

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

## **National Testing Programme**

### **Clinical Standard Operating Procedure (SOP) for Mass Testing with Lateral Flow Antigen Testing Devices – Workplace Asymptomatic Test Site**

#### **Version 2.2**

Date of publication: 06/02/2021

**Master SOP Template Authorised by: Dr Tom Fowler and Dr Peter Marks, National Testing Programme Health Protection and Public Health Leads**

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**Document Control and Approval****Version Control**

Version	Author	Summary of Changes	Reviewed By	Date
V1.1	Jamie McIntyre	Document creation – starting from <b>master clinical SOP V1.3</b> and previous employer-specific SOP from Use Case 5. <b>General Formatting Section</b>	<a href="#">Chris Kenny</a>	20201028
V1.2	Jamie McIntyre	Update to quantity of prescribed training and retraining requirements. Inclusion of a clause that in the absence of approved and released training materials, then the previous SOP remains in force. Updates done to reflect new swabs	<a href="#">Chris Kenny</a>	20201029
V1.3	Jamie McIntyre	Updated with changes from <b>master clinical SOP V1.9</b>	<a href="#">Chris Kenny</a>	20201103
V1.4	Amar Parmar	Updated with changes from <b>master clinical SOP v2.3</b>	<a href="#">Chris Kenny</a>	20201112
V1.6	Amar Parmar	Updated with changes from <b>master clinical SOP v2.4</b>	<a href="#">Chris Kenny</a>	20201120
V1.7	Amar Parmar	Updated with changes from <b>master clinical SOP v2.5</b>	<a href="#">Chris Kenny</a>	20201201
V1.8	Amar Parmar	Updated with changes from <b>master clinical SOP v2.6</b>	<a href="#">Chris Kenny</a>	20201209
V1.9	Gavin Murphy	Updated with changes from <b>master clinical SOP v2.8</b>	<a href="#">Chris Kenny</a>	20201217
V2.0	Gavin Murphy	Updated with changes from <b>master clinical SOP v2.9</b>	<a href="#">Chris Kenny</a>	20201215
V2.1	Gavin Murphy	Updated with changes from <b>master clinical SOP v3.1</b>	<a href="#">Chris Kenny</a>	20210120
V2.2	Gavin Murphy	Updated with changes from <b>master clinical SOP v3.2</b>	<a href="#">Chris Kenny</a>	20210127

**Approval**

<b>Cell Name / Role</b>	<b>Review / Approval</b>	<b>Version Reviewed / Approved</b>	<b>Date</b>
<b>Testing Programme / Deputy Director, Delivery Integration</b>	<b>Approval</b>	<b>1.0</b>	<b>20201023</b>
<b>Clinical / Public Health</b>	<b>Approval</b>	<b>1.2</b>	<b>20201027</b>
<b>Testing Programme / Deputy Director, Delivery Integration</b>	<b>Approval</b>	<b>1.3</b>	<b>20201027</b>
<b>Testing Programme / Deputy Director, Delivery Integration</b>	<b>Approval</b>	<b>1.9</b>	<b>20201103</b>
<b>Testing Programme / Deputy Director, Delivery Integration</b>	<b>Approval</b>	<b>2.0</b>	<b>20201105</b>
<b>Testing Programme / Deputy Director, Delivery Integration</b>	<b>Approval</b>	<b>2.3</b>	<b>20201110</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.4</b>	<b>20201118</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.5</b>	<b>20201125</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.6</b>	<b>20201202</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.7</b>	<b>20201208</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.8</b>	<b>20201216</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>2.9</b>	<b>20210106</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>3.0</b>	<b>20210113</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>3.1</b>	<b>20210120</b>
<b>National Testing Programme Health Protection and Public Health Leads</b>	<b>Approval</b>	<b>3.2</b>	<b>20210127</b>

## Lateral Flow Device SOP Scope Summary

<b>Use Case:</b>	<b>Workplace Testing</b>	
<b>Organisation:</b>		
<b>1. Public health aim</b>		
<i>Please speak to your PHCO liaison to define what your public health aim is. As a general rule, most workplace testing sites are active case finding, but there have been some surveillance cases as well</i>		<i>Select the relevant box below to mark with an 'X'</i>
<b>Active Case Finding</b> <i>'Identifying positive cases of COVID-19 within the population, and ensuring they self-isolate to reduce transmission to other people; this could include regular testing of the contacts of a case'</i>	<input checked="" type="checkbox"/>	
<b>Surveillance</b> <i>'Finding out the incidence and prevalence of COVID-19 in the population, and changes to these over time'</i>	<input type="checkbox"/>	
<b>2. Participation in Daily Contact Testing (DCT) service evaluation</b>		
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes		
<i>Deployment of Daily Contact testing requires approval from the Daily Contact Testing Governance Team.</i>		
<i>Has approval from the Daily Contact Testing Governance Team been granted? (Select the relevant box below to mark with an 'X')</i>		
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, approval granted		
<i>Has the Daily Contact testing module been incorporated in this SOP as an Appendix? (Select the relevant box below to mark with an 'X')</i>		
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, Daily Contact testing module added as an Appendix		
<b>3. Testing frequency</b>		
<b>Frequency of Testing</b> <i>(per individual within population)</i>	1-2 tests per week at employers' discretion	
<b>4. Workplace testing site includes a research study?</b>		
<i>If you believe there is a research component required to your study, please liaise with Sarah Tunkel (<a href="mailto:Sarah.Tunkel@dhsc.gov.uk">Sarah.Tunkel@dhsc.gov.uk</a>) to discuss research requirements including ethics approval</i>		
<input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, ethics approval granted <input type="checkbox"/> Yes, ethics approval required		
<b>5. Lateral Flow Device</b>		
<i>At the time of writing this document, only the Innova SARS-Cov-2 Antigen Test feature in this SOP, once additional devices are approved for workplace testing sites they will be updated into the SOP</i>		
Innova SARS-CoV-2 Antigen Test IFU	<input checked="" type="checkbox"/>	
SD Biosensor Saliva IFU, SD Biosensor Swab IFU	<input type="checkbox"/>	
Abbott Panbio COVID-19 Ag Rapid Test Device	<input type="checkbox"/>	
OrientGene Coronavirus Ag Rapid Test	<input type="checkbox"/>	
<b>6. Situation in which LFD will be used</b>		
Workplace Testing Site – DHSC clinical accountability for SOP and organisation accountability for implementing SOP	<input checked="" type="checkbox"/>	
<b>7. Population tested</b>		
<i>This document has been written on the basis for asymptomatic testing only</i>		
<input type="checkbox"/> Symptomatic <input checked="" type="checkbox"/> Asymptomatic		
<b>8. Sample type</b>		
Throat and Mid-turbinate Nose Swab (where possible)	<input checked="" type="checkbox"/>	
Throat Swab only	<input type="checkbox"/>	
Nasal (mid-turbinate) Swab only	<input type="checkbox"/>	
Nasal (double anterior nares) Swab only	<input type="checkbox"/>	
Saliva	<input type="checkbox"/>	
<b>9. Sample collection method</b>		
<input type="checkbox"/> Assisted <input checked="" type="checkbox"/> Self-implemented		
<b>10. Sample preparation, application to LFD and results interpretation</b>		
<i>At the time of writing this document, sample preparation, application to LFD and Results Interpretation was only approved to be done by trained staff, not by the Subject themselves</i>		
<input checked="" type="checkbox"/> Assisted <input type="checkbox"/> Self-implemented		

## Organisation end-to-end process and accountable organisation

Area	Processes	Accountable Organisation	Authorised Signature	Date
<b>Governance</b>	Clinical accountability for SOP	DHSC		
	Accountability for implementing SOP	Organisation		
<b>Evaluation</b>	Evaluation framework creation	DHSC		
	Evaluation data collection	DHSC		
	Evaluation data analysis and write up	DHSC		
<b>Workforce</b>	Training material	DHSC		
	Training delivery	Organisation		
	Organisation Set-up	Organisation		
	Organisation Delivery (swabbing)	Subject		
	Organisation Delivery (LFD Processing)	Organisation		
<b>Operations and Logistics</b>	Supplies: PPE	Organisation		
	Supplies: test kits	DHSC		
	Site set-up (general testing and analysis)	Organisation		
	Waste management	Organisation		
<b>Testing process</b>	Identification and recruitment of people to test	Organisation		
	Registration of participants	Subject		
	Sample collection	Subject		
	Sample processing	Organisation		
	Results analysis	Organisation		
<b>Incidents and Queries</b>	Results notification	DHSC		
	Response to queries from people tested	Organisation		
	Risk and incidence management	Organisation		
	Media queries	DHSC		
<b>Quality assurance</b>	Quality assurance: operational delivery	Organisation		
	Quality assurance: data analysis and reporting	DHSC		

## 1 Introduction

This document is a template for the standard operating procedure (SOP) for mass testing for COVID-19 using lateral flow technology. This testing framework has been provided by the Department of Health and Social Care (DHSC), delivered through partnerships with a number of private and public sector organisations and the Devolved Administrations.

The contents of this document were accurate at the time of publication, however are subject to change based on learnings from other workplace testing sites and policies of the National Testing Programme. This document is not considered to be final and subsequent approval will be required for each use case before scaling the service across a broader population. Organisations are expected to incorporate material updates to this document into their operations as the Master SOP is updated. If material updates to this SOP are produced by DHSC, organisations are expected to implement them in their operations as per the standard terms and conditions that you accepted.

Failure to update your operation will lead to a service being considered delivered 'at risk' and DHSC will not be accountable for any clinical risks/issues if SOPs and testing measures have not been updated accordingly.

### 1.1 Purpose of this document

This document describes the appropriate clinical governance and infection control for sampling and testing procedures at asymptomatic testing sites (ATS), responsibilities of site staff, how to conduct interactions with people being tested, and clinical data management principles.

ATS sites currently only offer tests where the test processing is conducted by a trained member of staff, however this SOP is designed to introduce the format where the end-to-end process is conducted by the Subject. The requirement for this will involve additional approvals over and above those currently covered in this document.

The target for this service is asymptomatic testing. The tests described in this document are designed to enable collection of a throat and nasal swab, which is analysed on at the testing location (not a laboratory) to detect the presence of the virus that causes COVID-19. This document describes the appropriate clinical and infection control for procedures for the Innova SARS-Cov-2 Antigen test, responsibilities of site staff roles interacting with Subjects and the clinical data management principles. As other devices or products are introduced across the network, the details e.g. IFU, will be incorporated into the SOP.

### 1.2 Audience

The primary audience for this document is clinical and public health review and all those with a clinical and public health interest in the testing. This document will be shared with key program stakeholders including the NHS, Public Health bodies, Local Resilience Forums (LRF) and the Devolved Administrations. These clinical SOPs are designed for safe implementation of approved processes, Major changes or innovations to these SOPs must pass through the same approval process before implementation.

Organisations that are planned in devolved administrations must have the clinical SOP reviewed and agreed by the devolved administration. This can be done via the Devolved Administration engagement for testing team.



### 1.3 Responsibilities / accountabilities

It is expected that clinical SOPs may need to rapidly iterate in light of local delivery aims and circumstances. Where DHSC is responsible for, or has oversight of delivery, and clinical SOPs deviate substantially it is expected these deviations will be flagged to clinical and public health leads for additional sign off. Where there is local responsibility or oversight of delivery sign off for tailored organisations clinical SOPs is local.

**Clear accountability for different aspects of a workplace testing site should be agreed and documented before commencement.**

**For workplace testing sites where DHSC does not have clinical responsibility, this document should be used as a guidance.**

### 1.4 Care Quality Commission

The law has now changed which makes COVID-19 an activity that falls outside the scope of registration with the Care Quality Commission (CQC). It is therefore not a requirement for employers studies of Use Cases to register with the CQC to provide COVID-19 diagnostic and screening services. UK Accreditation Service (UKAS) accreditation is not mandatory so long as the provider is not selling their test kits or services. It is still recommended that providers seek UKAS accreditation under the new adapted UKAS 3-stage accreditation scheme created for them to gain this at a quicker speed.

## 2 Clinical Governance

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. 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.

### 2.1 Clinical governance framework

Effective clinical governance requires:

- A supportive environment and organisational culture that recognises the importance of good clinical governance
- Effective systems, processes and information flows to assess, monitor and improve the quality and safety of services provided, including application of evidence-based practice
- Sufficient numbers of suitably qualified, competent and experienced staff to deliver care to the required standard
- Risk and incident management systems setting out the management of safety concerns, safety incidents and risk mitigation

In addition, rigorous audit will help reduce the risk of errors and where this occurs it will help identify them quickly and manage them effectively and sensitively.

**It is required that a clear end-to-end description should be in place to ensure people and organisations managing the testing have clear accountabilities and handover points. The process flow should include organisations and roles for clarity.**

**Organisations should ensure they have documented agreement of the model.**

Due to downstream implications for the local public health response, each organisation should engage with the local HPT and Director of Public Health (DPH) and confirm they are fully sighted on local workplace test sites.

## 2.2 Safe care and treatment

Care and treatment must be safe effective and appropriate with appropriate clinical accountability

- Ensuring that persons providing care or treatment to service users have the qualifications, competence, skills and experience to do so safely
- Ensuring that the premises used by the service provider are safe to use for their intended purpose and are used in a safe way
- Ensuring that the equipment used is validated and is used in a safe for both users and staff way by the service provider for providing care or treatment to a service user is safe for such use and is used in a safe way
- Where equipment is supplied by the service provider, ensuring that there are sufficient quantities of these to ensure the safety of service users and staff to meet their needs
- Assessing the risk of, and preventing, detecting and controlling the spread of infections, including those that are health care associated
- Where responsibility for the care and treatment of service users is shared with, or transferred to, other persons, working with such other persons, service users and other appropriate persons to ensure that timely care planning and information exchange takes place to ensure the health, safety and welfare of the service users
- Assessing the risks to the health and safety of service users of receiving the care or treatment
- Doing all that is reasonably practicable to mitigate any such risks

Several measures will be used to ensure the site operates safely and effectively and clinical governance is maintained:

- Reporting errors
- Serious incidents monitoring
- Risk and mitigation plans
- Operator-specific audit trail
- External audits to maintain security measures
- Staff training assessments and frequent observation exercises

## 2.3 Risk and incident management

**Organisations should define here their risk and incident management and accountability (guidance below)**

To prevent or minimise harm, the following simple three-step clinical risk management process is commonly used:

- Identify the risk;
- Assess the frequency and severity of the risk;
- Mitigate the risk;

The service provider should have a robust local risk management system (LRMS), which captures all incidents, from identification, investigation, review and closure. The service provider should as a minimum be able to analyse data to identify themes and trends. The local provider will identify lessons learnt that can be shared with other providers to support the prevention of similar incidents from occurring.

It is expected that all local providers of the track and trace service will follow the National Serious Incident Framework NHS England 2015.

- It is expected that incidents will be managed at local level using the providers' local policy. There is 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.
- There is a process for reviewing and investigating safety and safeguarding incidents and events when things go wrong. All relevant staff, services, partner organisations and people who use services involved in reviews and investigations.

There is a process in place to ensure are lessons learned and themes identified, and is action taken as a result of investigations when things go wrong?

It is expected that all staff on site will have received at least the minimum training in understanding how to recognise, report and respond appropriately when an incident occurs e.g. fire and safety, local knowledge and local system processes.

In all services, errors can and will happen. Some errors will be relatively minor but others may be serious. The purpose of managing safety incidents across clinical services is to set out the requirements for managing safety concerns, safety incidents and serious incidents. It provides clarity for staff who may be involved in identifying or managing an incident. This should complement local risk management strategies and processes.

All sites should have a risk assessment completed prior to sign off for launch. The risk assessment should be completed by DHSC where DHSC is running the workplace testing site. Where another institution is accountable for testing delivery, e.g. an Organisation that sets up and operates a testing site on their premises, the risk assessment is their responsibility.

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. DHSC should be involved as a stakeholder in the incident response process. In this scenario if incidents are due to DHSC systems (e.g. return of results informatics systems), processes should be in place to inform and involve local stakeholders.

**Teams accountable for the use cases are accountable for ensuring DHSC governance processes for managing incidents are in place, including responsibility for ensuring appropriate investigation and reporting is undertaken, including non-routine incidents.**

**In addition the DHSC Use Case or service lead (if not formally a Use Case) will be expected to nominate a 'Quality Lead' who will work across the interface of testing services and support delivery of the PHCO assurance requirements, including presentation of a monthly report into the Clinical Governance Group. Report should include, although this is not an exhaustive list; number of tests undertaken and results, thematic analysis of incidents, outbreak management, results of any audit and improvement actions and escalation of associated risks to delivery of the service.**

Incidents should be reported to DHSC and DHSC should be represented as a stakeholder in the incident response process. In the scenario that incidents are due to DHSC systems (e.g. return of results informatics systems), an incident process will be initiated with local authorities informed and involved as stakeholders.

Incidents should also be reported to the MHRA via the yellow card scheme. Instructions on how to report adverse incidents internally and to the MHRA can be found: <https://coronavirus-yellowcard.mhra.gov.uk/>

## 2.4 Premises and equipment

All premises must meet all relevant legislative, certification and validation inspections and requirements including health & safety. They must be:

- Accessible,
- Clean,
- Secure,
- Suitable for the purpose for which they are being used,
- Properly used,
- Social distancing measures in place,
- Properly maintained, and appropriately located for the purpose for which they are being used.

The registered person must, in relation to such premises and equipment, maintain standards of hygiene appropriate for the purposes for which they are being used. Relevant risk assessments should be undertaken if the premises used mean that hygiene standards are more difficult to maintain. For example, carpeted flooring should not be used. If there is no alternative, the carpet should be covered with an easily-cleanable material such as plastic sheeting and the host organisation should complete a risk assessment to identify the control measures which will be in place to mitigate the risk of using carpeted flooring.

Sites should have a designated individual with the responsibility to ensure safety measures are being adhered to and to collate a daily report on the adherence. An independent verification of the implementation of safety measures should be in place to reinforce social distancing, face coverings and other infection prevention and control measures.

## 2.5 Staffing

Sufficient numbers of suitably qualified, 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, 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

Testing sites will have a training plan including assessments and frequent checks for competency:

- Knowledge assessment at the end of on-line training
- Face-to-face training by trained supervisor during mobilisation or first day
- Staff competence and training checks

Frequent observation exercises will also be conducted to audit staff performance:

- Daily/weekly clinical governance audits 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.

## 2.6 Service improvement and learning

Quality improvement makes healthcare systems safe, effective, service user centered, timely, efficient and equitable. A quality improvement culture is an integral component of the governance and performance management processes. Each Use Case team and Site Lead Operator must ensure quality improvement is in place.

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.

## 2.7 Clinical effectiveness

An essential element of the programme is that we deliver clinically accurate testing – if the testing procedure is not carried out effectively, an individual who has COVID-19 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.

### 2.7.1 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.

An internal quality assurance programme will be run for each use case at selected sites, to ensure they are performing at the appropriate level. This will involve sites running known samples at periodic intervals.

This will be phased over time and will be coordinated by the National Testing Programme who will provide a detailed work instruction to the sites in scope for this process. Further guidance will be provided on the timing and scope of this process.

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)

### 2.7.2 On-going programme-level evaluation

Dual swabbing at a selection of sites (determined through the development of use case archetypes) will be enacted for the purpose of ongoing evaluation. Analysis will be performed at an aggregate level for the archetype as a whole, and not for individual sites. This will be coordinated centrally by the National Testing Programme who will provide a detailed work instruction to the sites in scope for this process.

## 2.8 Accountability and monitoring

As a part of the test facility workforce, as outlined in this document, each site will be required to designate a member of the team to act as Quality and Governance Lead (or Testing Supervisor) who will have accountability for the clinical quality and risk management of the service within the context of a non-laboratory environment. This person will undertake the following:

- Implement appropriate quality assurance
- Monitor results and KPIs
- Ensure an internal quality assurance plan is in place and maintained
- Ensure participation in the on-going programme-level evaluation if requested
- Implement a quality & safety incident and risk reporting system
- Support the site manager in maintaining site risk register, develop and implement mitigation plans
- Report on quality assurance, incidents, risks and mitigations.
- Review testing staff training records and undertake testing staff performance reviews
- Ensure the promotion of good quality practice across the service delivery
- Undertake quality audits

Where private providers are assuming clinical responsibility for the testing, they will also be responsible for quality assurance component.

## 3 Public Health Purposes and Evaluation

The population aims of testing need to be clear. This could include the following:

- Case finding – identifying positive cases of COVID-19 within the population, and ensuring they self-isolate to reduce transmission to other people; this could include regular testing of the contacts of a case

The aims of the workplace mass testing are as follows:

- to assess routine frequent testing of staff to support and inform the DHSC's return to work guidance during the ongoing Covid-19 pandemic and to reduce community transmission of the virus;
- to assess the feasibility of lateral flow device ("LFD") antigen testing for routine and mass testing at scale; and
- to develop a risk-based approach for prioritising access to LFD testing in the working population

All organisations are required to register with the MHRA unless specifically agreed otherwise. This is done via the regulatory support within the LFD Supplies team. Use case teams are expected to collate this information from workplace testing sites within their remit.

## 4 Testing Technology

### 4.1 Lateral Flow Antigen test

Lateral Flow Antigen testing involves the processing of human nasal swabs, throat swabs, or sputum samples with a Lateral Flow device. The device detects a protein (antigen) produced by the virus at its most infectious stage. If present in the person's sample, a coloured line appears on the device after 10-20 minutes. This uses a well-established technique called immunochromatography, which draws the sample along the device in a similar way to a home pregnancy test kit.

#### 4.1.1 How the test works

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. In general, it takes up to 20 minutes for a positive result to appear. The manufacturer's guidance is to wait a full 30 minutes to confirm that a result is negative.

Training in handling and analysis of the samples, including relevant principles of infection prevention and control, will be provided to all operators at each testing site.

#### 4.1.2 Product specifics

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.

Some organisations' operational implementation may be outside the manufacturer's instruction for use (IFU). Specific elements described in this document (SOP) 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.

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.

#### 4.1.3 Implication of LFD results

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.



#### 4.1.4 Instructions for use (IFU)

The manufacturer's instructions for use can be found here: [Innova SARS-Cov-2 Antigen Test IFU](#)

## 5 Workforce

A workforce blueprint has been developed to outline the organisation structure required for a LFD testing site (please refer to the ATS Workforce Blueprint document for more detail). The key roles outlined in the blueprint in order to operate a workplace testing site are as follows (note some roles can be removed or merged for smaller testing sites):

Site Roles	Staff Positions	Key Responsibilities
Team Leader	Team Leader*	<b>Responsible for the overall on-site operations at the test site, including day-to-day workforce management.</b> <ol style="list-style-type: none"> <li>Running day-to-day operations including on-site workforce management, managing site health &amp; safety and receiving and managing stock</li> <li>Point of escalation for any issues on site, and escalates to local public health officials as appropriate</li> <li>Ensure adherence to SOP and clinical guidance is maintained throughout operations</li> <li>Responsible for safety and security of the site</li> <li>If subjects raise any data privacy concerns, directs subjects to the Data Privacy Notice which explains how we will use their data (<a href="https://www.gov.uk/government/publications/coronavirus-covid-19-testing-privacy-information">https://www.gov.uk/government/publications/coronavirus-covid-19-testing-privacy-information</a>)</li> </ol>
	Queue Coordinator	<b>Ensures orderly entry of subjects onto the testing site.</b> <ol style="list-style-type: none"> <li>Ensures crowd control and social distancing is maintained in subject queueing areas</li> <li>Monitor subjects in the queue who are showing symptoms of COVID and acts accordingly if they are</li> <li>In case of long queue, encourages people in line to start registering online</li> <li>Supports general site set up, including appropriate signage to manage subject flow</li> </ol>
Site Operative	Registration Assistant	<b>Responsible for ensuring subjects have registered and distributing test kits on arrival.</b> <ol style="list-style-type: none"> <li>Greets subject at arrival, asks them to sanitise hands and ensures the subject is eligible for asymptomatic testing</li> <li>Aids the subject in registering for the test if they are unable to</li> <li>Provides assistance for people who might not have the relevant digital information such as phone number and email address</li> <li>Guides people who are coming and for a valid reason need to test anonymously</li> <li>'Drip feeds' subjects into testing area, ensuring testing area does not exceed maximum capacity</li> <li>Communicate to test subjects the purpose of participating in testing at your site and the testing journey.</li> </ol>
	Test Assistant	<b>Provides guidance to subjects on swabbing as requested, and ensures cleaning of booths or sample collection station.</b> <ol style="list-style-type: none"> <li>Directs subject to available testing stations and directs them to the exit when they are finished</li> <li>On hand to provide subject with additional verbal instructions if required</li> <li>Provides regular cleaning to testing stations throughout day (subjects are also asked to self-clean between each test)</li> </ol>
Testing Operative	Processing Operative	<b>Prepares test sample for analysis and interprets result.</b> <ol style="list-style-type: none"> <li>Sets up sample for analysis, and pipettes reagent to sample</li> <li>Times the sample analysis</li> <li>Await and read result displayed, and mark it on device</li> <li>Provides to Results Recorder to upload to digital platform</li> </ol>
	Results Recorder	<b>Collates results from Processing Operatives and uploads to digital solution.</b> <ol style="list-style-type: none"> <li>Reads test result outcome (marked by Processing Operative)</li> <li>Enters result into the results logging web app, if using a locally provided device, or native iOS results logging app, if using a DHSC provided managed device. This includes scanning of QR code (result is automatically sent to Test &amp; Trace)</li> </ol>



\*Several Supervisor or Deputy Team Leader roles may be needed for larger sites. Where this is the case, it is recommended at least one Supervisor for all testing roles should be included, who will also provide QA to testing operations. It is advised the span of control does not exceed 15 people on per supervisor role

Workforce roles included only cover site operations workforce. Additional resource will be required for central planning at a Local Authority level.

A quality and clinical governance lead is not included in this blue print as this function is expected to sit within the relevant accountable organisation, but may need to be considered as a specific role in some workplace testing site settings.

An appropriate training package should be in place for operators to be trained to be able to conduct the test in a safe and effective manner. As a minimum to be fit for purpose this package should include the following:

- Watching approved video package which demonstrates how physical tests are conducted
- Read through of materials outlining the infection prevention and control measures and the appropriate use of personal protective equipment, including the proper procedure for donning and doffing PPE. Also an understanding of how to deal with any contamination or other untoward incidents
- Regularly undertaking updated online training to ensure standards are adhered to and any new requirements are included. The frequency of this training to be assessed by Workforce team and agreed by each use case.
- Undertaking a number of tests under supervision
- Regular audit of performance and overall testing process
- Instruction on how to report adverse incidents internally and to the MHRA yellow card scheme <https://coronavirus-yellowcard.mhra.gov.uk/>

Please liaise with the Workforce team to access the latest training materials.

The roles and responsibilities will need to be adapted on a site to site basis, depending on the size and set up of the sites. Some roles can be removed or merged, whereas some roles may need to be added or adapted for setting specific requirements.

It is understood that the organisation test site will involve oversight from business as usual operators such as a First Aider.

The ratio of personnel required to participants is dependent on type of setting, numbers tested and area of testing place used. While the specific staffing requirements are dependent on the use case or organisation, the procedures described in this document including but not limited to PPE instructions, cleaning, waste management are to be followed under all circumstances.

## 6 Site Set-up

### 6.1 General site set-up

Before any site is chosen and set up the following need to be considered:

- Specify infrastructure, flooring and equipment
- Layout and traffic flow including risk mitigation
- Define who is accountable and responsible
- Management of healthcare waste generated

Before testing can begin, the site operator will identify and set up a clinically suitable testing environment on, at or near their premises. The test site will make considerations for, including but not limited to:

- Social distancing before, during and after the test
- PPE required, as in line with the latest clinical guidelines
- The clinical guidelines on personal and spatial hygiene
- Consideration of the need for privacy for participants to self-administer a test
- Health and safety, disability access, and fire safety regulations that govern deployment sites
- Washrooms for test samples are not appropriate due to the potential of contamination of equipment/test etc.
- Ready access to hand hygiene (soap and water/appropriate alcohol-based hand rub)
- Ideally the flooring is easy to clean and carpeted flooring should be avoided. If carpet cannot be avoided, a covering material which is easily cleaned (such as plastic sheeting) should be installed over the carpet and the host organisation should complete a risk assessment to highlight the control measures which will be put in place in order to mitigate against the risks of using this flooring
- The testing area, sample collection stations and privacy booths should be easy to clean and sterilise
- All surfaces should be de-cluttered of equipment that is not required to run the testing
- Sufficient room for storage

An organisation's test site may be set up as any one of the two following types:

- Indoor (most likely)
- Outdoor (this has not been piloted yet)

Infrastructure, flooring and equipment in all test settings must be approved as suitable for use both in the testing process and to allow for appropriate cleaning to be carried out to minimise the risk of virus transmission. Layout and subject flow will vary from site to site, depending on available space and physical constraints, with plans agreed during site activation. Perimeter fencing or an enclosure restricting access to site may be required.

The specific configuration of an organisation site will depend on infrastructure and environmental constraints. However, where possible, testing will be conducted on multiple participants in parallel. This may be performed at adjacent sites, and/or in multiple lanes, using a one-way system. Social distancing measures put in place by the organisation will be adhered to in the design of the sampling location(s).

The site layout may involve the following:

#### **Queuing area:**

- a) External access way in / queuing area for site arrivals.
- b) Distinct barriers will ensure social distancing between Subjects and the general public

**Welcome desk:**

- a) This will be the initial point of encounter with subject.
- b) Demarcated one-way system for subjects
- c) Check-in point where subjects receive test kits, peripherals and instructions, before being directed to a testing bay/testing assistant

**Sample collection:**

- a) Demarcated one-way walking system and traffic flow
- b) Multiple sample collection stations or booths
- c) Demarcated exit route

**Processing and results area:**

- a) Desk for timing the development of LFDs
- b) Desk with computer for subject registration
- c) The preparation and analysis process is administered in line with manufacturer instructions for use

**Waiting area (optional):**

- a) Area for subjects to wait on-premises while results are processed
- b) Demarcated area to maintain social distancing and an appropriate queuing system

If the site has a waiting area, there should be clear reinforcement of the requirements for 2m social distancing, wearing face coverings and other control measures throughout the end to end process. There should be a robust process for assurance of these measures. There should be a designated individual with the responsibility to ensure these measures are being adhered to and to collate a daily report on this.

**Storage area**

To ensure safety procedures are followed at the test site the following measures are taken:

- a) Adequate signage to ensure subjects comply with one-way flow and socially distanced queueing.
- b) Subjects will be organised into test groups to manage cadence and testing safety
- c) Waste is disposed of according to agreed protocol with respect to the respective waste stream described in the waste management section (differentiating healthcare and non-healthcare waste)
- d) Any non-PPE wearing personnel are kept at an appropriate distance or in designated 'safe' zones – however it is expected that all staff involved in the front-end testing operations will be compliant with PPE guidelines set out.
- e) There are adequate safety procedures / policies in place to support staff in how to address:
  - i. a serious medical emergency
  - ii. fire evacuation
  - iii. a staff member who feels unwell / develops COVID-19 symptoms
  - iv. a spillage

We recognise that an Employer or host organisation 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 employer/host organisation, it is expected that organisations will understand the following site considerations:

1. Test Site staff should be allocated to the Test Site full time to provide a dedicated and consistent Testing service
2. Test Site should be separate from the main area of business operations for privacy, safe queue management, and to limit disruption to both testing and BAU activity
3. 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

4. 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
5. Fire, health and safety, and evacuation routes should be clearly marked in line with the rest of the building
6. 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
7. Clinical test site and non-healthcare BAU 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 organisation protocols for making the area safe, it is the organisation'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 organisation 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, if possible, arrange to travel home and follow the latest government guidance on treatment (this may involve contacting the prescribed emergency number where necessary). No clinical advice other than first aid should be provided to a staff member by another staff member. 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.

## 6.2 Testing site set-up:

Please refer to section Appendix C, for layout examples.

The specific configuration of an organisation site will depend on infrastructure and environmental constraints. However, where possible, testing will be conducted on multiple participants in parallel. This may be performed at adjacent sites, and/or in multiple lanes, using a one-way system. Social distancing measures put in place by the employer or host institution will be adhered to in the design of the sampling location(s).

Sample collection stations will be arranged as appropriate for each test site.

Sample collection station will have a supply of surface disinfectant and alcohol-based hand rubs. A sick bowl will be placed near the front of the sample collection station so that they remain accessible to the subjects if needed.

Each collection station will be overseen by a Test Assistant. Consideration should be given to the need for privacy from the subject's colleagues / other subjects.

Testing sites are intended to be set-up at fixed locations indoors in a dedicated separate area within another complex (e.g. university, community hall, church hall, event or function room). The specific configuration of a test site will depend on each use case, however the principles of the design will comprise the following layout components:

- a) External access way in / queuing area for site arrivals, distinct barrier that ensures social distancing between Subjects and the general public
- b) Check-in zone: Subject receives kit, peripherals and instructions, before being directed to a testing bay
- c) Testing booth (*where provided*): A dedicated test booth containing a table, chair (optional), mirror, healthcare waste bins (separate bins for chemical e.g. used test kits and PPE/wipes), alcohol-based hand rub dispenser and instructions on the wall. It is advised that each test booth will be a minimum of 1.2m X 1.2m. Two of the sides may contain a solid partition, whereas one wall will face the receiving bench (where the Test Assistant will be monitoring) and will contain a protective plastic screen, with an open slot where the Subject can pass their sample through. The booths are intended to offer privacy from other Subjects.
- d) Sample collection station (*where provided*): where "open plan" sample testing stations are provided these should comprise at a minimum: table, healthcare waste bins (separate bins for chemical e.g. used test kits and PPE/wipes), alcohol-based hand rub dispenser and laminated instructions. Optionally a mirror and chair may be provided. The station should be constructed in such a way as to maintain 2m social distancing.
- e) The proposed 'screen' for 'minimum build' or 'desktop' testing is clinically and operationally advisable but not mandatory for testing in close proximity without partitions. The screen minimises subject and operator discomfort, provides additional protection from adverse reactions to the swabbing process (vomiting, sneezing etc.) and enables lower cost mirrors and instructions to be stationed at each swabbing location without disposing of them between each subject attending.
- f) Receiving area: located on the opposite side of the testing booths. No partitions between booths, rather the receiving bench will allow the Test Assistant to observe up to 5 booths.
- g) Prepping space: area where Processing Operatives work
- h) Cleaning area
- i) Demarcated exit route
- j) Internal queuing area with social distancing.

### 6.3 Set-up for analysis:

Testing will be conducted on a flat surface with adequate light.

Reagents and devices must be at room temperature (15–30 °C) when used for testing.

The analysis area will include dedicated space for:

- LFD timing, reading and recording
- Results uploading

Required at workstation:

- LFD cartridges
- Extraction solution
- Extraction tubes
- Extraction tube nozzles
- Tube rack
- Healthcare waste bins: these bins should have a lid that is operated 'hands free' (e.g. with a foot pedal), be made with a surface that can be cleaned without compromising the integrity of the container, be fire retardant and have smooth surfaces to prevent debris formation
- Appropriate cleaning product (Refer to Section 11.2) i.e. combined disposable wipes
- Paper towel roll
- Pen/Pencil
- Timing clock(s)
- Permanent marker pens (see below: for requirements)

- Trays (to be cleaned with alcohol after each LFD batch has been transferred to the processing/results table)

## 7 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.

#### 7.1 Eligibility

Subject eligibility criteria will be prescribed by the organisation, but the following assumptions apply:

- The subject will be the responsibility of the organisation under consideration (e.g. an employee)
- The subject will be asymptomatic
- The subject will consent to participation in the test
- The subject will consent to sharing their data with the National T&T programme
- Young people aged 16-17 can self-swab

#### 7.2 Initial case finding for Daily Contact Testing

[Sections 7.2.1 - 7.2.4 are only relevant for Pilots using Daily Contact Testing. Please refer to the Appendix for the information to be added to this Section where relevant]

#### 7.3 Registration

Subjects will be identified by the Employer. The Employer will inform their subjects of the purpose of the study, the testing process and their responsibilities as a participant, and how their data will be used by DHSC and NHS Digital.

The Employer will organise their subjects, at their discretion, into testing groups to set the cadence of testing – this will help control the flow of subjects and maximise safety. Within the scope of this SOP, weekly testing is assumed but the testing cadence will depend on factors, including but not limited to, workforce, resources, and Public Health England/DHSC guidelines for your scenario.

Subjects will be required to register for each test they take using the gov service:  
<https://gov.uk/enter-lateral-flow-test>

They must do this after they have received a test kit barcode and can be done before or after completed a test (swab). This will link their personal details to a test record and allow their results to be issued. You may be required to help your employees through this process at their request.

### 7.3.1 Need for consent

Organisations 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. Organisations must make sure that they seek the appropriate consent and that the people who are providing consent are fully informed to make the decision.

## 7.4 Face coverings

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).

Please note the face covering requirements, including age specifications, may vary in the Devolved Authorities.

## 7.5 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 in accordance with the local process agreed by their operating organisation (the institution running the test site) and consent to participate in testing at the site.
3. Subjects will be prescribed a test time slot and/or test group (subject to factors such as organisation site location, size, and the number of participating subjects)
4. The organisation will mobilise and set up the test facility:
  - a) Order or be provided with enabling, clinically-appropriate materials including, but not limited to, test kits, PPE, test-site infrastructure, waste management etc.
  - b) Identify and train test site operators
  - c) Prepare for testing run through
5. Carrying out the throat and mid-turbinate nasal swab
  - 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 throat and mid-turbinate nasal 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
6. Samples will be analysed
  - a) Analysis conducted on-site by the Processing 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 tray must be kept horizontal.
7. Sample matching and results notification
  - a) Results will be captured by the Results Recorder
  - b) Results of LFD will be shared with the national testing 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
- 8. Follow up of results
  - a) The employer or host institution and subject will follow Public Health guidelines and procedure on follow up

\*Exclusions (those non-consenting to test, parental refusal, unable to self-swab)

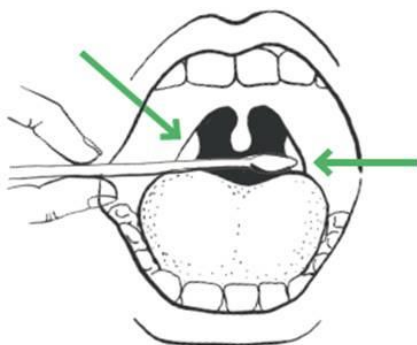
## 7.6 Detailed testing process

### 7.6.1 Self-swabbing sample collection procedure:

Subjects will be given a sealed sterile swab in 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. The subject should have been asked to avoid eating or drinking for at least 30 minutes before taking the test to reduce the risk of spoiling the test.

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 mask 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 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, for example if they have had a tracheostomy, they should instead swab both nostrils.



*Figure 1 Swab rubbing the tonsil*

4. The subject should complete hand hygiene using the alcohol based hand rub provided in the booth
5. The subject should identify the soft, fabric tip of the swab its sealed, sterile packaging, peel open the packaging and gently remove the swab whilst taking care to not touch the soft, fabric tip of the swab
  - 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 (chemical) 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.**
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 mid-turbinate nasal swabbing can be used.
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 Section 11.2)
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.

### 7.6.2 Sample processing and analysis procedure

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

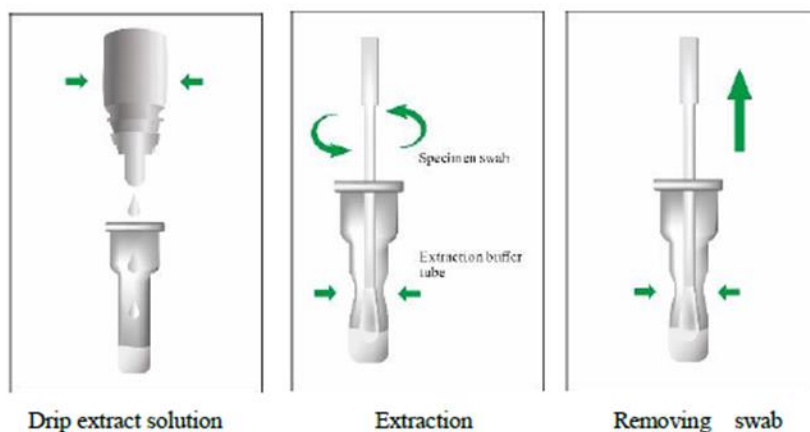
The Processing Operative should only process one sample at a time.

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) 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.
    - 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.
  - c) 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
    - 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)
  - 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.

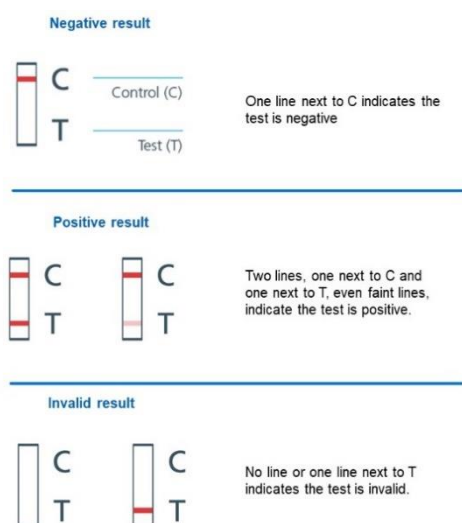
### 7.6.3 Reading and interpreting LFD result

1. Reading: The result is read by staff according to manufacturer IFU between 20 and 30 minutes
2. Results Interpretation:

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

If a positive signal appears after 30 minutes, it should not be reported as positive. Line C must be coloured to have a valid test result.

*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 showing as follow pictures, indicating that there is SARS-CoV-2 antigen in the specimen.

#### Invalid results:

There is no coloration on line C, as shown in Figure 3. The test is invalid or an error in operation occurred.

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

3. 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 – removed any time before 30min
  - 'V' mark for invalid – removed 30min after "drop"
  - '-' mark for negatives – removed 30min after "drop"
4. The LFD can then be moved to the next station for data logging/result recording
5. The area where the device was situated is then cleaned after it has been removed

#### 7.6.4 Recording of results

##### **Results logging using 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 Section 11.2)
5. Once result has been logged, the LFD are disposed of as per the requirements outlined in the waste management section (0).

##### **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 photo 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 Section 11.2)
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 of 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.

#### 7.6.5 Communication of results

If giving the result in person (in the context of a workplace testing site), this needs to be delivered using a prepared script, and people will be advised to contact one of the NHS T&T nurses for further advice if necessary. This script should include (but is not limited to):

- Detail of the result (negative, void, positive)
- Instructions on what to do for void results (retest LFD, register for home PCR)
- Instructions on what to do for positive results (go home immediately and follow self-isolation guidelines)
- Travel advice for subjects
- How to register for a confirmatory test (where applicable)

The ATS will analyse the sample and upload the test results linked to the barcode to NHS Test & Trace digital system. The ATS is unable to link any results to individuals. The Test & 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.

### 7.6.6 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 void) provided the correct demographic information is provided. This has been agreed with Joint GP IT Committee.

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. 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.

### 7.6.7 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) or 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 and the use of face coverings.

### 7.6.8 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](https://www.gov.uk/get-coronavirus-test) and choose 'home testing' (do not choose a test site).

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

### 7.6.9 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.

3 days after the LFD positive result the subject will receive a follow-up text message to ensure they and everyone in their household continue to self-isolate for 10 days. If they or anyone in their household get symptoms, they should self-isolate from the day symptoms started and for the next 10 full days. The subject can return to work the day after you finish self-isolating if you've not had a high temperature in 48 hours, even if you still have a cough. Contact your employer first.

Please note the above guidance does not apply to testing in the Devolved Authorities, Care Homes or self-reporting (see below).

#### **Confirmatory testing:**

Public Health England have informed Directors of Public Health of their decision to temporarily suspend the requirement for routine confirmatory PCR for positive LFD results while prevalence is very high nationally (the proportion of false positives compared to all cases decreases as prevalence rises). This change is effective as at 27<sup>th</sup> January 2021..

The suspension will apply to test sites in England offering assisted testing (where results are logged by a member of the ATS using Log results portal/app). In this situation, a positive LFD result triggers the need for self-isolation (as described above). Under the new system, a positive LFD result will trigger: the legal duty to self-isolate; eligibility for support payments; and contact tracing for those who do not report their own LFD results.

Confirmatory PCR testing will remain for NHS England staff and in Adult Social Care, where the test is taken as part of an asymptomatic testing workplace programme and results are registered using a self-reporting tool. It will also remain for primary school workers where testing is done at home, but not for secondary school workers who take tests at school. Utilising confirmatory PCR in settings that use a self-reporting tool will minimise the risk that incorrectly reported positive results are registered. Confirmatory PCR testing will also be used for vaccine and LFD testing surveillance, genome sequencing and for self-administered tests.

Scotland, Wales and Northern Ireland will continue to use confirmatory PCR testing, in accordance with the decisions of their Chief Medical Officers.

For testing services where confirmatory PCR will continue:

- The legal duty to self-isolate and tracing period will continue to be triggered by a positive confirmatory test result.
- Subjects in these situations must continue to take a different follow-up test on the same day (or as soon as possible) after receiving a positive LFD result. They should follow the instructions given to take the follow-up test.
- If not given instructions at the Test Site, they should go to [www.gov.uk/get-coronavirus-test](https://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.
- The subject and everyone in their household are required to self-isolate immediately for 10 days. This includes the day of the test and the next 10 full days (or 14 days for Care home residents). The subject can leave their home for the follow-up test.
  - If the follow-up test is negative, the subject can stop self-isolating.
  - If the follow-up test is positive, the subject will need to self-isolate for 10 days from the time of the positive test.

#### 7.6.10 Travel advice for positive results

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

- Travel home immediately, wearing a face covering
- Wherever possible they should travel home in their own vehicle or by walking or cycling
- If it is not possible to do so, they should arrange for a member of their household to pick them up
- Positive cases should follow national guidance provided by the Department for Transport when travelling home
- Asymptomatic contacts of positive 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.

#### 7.6.11 Repeat testing

Current advice is that for most use case scenarios a previous PCR positive test is likely to make testing with an LFD antigen test not necessary. However, as the evidence base regarding this is awaiting full assessment and policy implementation, it is recommended that individuals are informed testing may not be necessary but is still an option. Before implementation, use cases should always consider the public health aims and implications of not testing, e.g. where the aims are in the context of risk reduction, rather than case finding, and are in a high risk setting for potential harm then full testing should still be encouraged. Specific guidance should be sought if there are particular concerns.

If you have recently (within 90 days) tested positive for COVID-19 (and where appropriate had this test confirmed), you are likely to have developed some immunity, and therefore a repeat LFD test is unlikely to be necessary within this period. However, subjects can take an LFD test after the isolation period and the decision to do so will depend on the local testing regime. If having recently tested positive for COVID-19, you choose to have an LFD test as part of this programme, please ensure the LFD test is not taken whilst still within your period of isolation following the last confirmed test. If symptoms [other than cough or a loss of, or change in, your normal sense of taste or smell] persist, this could be longer than the normal 10-day self-isolation period for confirmed cases. This is described in [Stay at home: guidance for households with possible or confirmed coronavirus \(COVID-19\) infection](#).

#### 7.6.12 Contact Tracing

The Employer is encouraged to contact PHE and/or their local authority to seek guidance or support contact tracing

Contact tracing within the workplace will be controlled and managed by the Employer following the latest clinical definition of contact while making consideration and concession for any preventative infection control measures that are in place which may reduce the risk of transmission. This may include, but is not limited to, on-site PPE, PVC barriers or plexiglass barriers between individuals and frequent hand hygiene.

At October 2020, the definition of contact, precluding infection control and social distancing measures, is:

- Be within 2 meters of an individual for 15 mins or more
- Be within 1 meter of an individual for any period of time



The definition of contact is available on:

<https://www.nhs.uk/conditions/coronavirus-covid-19/self-isolation-and-treatment/when-to-self-isolate-and-what-to-do/>



## 8 PPE

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

Role	Disposable gloves	Disposable plastic apron	Fluid-resistant (Type IIR) surgical mask (FRSM)	Eye protection
Processing Operative <sup>2</sup>	✓	✓	✓	✓
Indicates single or sessional use	Replace after each <u>test (single)</u>	Replace after each <u>session</u>	Replace after each <u>session</u>	Replace after each <u>session</u>
Cleaning Staff <sup>3</sup>	✓	✓	✓	✓
Test Assistant <sup>4</sup>	✗	✗	✓	✗
Site Coordinator / Team Leader	✗	✗	✓	✗
Registration Assistant	✗	✗	✓	✗
Results Recorder <sup>5</sup>	✗	✗	✓	✗
Supplies Coordinator	✗	✗	✓	✗
Queue Coordinator	✗	✗	✓	✗
Indicates single or sessional use	Replace as indicated in notes <sup>6</sup>	Replace after each <u>session</u>	Replace after each <u>session</u>	Replace after each <u>session</u>

Notes:

- 1) Anything not identified as “single use” is for “sessional” use (a session ends when a worker leaves the care setting, fresh PPE is used at the start of each session) i.e. at break or end of shift. PPE is sessional however should be changed if protective properties are compromised or contaminated from secretions.
- 2) Processing Operatives should wear apron/visor and mask sessionally and change gloves between samples.
- 3) Cleaners need to change gloves and apron if cleaning a spillage
- 4) In this SOP the Test Assistant is not administering the swab and is only supervising, therefore Test Assistants do not need to wear apron, gloves and visor, but they need immediate access to gloves if intervening
- 5) Results recorders are not expected to be handling the LFD cartridge. If required to intervene and handle devices they should have gloves available as an exception and take off and dispose of gloves after completing the activity or task
- 6) Use of gloves:
  - Gloves are single use items and should be changed after each use or upon completion of a task
  - If single-use disposable gloves are used they **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**

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.

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

Cleaners should only be entering the testing area when testing activity is no longer being conducted. In accordance with NHS guidance ‘*Cleaning and Disinfection process COVID -19*’ there should be no subject contact within 2m and fluid resistant surgical masks type IIR are to be worn in all non COVID secure areas by cleaning staff.

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 below in the Appendix of this document.

## 9 Supply & Equipment

DHSC support team will provide sample collection kits and lateral flow antigen test devices to the employer or host organisation.

DHSC will provide:

- Sample collection kits (all types including registration cards and barcodes)
- Lateral flow devices (all types)

The organisation will take responsibility for managing, tracking and ordering all other equipment required for the set-up and day to day running of a test site, including but not limited to:

- PPE (including gloves, aprons, masks, goggles/visors)
- Medical consumables (including cleaning agent, tissues)
- Physical infrastructure including toilets
- Signage
- Consumables (non-medical) (including catering)
- Safety (can include fire extinguishers, defibrillator)
- Healthcare waste (including bins, bags, containers)
- General waste (including bins, bags, containers)
- Miscellaneous (including mobile devices, scanning devices, whiteboards, printers, tools)

*Note: A detailed list of all the entire site inventory will be made available to the organisation*

## 10 Data Management

### 10.1 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)

## 10.2 Consent from the data subject

The organisation 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 organisation is responsible for capturing consent. The organisation must store a copy of the subject's consent for the duration of the workplace testing site.

### ***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

## 11 Appendix A: Infection Prevention and Control (IPC)

### 11.1 General guidance

No subjects should attend the testing location with symptoms of COVID-19. The on-boarding operative will ensure eligibility as per section: Subject eligibility.

Any non-compliance will be escalated through existing organisation 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 COVID-19: <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-and-control>

All workers on site must be fully briefed and trained about PPE and IPC standards, including those approved by the NHSE/IPC Cell. Guidance of IPC standards must be clearly displayed at all sites. All staff members are encouraged to not neglect the importance of hand hygiene, not to touch their face whilst working with samples, and importantly stay at home if they develop COVID-19 related symptoms.

Testing procedures incorporate IPC guidance, to prevent potential contamination of staff members and subjects whilst operating the testing site.

On-boarding operative staff will focus on maintaining social distancing when communicating with subjects.

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

1. Hand washing
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, in accordance with government guidance
5. Equipment distancing and cleaning
6. Effective segregation and disposal of waste

### 11.2 Cleaning policy

Regular cleaning plays a vital role in limiting the transmission of COVID-19. 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. The frequencies of the frequent clean is dependent on the number of people using the space, whether they are entering and exiting the setting and access to hand hygiene i.e. hand washing or use of an alcohol-based hand rub. 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, avoid Subject contact within 2 meters and change their PPE after cleaning.

In view of the minimal level of spillage expected, the following cleaning guidelines must be respected:

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 and place in the offensive waste bin (tiger bag)**
3. If disposal wipes are used, if a disinfectant wipe i.e. alcohol wipe is used, the area must be cleaned with a detergent first (see below) to enable the disinfectant to achieve the outcome required
4. Any cloth and mop heads used for cleaning must be disposed of and should be placed into the offensive (tiger bag) waste bin provided
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

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 contact 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 within the organisation 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.

Any cloths and mop heads used must be disposed of and should be put into the offensive waste stream (tiger bag) as outlined in this document

The minimum specifications stipulated by the government for surface disinfectant wipes, is that the disinfectant is effective against envelop 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.

### **Disposable cleaning wipes**

If a disinfectant wipe is used, it is important to note that they do not contain a detergent. If this method is used, a two-stage process is required, the area requires to be cleaned properly with a detergent, rinse, dry before a disinfectant wipe is used.

Where possible use a combined wipe (wipe has a detergent and disinfectant combined), this will be a one-stage process.

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

## Efficacy testing standards:

Bactericidal activity (antimicrobial)	EN 1276, EN14348, EN 13727, EN1040, EN1499
Fungicidal / yeasticidal activity	EN 1650, EN 13624
Virucidal activity	EN 14476

## Labelling Requirements

- Brand name
- Product Description
- Disposal method warning
- Quantity of wipes
- Safety Precautions
- BS EN number to which the products conforms
- Manufacturer details
- Single Use (indicated with a symbol of a 2 in a circle with a line through it)
- CE Mark
- LOT number
- Expiry date (this is often indicated with a symbol of an egg time)
- Table with contact times required to achieve sanitation against specific microorganisms (not a specific requirement, but very useful information)

## 11.3 Hand sanitisation

Performing hand hygiene means the physical removal of visible dirt, blood and body fluids as well as microorganisms, it has a dual role in protecting others and the member of staff from acquiring microorganisms, which may cause them harm.

**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.
- Ensure fingernails are clean and short, and do not wear artificial nails or nail
- 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

**When to perform hand hygiene?**

Hand hygiene must be undertaken at critical points in order to prevent cross transmission, following World Health Organization (WHO) '5 Moments' principles, including before putting on and after removing gloves and other levels of personal protective equipment:

- Before touching a Subject
- Before carrying out a procedure
- After body fluid exposure risk
- After touching a Subject
- After touching Subject's immediate surroundings

## 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/ 2019)

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

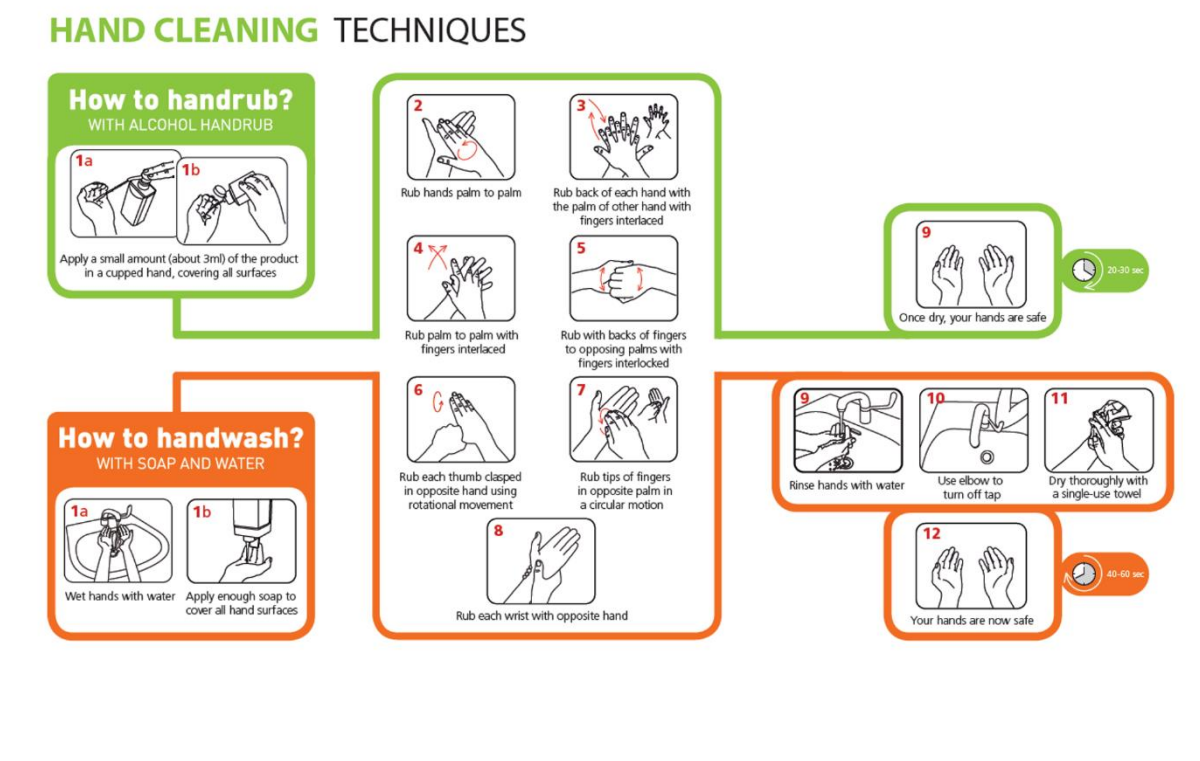
**Washing:** hands must be vigorously rubbed together following the hand washing technique. Rinse off the liquid soap under running water

**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.

Appropriate hand cleaning techniques can be found in the schematic below:





## 12 Appendix B: Waste Management

**Please note that this guidance will need to be reviewed by the relevant agencies in Devolved Administrations for local application as they may require specific changes to be made to align with their regulations.**

### 12.1 Classification

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 Testing 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.

### 12.2 Regulatory Position Statement C23

The Environment Agency has published RPS C23 Incinerating specified healthcare wastes at a municipal waste incinerator: which can provide an option of disposing of these mass testing wastes via municipal waste incinerators in England, even if the incinerator operator does not have the appropriate waste codes on the permit.

For further details see:

<https://www.gov.uk/government/publications/coronavirus-covid-19-lateral-flow-tests-waste-codes/waste-codes-for-mass-testing-with-lateral-flow-antigen-testing-devices>

### 12.3 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 Local Authority (LA) and/or 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 safety 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 EFW/Municipal incinerators area 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 incinerate 18 01 04 and 18 01 047 wastes and reliance on the RPS C23 may be required contact the incinerator operator to confirm that they will accept the waste and in what form it needs to be delivered
- Where incinerator operators are willing to accept the waste ensure that the obtain permission from the local Environmental Agency Officer and demonstrate that they can meet the conditions set out in the RPS
- Once they have confirmed that permission is in place, arrange a disposal collection schedule



## 12.4 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).

## 12.5 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 not transported as Category B waste)

## 12.6 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) markings
- Yellow bag with a black strip (tiger bag)

## 12.7 Storage: 72 hours storage and reclassification is not acceptable

Double bagging and allowing a 72 hour holding period in a secure place, prior to the waste being disposed of in the household waste is only applicable to household produced waste and is not fit for purpose approach for the disposal of waste generated at test sites, including mass testing.

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 allows waste management companies to dispose of COVID-19 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](mailto:covidsupplies@speedyservices.com)

Please be aware that it is not acceptable to store chemical healthcare or offensive waste for a prolonged period of time e.g. 72 hours and then dispose of via municipal route. Waste in these categories must be treated in accordance with the instructions below.

## 12.8 Waste streams for Asymptomatic Testing Site - Lateral Flow Testing

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
<b>General Waste</b>	Sandwich wrapper	Domestic/ recycling	20 03 01	1 <sup>st</sup> Option: Materials Recovery Facility 2 <sup>nd</sup> Option: Energy from waste 3 <sup>rd</sup> Option: Landfill	Not applicable
<b>All packaging</b>	Outer packaging on equipment	Domestic / recycling	15 01 01 15 01 02 15 01 05 15 01 06	1 <sup>st</sup> Option: Materials Recovery Facility 2 <sup>nd</sup> Option: Energy From Waste 3 <sup>rd</sup> Option: Landfill	Use existing municipal route
<b>Swabs</b>	Absorbent pads Vials Tissues	Chemical	18 01 07 Plus 18 01 04	1 <sup>st</sup> Option: Energy from Waste 2 <sup>nd</sup> Option: Municipal Incineration 3 <sup>rd</sup> Option: Clinical Waste Incinerator	1 <sup>st</sup> Option: Unmarked yellow neutral container/bag 2 <sup>nd</sup> Option: White / clear container/bag 3 <sup>rd</sup> Option: Tiger bag <b>Do not use hazardous waste packaging</b>
<b>Cartridges / Devices</b>	LFT cartridge	Chemical	18 01 07 Plus 18 01 04	1 <sup>st</sup> Option: Energy from Waste 2 <sup>nd</sup> Option: Municipal Incineration 3 <sup>rd</sup> Option: Clinical Waste Incinerator	1 <sup>st</sup> Option: Unmarked yellow neutral container/bag 2 <sup>nd</sup> Option: White / clear container/bag 3 <sup>rd</sup> Option: Tiger bag <b>Do not use hazardous waste packaging</b>
<b>Personal Protective Equipment</b>	Apron Face mask Gloves	Offensive	18 01 04	1 <sup>st</sup> Option: Energy for waste 2 <sup>nd</sup> Option: Municipal Incineration 3 <sup>rd</sup> Option: Landfill (last resort)	1 <sup>st</sup> Option: Tiger bag

## 13 Appendix C: Site Layout

There are two main design options for Test Site layout depending on the space available and the desired throughput.

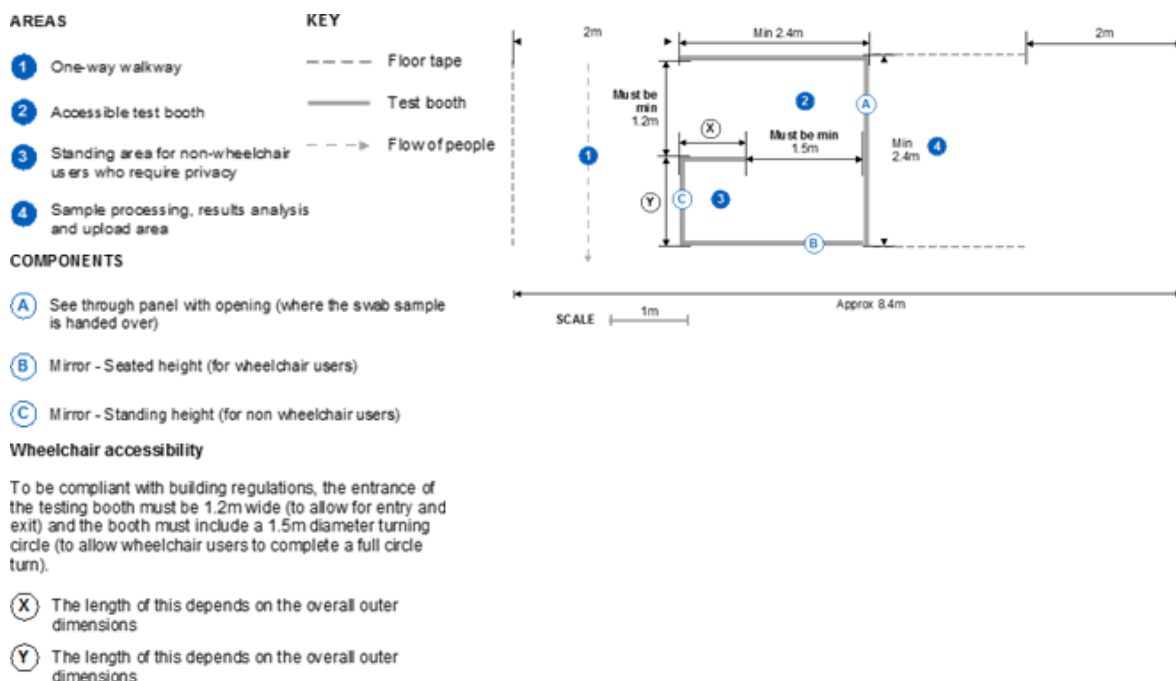
**These designs are being continually refined based on feedback from organisations and final designs will be subject to NHS IPC Cell review.**

### 13.1 Booth layout

Features of the booth layout include:

- Useful if test site space is limited
- Offers privacy for testing (requires walls or screens to be set up to create booths)
- A booth with accessible access may be required, which has larger dimensions than a standard booth
- Low throughput: Small or mid-size room suitable for the construction of a single or several booths
- High throughput: Conference room or large open area for the construction of multiple booths

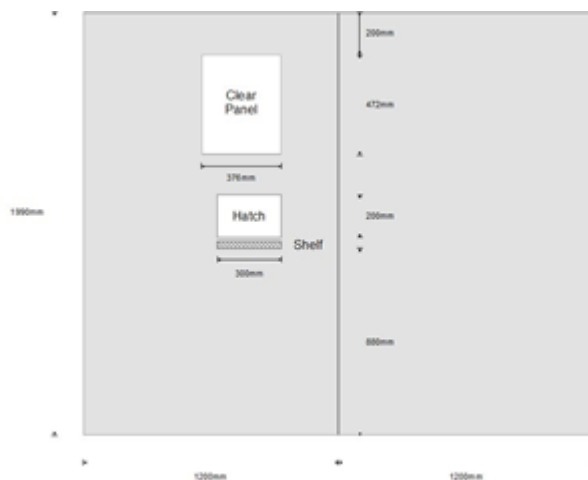
#### 13.1.1 Single booth layout



### 13.1.2 Booth layout: further requirements

Along the front panel of the booth, there will be a clear screen and a 'hatch'. It is recommended that the front panel adhere to the following criteria:

- The opening on the front panel must be wide enough for the subject to pass a 15cm long swab through to the Processing Operative without touching the sides. Ideally the opening is 200mm in height and 300mm wide.
- A ledge is required that is perpendicular to the hatch, that must be large enough for a subject to place a swab, bar codes, tissue and other supporting equipment e.g. scissors. The minimum depth is 200mm
- The clear screen should be large enough so that it is reasonable for the Processing Operative and subject to maintain clear line of sight
- Proposed dimensions of the front panel are:



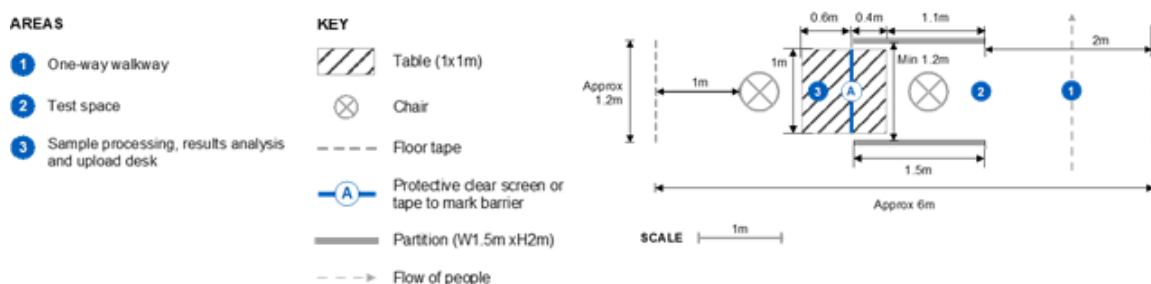
The booth materials (all sides) need to be made with a material that can withstand cleaning using an agent that is 1,000ppm chlorine.

## 13.2 Open plan layout

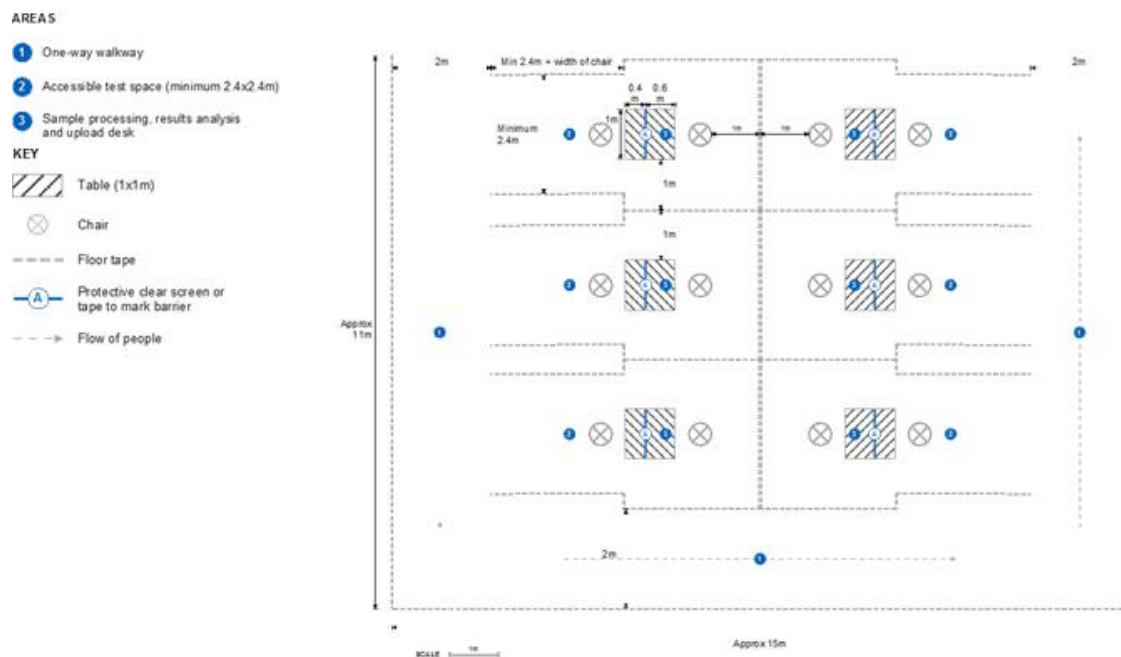
Features of the booth layout include:

- Single or multi-table layout in an open plan space
- Requires more space than a booth layout due to social distancing requirements
- Suitable for single room/office space, or large test site area that can be demarcated with tape
- Low throughput: Small room for single test and analysis table
- High throughput: Large open test area for multiple tables

### 13.2.1 Single open plan layout



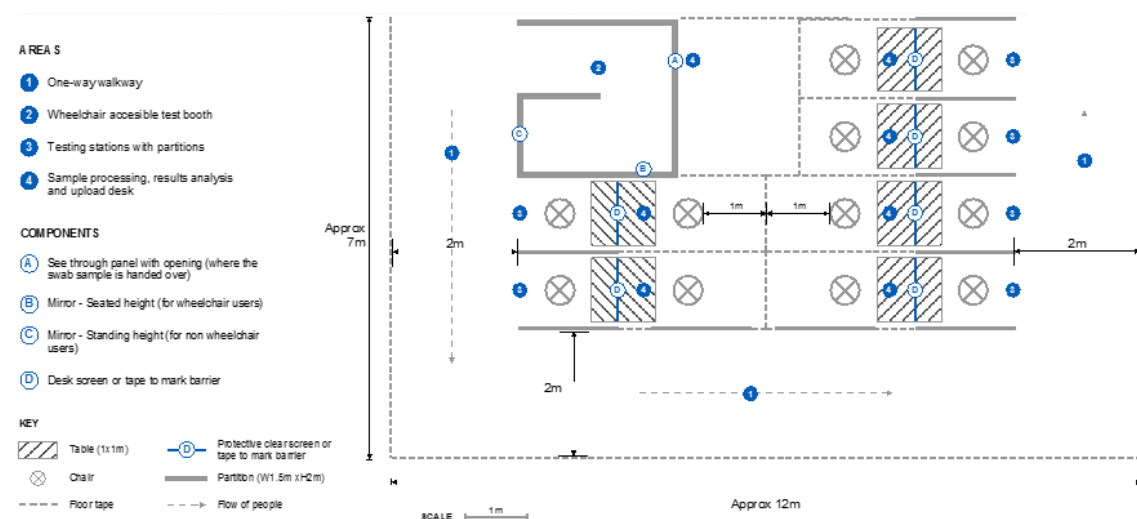
### 13.2.2 Multi-open plan layout



#### Key Features:

- Example for 6 testing stations
- No physical barriers between Participants
- Requires a much larger space than “partitions” as social distancing is required
- Participants follow a one-way system around the test site to enter and exit
- Test Operatives have enough space to socially distance themselves

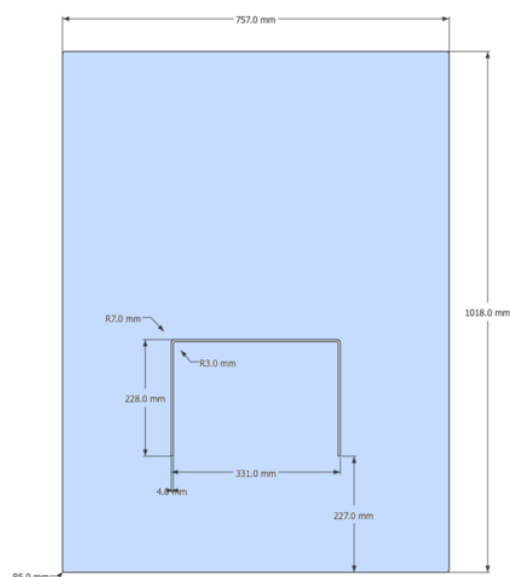
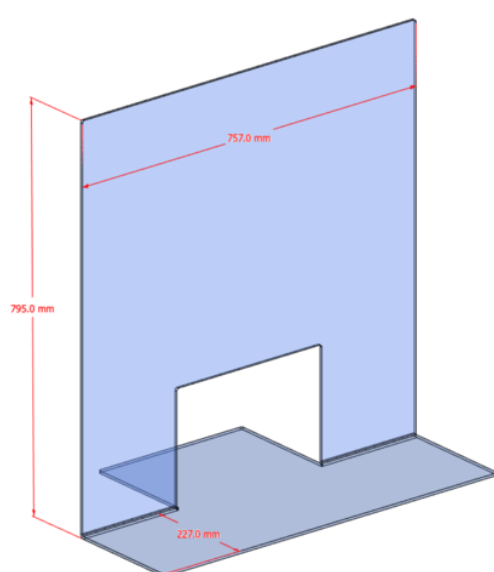
### 13.2.3 Multi-open plan layout with partitions



### 13.2.4 Open plan: further requirements

The open plan option, contains an acrylic screen that is affixed to the table. It is recommended that the equipment adhere to the following criteria:

- Stand must be stable with no wobble with a device to affix to the table so that it is sturdy
- All sharp edges to be deburred/finished to prevent risk of injury
- The booth materials (all sides) need to be made with a material that can withstand cleaning using an agent that is 1,000ppm chlorine.
- Proposed dimensions of the front panel are:





### 13.3 Organisations to build their own site

There is also an alternative for organisations to build their own sites provided that they meet the minimum clinical requirements outlines in this document. Features of the site:

- Have enough space to allow the employee test group to maintain social distancing (as per government guidelines, before, during and after the test)
- Have one-way systems to manage the flow of people
- Be accessible to all test participants take account of the provisions of the Building Regulations (including Approved Document M - 'Access to and use of buildings') and the Equality Act 2010
- Have hard, non-porous flooring that can withstand chlorine cleaning agents
- Natural airflow is recommended for test site staff and participant comfort
- Have access to hand hygiene (soap and water/appropriate alcohol-based hand rub)

## 14 Appendix D: Self-swabbing Instructions


UK Government


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



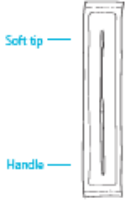
Gently blow your nose into a tissue.  
Throw the used tissue into the healthcare waste bin provided.  
This is so that you get rid of excess mucus.

3



Use hand sanitiser to clean your hands.  
This is so that you do not contaminate the test kit.

4




Soft tip

Handle

Check if there is a swab in a sealed pack in front of you.  
Identify the soft, fabric tip of the swab.

5



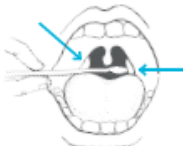
Open the package and gently take out the swab.  
This will be used for both tonsils and nose.

**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


4 times



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

10 circles



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.**

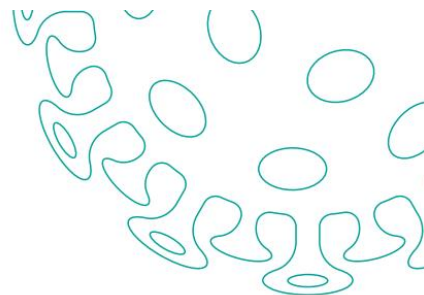
TC Jan 2021



## 15 Appendix E: PPE instructions – putting on and taking off



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](https://youtu.be/-GncQ_ed-9w)

### Pre-donning instructions:

- Ensure healthcare worker hydrated
- Remove jewellery
- Tie hair back
- 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.



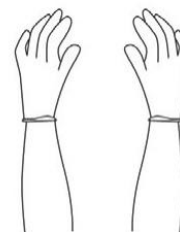
- 4** With both hands, mould the metal strap over the bridge of your nose.



- 5** Don eye protection if required.



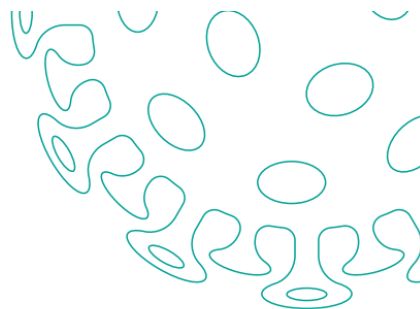
- 6** Put on gloves.







Public Health  
England



# Taking off personal protective equipment (PPE)

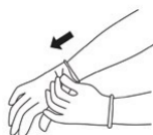
## Standard Infection Control Precautions

Please see donning and doffing video to support this guidance: [https://youtu.be/-GncQ\\_ed-9w](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.

