be asked to wait until your result is ready which will take approximately 30 minutes.]
- [IF SUBJECT WILL NOT BE WAITING FOR RESULT ON-SITE: Once you have handed over the swab, you will be asked to leave the test site and wait to be notified of your result by text or email.]

After swab has been conducted
[IF SUBJECT WILL BE WAITING FOR RESULT ON-SITE: PREFERRED OPTION:]

Thank you for taking the test. Please wait [PROVIDE SITE SPECIFIC INSTRUCTIONS]. When your test is ready and has been read, we will tell you your result verbally, and NHS Test & Trace will send you your result via SMS and/or the e-mail that you provided on the online registration form – this may take several hours.

[IF SUBJECT WILL NOT BE WAITING FOR RESULT ON-SITE:]

Thank you for taking the test. Please leave the test site and wait to be notified of your result. After your test has been read and registered, NHS Test & Trace will send you your result via SMS and/or the e-mail that you provided on the online registration form – this may take several hours.

Giving results

LFD POSITIVE

Your coronavirus lateral flow test result is positive. This means it's likely you had the virus and were infectious when the test was done. – PROVIDE SITE-SPECIFIC INSTRUCTIONS HERE.

You and everyone you live with must self-isolate immediately for 10 days. This includes the day of your test and the next 10 full days.
If you or the people you live with get symptoms, 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.
For medical help, contact 111. In an emergency dial 999.

See www.gov.uk/coronavirus for more advice.

LFD NEGATIVE

Your coronavirus test was negative. This means it is likely that you were not infectious when you had your test.

You may return home. It's important to recognise that although you have a negative test today you must still observe all the national guidance including social distancing and wearing a face covering. You must:

- Stay home if you are feeling unwell, including if you have a fever, a cough or a change or loss of your taste and smell. If you develop symptoms you should get another test by booking through the app or portal
- Follow national guidance, including limiting your contact with other people and wearing a mask in public if possible.
- Observe social distancing with anyone outside of your household or bubble and wash your hands regularly.

You only need to self-isolate if:

- you get symptoms of coronavirus
- someone you live with tests positive, or has symptoms and has not been tested yet
- you've been traced as a contact of someone who tested positive

LFD INVALID
We could not read your coronavirus sample. This means it is not possible to say if you are infectious today.

[IF THIS IS THE **FIRST** INVALID RESULT:]
You will need to take another test as soon as possible at this test site [PROVIDE SITE-SPECIFIC DETAILS OF HOW TO GET ANOTHER LATERAL FLOW TEST NOW]. If this is inconclusive too, we will discuss your result with you and arrange a confirmatory test.
[IF THIS IS THE **SECOND** INVALID RESULT, IF THE SUBJECT WILL NOT STAY OR IF IT IS OPERATIONALLY DIFFICULT TO RETEST WITH LATERAL FLOW DEVICE GO STRAIGHT TO PCR RETEST:]

You will need to take a different test which we will provide and register for you here at the test site – PROVIDE SITE-SPECIFIC INSTRUCTIONS HERE. If you choose not to wait you may go home immediately and have the second test ordered to be received at home for you to take and return by post, but the result may take longer.]

When you get home, go to www.gov.uk/get-coronavirus-test to book the second test.

You will receive your result in around 48 hours. If your repeat test is positive, NHS Test & Trace may contact you to ask you for your contacts

You only need to self-isolate if:

- you have or get symptoms of coronavirus
- someone you live with tests positive, or has symptoms and has not been tested yet
- you've been traced as a contact of someone who tested positive

IF THE PERSON CHOOSES NOT TO STAY TO RECEIVE THEIR RESULT

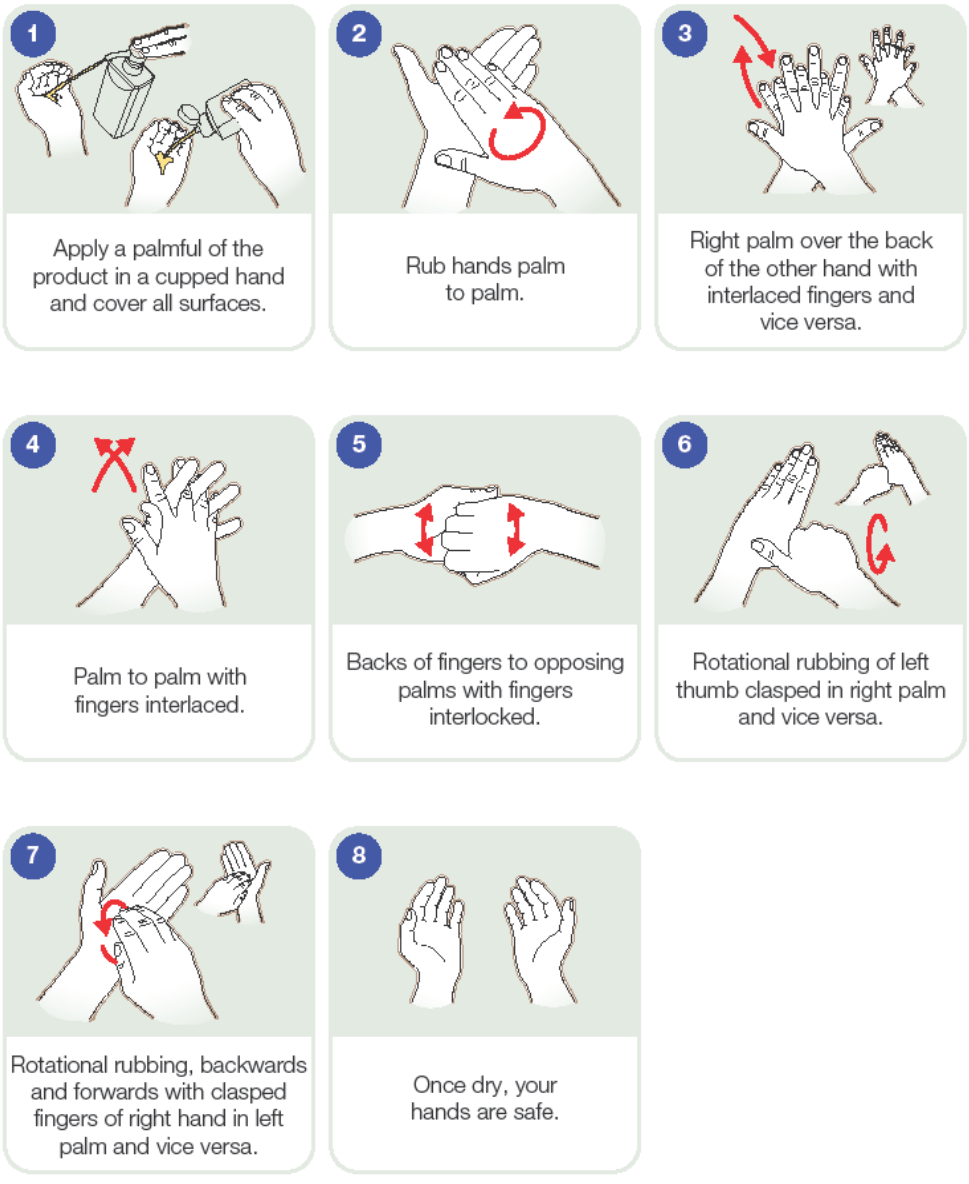
If you choose to leave the site before your result is available you can go home immediately and receive your result by test message or email depending on the contact details you have given. If your result is positive you must have a second confirmatory test.

When you get home, go to www.gov.uk/get-coronavirus-test to book the second test and choose a drive through site if possible. If this is not possible, then a walk through site or home test can be chosen.

Appendix C: Handwashing posters

Public Health England

Best Practice: How to handrub step by step images



Adapted from the World Health Organization/Health Protection Scotland

Public Health England

Best Practice: How to hand wash step by step images

Steps 3-8 should take at least 15 seconds.

Adapted from the World Health Organization/Health Protection Scotland

*Any skin complaints should be referred to local occupational health or GP.

Appendix D: PPE Instructions – putting on and taking off

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/911311/PHE_Putting_on_PPE__Standard_infection_control_procedures.pdf

Public Health England

Putting on personal protective equipment (PPE)

Standard Infection Control Precautions

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

Pre-donning instructions:

- Ensure healthcare worker hydrated
- Tie hair back
- Remove jewellery
- Check PPE in the correct size is available

1. Perform hand hygiene before putting on PPE.

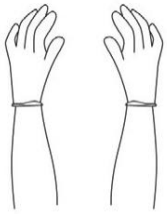
2. Put on apron and tie at waist.

3. Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.

4. With both hands, mould the metal strap over the bridge of your nose.

5. Don eye protection if required.

6. Put on gloves.



https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/911312/PHE_Taking_off_PPE_standard_infection_control_procedures.pdf

Public Health England

Taking off personal protective equipment (PPE)

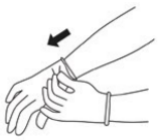
Standard Infection Control Precautions

Please see donning and doffing video to support this guidance: https://youtu.be/-GncQ_ed-9w

- **PPE should be removed in an order that minimises the risk of self-contamination**
- **Gloves, aprons (and eye protection if used) should be taken off in the patient's room or cohort area**

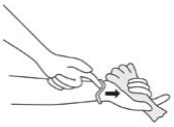
1 Remove gloves. Grasp the outside of glove with the opposite gloved hand; peel off.

Hold the removed glove in the remaining gloved hand.



Slide the fingers of the un-gloved hand under the remaining glove at the wrist.

Peel the remaining glove off over the first glove and discard.



2 Clean hands.

3 Apron.

Unfasten or break apron ties at the neck and let the apron fold down on itself.

Break ties at waist and fold apron in on itself – do not touch the outside – **this will be contaminated**. Discard.

4 Remove eye protection if worn.

Use both hands to handle the straps by pulling away from face and discard.

5 Clean hands.

6 Remove facemask once your clinical work is completed.

Untie or break bottom ties, followed by top ties or elastic, and remove by handling the ties only. Lean forward slightly. Discard. DO NOT reuse once removed.

7 Clean hands with soap and water.

F

Appendix E: Self-swabbing Instructions for Innova

UK Government

NHS Test and Trace

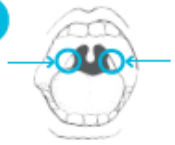
Take swab sample

Step-by-step guide

Need help?

If you have any questions or problems with this test kit, please alert a member of staff.

1



Remove your face covering.

Look inside your mouth, and find your tonsils at the back of the throat.

You can use the mirror to help.

Your tonsils or where they would have been (if they are removed) are where you will swab your sample.

2

Gently blow your nose into a tissue

Throw the used tissue into the healthcare waste bin provided.

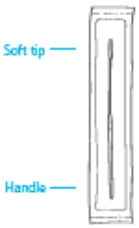
This is so that you get rid of excess mucus.

3

Use hand sanitiser to clean your hands.

This is so that you do not contaminate the test kit.

4



Check if there is a swab in a sealed pack in front of you.

Identify the soft, fabric tip of the swab.

5

Open the package and gently take out the swab.

This will be used for both tonsils and nose.

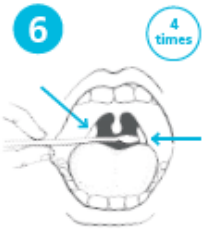
Important: **Do not touch your tongue, teeth, cheeks, gums, or any other surfaces with the fabric tip of the swab.**

The swab is invalid if it touches these parts, and you will need to get a new swab. If this happens ask a member of staff to get assistance.

Important: **The swabbing may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.**

If there is blood or vomit on the swab sample, please alert a member of staff.

6



Holding the swab between your fingers, open your mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with **firm contact 4 times on each side** (use a mirror to help you do this).

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

7

Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm or 1 inch up your nose).

Roll the swab firmly around the inside of the nostril, making 10 complete circles and slowly remove it.

Important: **After collecting the sample hold the swab upright in your hand, do not put it down and notify one of the Testing assistants.**

Be careful not to touch any surfaces with the swab.

Put on your face covering.

Follow the instructions from a member of staff on what to do next.

Use hand sanitiser after handing in your sample.

TC Jan 2021

Appendix F: Assisted swabbing instructions for testing subjects with additional needs with Innova

UK Government

NHS Test and Trace

Assisted swab sample

Step-by-step guide

Need help?

If you have any questions or problems with the test kit, please alert a member of staff.

Explain the process to the individual with terms they can understand and remain calm and confident during the process.

You should wear a face covering throughout the process.

1

Ask the individual to remove their face covering (if they are wearing one).

Ask the individual to open their mouth as wide as they can and say "Ahhhh" for as long as they can and find their tonsils (or where they would have been). This is where you will swab.

2

Ask the individual to gently blow their nose into a tissue.

Throw the used tissue into the healthcare waste bin provided.

This is so that they get rid of excess mucus.

3

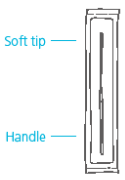
Use hand sanitiser to clean your hands.

This is so that you do not contaminate the test kit.

4

If you are not part of the individual's support bubble, you are required to wear gloves whean taking their swab sample.

5



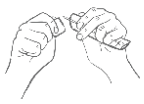
Check if there is a swab in a sealed pack in front of you.

Identify the soft, fabric tip of the swab.

Important: Do not touch the tip of the swab or let it touch any surfaces.

The swab is invalid if it touches these parts, and you will need to get a new swab. If this happens ask a member of staff to get assistance.

6



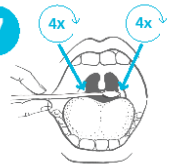
Open the package and gently take out the swab, holding it at the stick end.

This will be used for both tonsils and nose.

Important: The swabbing may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

If there is blood or vomit on the swab sample, please alert a member of staff.

7



Holding the swab between your fingers, ask the individual to open their mouth as wide as they can and tilt their head back. Rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with **firm contact 4 times on each side.**

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

If you cannot swab their tonsils, you can swab both of their nostrils instead.

Note: The result may be less accurate than a nose and tonsil swab.

8

Put the same swab gently into one nostril until you feel a slight resistance.

Roll the swab firmly around the inside of the nostril, making 10 complete circles and slowly remove it.

Important: After collecting the sample place the swab directly in the prepared extraction tube. Be careful not to touch any surfaces with the swab.

Ask the individual to put on their face covering (if safe for them to wear one).

Follow the instructions from a member of staff on what to do next.

If you were required to wear gloves when taking the sample, a staff member will tell you how to dispose of these.

Use hand sanitiser after handing in their sample.

TC Jan 2021

Appendix G: Testing information poster

HM Government

NHS Test and Trace

Information about your test

During the test, you will need to swab your nose and/or mouth depending on the test used.

If you take the test at home, you will need to report your result online using a smartphone, a tablet or a computer.

You will be sent your test result by text or email.

No test is perfect. Sometimes they can give an incorrect result.

A positive result means it's likely you had the Coronavirus when the test was done. You and anyone you live with must self-isolate immediately. Avoid using public transport.

Someone from our team of Contact Tracers may also contact you.

If you receive a positive result, you may be told to get a follow-up test to confirm the result.

A negative result means that the test has not detected any virus today. You could still have the virus, so you need to keep following guidelines to avoid spreading Covid-19.

If your result cannot be read, you may be advised to get another test.

Appendix H: 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. The file containing the commonly asked clinical and public health issues can be found below.

Common Clinical and Public Health Issues V

Appendix I: Example Risk Assessment

CTP Example risk assessment.docx

Appendix J: Sample Quality and Competency Checklists

QUALITY CHECKLIST.pdf

Recorder Competency Assessment.pdf

Test Processor Competency Assessment.pdf

Testing Area Supply Checklist.pdf

Testing Assistant Competency Assessment.pdf