Department of Health & Social Care

Agreement in relation to the facilitation of Covid-19 testing for attendees at the World Snooker Championships at the Sheffield Crucible

Date: 14 April 2021

This agreement ("**Agreement**") is entered into between the Secretary of State for Health and Social Care of 39 Victoria Street, Westminster, London, SW1H 0EU, United Kingdom ("**DHSC**") and **SHEFFIELD HALLAM UNIVERSITY HIGHER EDUCATION CORPORATION** of **Howard Street, Sheffield, S1 1WB** ("**Sheffield Hallam**").

1 Definitions

1.1 In this Agreement the following definitions apply:

"**ATS Guidelines**" mean all sections of the DHSC Guidelines which are applicable to ATS Testing;

"**Bill of Materials**" means the list of DHSC Supplies to be provided by DHSC as set out in Schedule 2;

"**Confidential Information**" means information, data (including personal data) and material of any nature, which either party may receive or obtain in connection with the conclusion and/or operation of this Agreement which is designated as confidential by either party or that ought reasonably to be considered as confidential (however it is conveyed or on whatever media it is stored);

"**Covid 19**" means SARS-CoV2-19;

"**Designated Area**" has the meaning given in clause 5.1.1;

"**DHSC Guidelines**" means the guidelines relating to COVID 19 testing as issued by the DHSC from time to time;

"**DHSC Supplies**" has the meaning given to it in clause 6.2.1;

"**Event**" means the world snooker championships taking place at the Sheffield Crucible;

"**Event Testing Dates**" means the dates on which Sheffield Hallam shall conduct Event ATS Testing during the Operating Hours in connection with the Event as set out in Schedule 3 or such other dates as the parties may agree in writing (including by email);

"**Event Test Subjects**" mean individuals who are either: (i) attending the Event; or (ii) who are part of the workforce for or otherwise involved in organizing the Event (including the workforce from the Sheffield Crucible and World Snooker).

"**Event ATS Kits**" means the LFD antigen testing kits supplied by DHSC under this Agreement for use in the Event ATS Testing;

"**Event ATS Testing**" means Covid-19 testing of Event Test Subjects on-site in a Designated Area at the Facility in accordance with the SOP;

"**Facility**" means the existing Covid-19 testing facility located in Hallam Hall in the Owen Building and operated by Sheffield Hallam in connection with its participation in the HEI Testing Programme;

"**HEI Testing Programme**" means the national programme of mass testing at higher education institutions;

"**MHRA**" means the Medicines and Healthcare products Regulatory Authority;

"**Operating Hours**" the hours of operation of the Event ATS Testing at the Facility in connection with the Event as set out in Schedule 3 or such other operating hours as the parties may agree in writing (including by email);

"**SOP**" has the meaning given to it in clause 4.1; and

"**Term**" has the meaning given in clause 3.1.

2 Event ATS Testing

2.1 DHSC requires the provision of Event ATS Testing to test Event Test Subjects for Covid-19 either prior to admission to the Event or prior to working or otherwise participating in the Event. Sheffield Hallam has an existing Facility it operates under the HEI Testing Programme at which it can provide onsite testing for Covid-19 and agrees to provide Event ATS Testing on behalf of DHSC subject to the terms and conditions of this Agreement.

2.2 The terms and conditions of this Agreement apply to the Event ATS Testing which Sheffield Hallam will provide on behalf of DHSC in connection with the Event only. For the avoidance of doubt, this Agreement does not apply to any other Covid-19 testing (including under the HEI Testing Programme) that Sheffield Hallam has agreed to carry out under separate arrangements with DHSC.

3 Term

3.1 This Agreement is entered into between DHSC and Sheffield Hallam on [DATE] and shall continue, unless earlier terminated in accordance with its terms, up to an including 3 May 2021, at which point this Agreement shall expire ("**Term**").

4 Standard Operating Procedure

4.1 Sheffield Hallam has been provided with the "Clinical Standard Operating Procedure (SOP) for Mass Testing with Lateral Flow Antigen Testing Devices" ("**SOP**") (the current version of which is attached at Schedule 1), which sets out a detailed description and plan of the testing and ancillary responsibilities that, save as set out in this Agreement, apply to the Event ATS Testing to be facilitated by Sheffield Hallam pursuant to this Agreement.

4.2 Save as specified in this Agreement, Sheffield Hallam agrees to carry out the Event ATS Testing on Event Test Subjects in accordance with the SOP.

4.3 Sheffield Hallam acknowledges and agrees that:

4.3.1 the provisions in the SOP shall apply to the Event ATS Testing to the extent that they relate to onsite asymptomatic testing to be facilitated by Sheffield Hallam at its Facility; and

4.3.2 references to 'students' in the SOP shall be deemed to include and shall be interpreted as including the Event Test Subjects for the purpose of this Agreement.

4.4 DHSC may update the SOP during the Term from time to time and following such update will provide, or make available, to Sheffield Hallam a copy of the updated SOP as soon as reasonably practicable. Sheffield Hallam will advise DHSC as soon as possible if it is unable to comply with any changes that have been made in the updated SOP when carrying out the Event ATS Testing.

4.5 In the event of conflict between the SOP and the terms of this Agreement, the terms of this Agreement shall prevail.

5 Sheffield Hallam's responsibilities

Set up of Facility & carrying out Event ATS Testing

5.1 The Parties acknowledge that Sheffield Hallam already has in place a Facility for Covid-19 testing which it resources, manages and controls in accordance with the separate terms and conditions for the HEI Testing Programme. Sheffield Hallam agrees to use this Facility for the Event ATS Testing and shall:

5.1.1 designate a specific area within its Facility which shall only be used to carry out the Event ATS Testing on the Event Testing Dates ("**Designated Area**") and shall not use that Designated Area for any other testing (including under the HEI Testing Programme) on Event Testing Dates;

5.1.2 ensure that the set-up and configuration of the Designated Area complies with the requirements of the SOP and is in accordance with applicable laws and guidance, including appropriate Covid-19 measures and appropriate site risk assessment; and

5.1.3 have adequate signage and processes in place at its premises to direct Event Test Subjects to the Designated Area only and to restrict any individuals other than the Event Test Subjects from being tested in the Designated Area;

5.1.4 make available to Event Test Subjects in the Designated Area all necessary information and communications regarding the Event ATS Testing as specified in the SOP;

5.2 Sheffield Hallam shall facilitate Event ATS Testing during the Operating Hours on the Event Testing Dates in the Designated Area.

5.3 Sheffield Hallam shall use all reasonable skill and care in carrying out the Event ATS Testing and shall conduct the Event ATS Testing in accordance with the SOP and all applicable laws and regulations.

5.4 Sheffield Hallam shall appoint a programme lead who will be the main points of contact for DHSC and NHS Test and Trace.

5.5 In carrying out the Event ATS Testing Sheffield Hallam shall:

5.5.1 ensure that the Event ATS Testing is conducted using the Event ATS Kits only and in compliance with the instructions for use for the Event ATS Kits provided by DHSC;

5.5.2 arrange for Event Test Subjects to register for the test online on their arrival at the Designated Area, including entering their personal details and details of their test kit barcode, using the relevant NHS Test and Trace website or digital solution as listed in the SOP or as otherwise agreed;

5.5.3 save where the parties agree otherwise in writing in advance: (a) solely use the Event ATS Kits provided by DHSC for the purpose of the Event ATS Testing pursuant to this Agreement; and (b) promptly on request return any unused or surplus Event ATS Kits to DHSC;

5.5.4 carry out the sample collection and analysis, and recording of results in accordance with the SOP;

5.5.5 not store or use test samples for any purpose other than for the Event ATS Testing; and

5.5.6 submit all test results linked to the relevant barcode through the NHS Test and Trace digital system in accordance with the SOP or as otherwise agreed.

5.5.7 at all times comply with applicable laws and regulation in carrying out the Event ATS Testing, including but not limited to the Control of Substances Hazardous to Health 2002;

5.5.8 be responsible for the health and safety of Event Test Subjects and any DHSC, or third party personnel whilst such persons are present at the Facility;

5.5.9 put in place and maintain appropriate arrangements for the clinical governance of the Event ATS Testing, including but not limited to incident reporting, safeguarding and evaluation, and for any other aspects of governance applicable to the Event ATS Testing;

5.5.10 ensure that any queuing to take part in the Event ATS Testing is done in a Covid-19 secure manner in compliance with all applicable laws and regulations;

5.5.11 report any material problems or incidents with the DHSC Supplies to DHSC as soon as reasonably practicable in accordance with any processes agreed by the parties from time to time;

5.5.12 separately from any business as usual waste, safely dispose of any waste, including samples, test kits, kit peripherals and PPE, and any waste suspected of being contaminated with Covid-19, in accordance with the SOP;

5.5.13 implement a process for reviewing and investigating all safety and safeguarding incidents and events that occur as part of the Event ATS Testing and promptly report such incidents to DHSC. Any serious incident shall be reported to DHSC within 24 hours of the incident.

Procurement of personnel

Sheffield Hallam shall:

5.6 provide or procure the necessary amount of suitably qualified, competent, skilled and experienced employees, contractors and/or other third parties to operate and manage the Event ATS Testing in the Designated Area and who will do so in accordance with the SOP and all applicable laws and regulations; and

5.7 ensure that personnel who are to be involved in the Event ATS Testing shall attend all training as required by the SOP or by DHSC in advance of being involved in the Event ATS Testing, and shall perform their role in relation to the Event ATS Testing in accordance with any such training;

5.8 provide DHSC's employees, contractors and nominated third parties with access to the Designated Area in connection with the performance of DHSC's responsibilities under this Agreement and as otherwise reasonably required by DHSC; and

5.9 at DHSC's request, provide DHSC with a copy of any policy which DHSC and its employees, contractors and/or third parties must comply with whilst on-site at the Facility.

Procurement of materials

Sheffield Hallam shall:

5.10 provide all consumables, equipment, resources, incidentals and facilities that are necessary for Sheffield Hallam to carry out the Event ATS Testing in the Designated Area, save for the DHSC Supplies which are to be provided DHSC pursuant to this Agreement;

5.11 inspect the DHSC Supplies after delivery in accordance with clause 7.2.2; and

5.12 store all DHSC Supplies provided by DHSC safely and securely in accordance with the SOP and ensure that any DHSC Supplies (including Event ATS Kits) provided under this Agreement specifically for the purpose of the Event ATS Testing are kept separately from any other supplies from DHSC held by Sheffield Hallam in connection with any other Covid-19 testing (including under the HEI Testing Programme).

General

5.13 Sheffield Hallam shall:

5.13.1 hold and maintain all necessary licences, permits and/or consents necessary for it to perform the Event ATS Testing; and

5.13.2 ensure that it has appropriate insurance in place which covers the conduct of the Event ATS Testing and storage of DHSC Supplies and any other items supplied by Sheffield Hallam as envisaged under this Agreement.

6 DHSC responsibilities

6.1 DHSC shall provide Sheffield Hallam with a reasonable level of support and guidance in order to assist Sheffield Hallam in facilitating the Event ATS Testing.

6.2 In addition, DHSC shall provide (or shall procure the provision of):

6.2.1 in accordance with clause 7, Event ATS Kits to an agreed location, together with appropriate kit peripherals (including guidance material and instructions) and any other items set out in the Bill of Materials in such quantities as are notified to Sheffield Hallam by DHSC ("**DHSC Supplies**"). The DHSC Supplies provided by DHSC pursuant to this Agreement are provided for the Event ATS Testing only and not for any other purpose; and

6.2.2 providing access to an online training and assessment tool for use by the individuals selected by Sheffield Hallam to carry out the Event ATS Testing and, where applicable, Sheffield Hallam shall provide an assurance to DHSC that such persons have completed the relevant training.

6.3 On request by Sheffield Hallam, DHSC may at its discretion provide Sheffield Hallam with templates for regulatory documents that are necessary as a result of the Event ATS Testing, including a data protection impact assessment and site risk assessment.

6.4 DHSC shall be responsible for ensuring that:

6.4.1 sufficient stock of DHSC Supplies are delivered to Sheffield Hallam prior to the Event Testing Dates in order for Sheffield Hallam to be able to carry out the Event ATS Testing under this Agreement.

6.4.2 the SOP is appropriate for Event ATS Testing in accordance with this Agreement and applicable law and regulation (provided that Sheffield Hallam acknowledges that implementation of the SOP by Sheffield Hallam need to take account of the particular circumstances of Sheffield Hallam and accordingly the SOP cannot include a comprehensive list of all actions that will be required to carry out the Event ATS Testing in the Designated Area);

6.4.3 the DHSC Supplies are appropriate for use by Sheffield Hallam to carry out the Event ATS Testing in accordance with the SOP and this Agreement; and

6.4.4 the DHSC Supplies are of the necessary quality and standard to enable Sheffield Hallam to carry out the Event ATS Testing and are free from material defects. Subject to clause 7.2, if Sheffield Hallam notifies DHSC that any DHSC Supplies have material defects, DHSC shall endeavour to provide replacements in accordance with clause 7.

6.5 Insofar as DHSC has access to the Facility as part of the delivery of the Event ATS Testing, DHSC shall, and shall ensure that DHSC's employees and its contractors shall, only use such access for the purpose of providing the Event ATS Testing and shall comply with any relevant Sheffield Hallam policies that have been provided to DHSC in respect of any such access.

7 DHSC Supplies

7.1 Subject to the availability of DHSC Supplies and to clause 7.2, DHSC shall arrange for the delivery of the DHSC Supplies for the Event ATS Testing to a location agreed with Sheffield Hallam.

7.2 Unless otherwise agreed by the Parties in writing, any DHSC Supplies provided by DHSC for use by Sheffield Hallam:

7.2.1 shall be provided at DHSC's sole discretion;

7.2.2 shall be inspected by Sheffield Hallam in order that Sheffield Hallam can as soon as reasonably practicable inform DHSC if any of the DHSC Supplies are missing or damaged; and

7.2.3 must be returned to DHSC within any agreed timescales for such return or otherwise upon the request of DHSC.

8 Data protection

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

8.1.1 subject to clause 8.1.2, Sheffield Hallam shall be the data controller in respect of any personal data it collects from Event Test Subjects (including in managing the attendance of Event Test Subjects at the Facility); and

8.1.2 DHSC shall be the data controller in respect of any personal data which: (a) DHSC collects from Sheffield Hallam and/or its personnel for the purposes of procuring the provision of training under clause 6.2.2; or (b) is processed through the NHS Test and Trace digital system.

8.2 To the extent that the parties each process personal data relating to the Event Test Subjects, each will do so as a separate data controller.

8.3 In carrying out its obligations under this Agreement, each party shall comply with its obligations under the Data Protection Act 2018, the General Data Protection Regulation (EU) 2016/679 (as such regulation is implemented into English law) and any other applicable laws relating to the protection of personal data and the privacy of individuals (all as amended, updated or re-enacted from time to time).

8.4 In the event that either party receives a data rights request relating to personal data processed under or in connection with this Agreement, such party will ensure that such request is appropriately actioned in respect of the personal data for which the recipient of the request is a data controller.

9 Confidential information

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

9.2 Notwithstanding clause 9.1, each party shall be entitled to disclose Confidential Information received from the other party to:

9.2.1 the extent such Confidential Information is required to be disclosed by law, by any governmental or regulatory authority or by a court or authority of competent jurisdiction; and

9.2.2 its contractors to the extent necessary to enable the party to exercise its rights and/or carry out its obligations under this Agreement.

9.3 Notwithstanding the termination or expiry of this Agreement for whatever reason, the obligations and restrictions in this clause shall be valid for a further period of five (5) years from the date of termination or expiry.

9.4 Nothing in this Agreement shall restrict or prevent DHSC from disclosing the name of Sheffield Hallam, the address of any Facility, or details of the Event ATS Testing to be carried out under this Agreement, to any other organisation involved in the DHSC Covid-19 testing programme.

10 Freedom of Information Act

10.1 The parties acknowledge that each party has obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations 2004.

10.2 A party ("**Notifying Party**") shall notify the other party ("**Collaborating Party**") in writing within two (2) business days if it receives a Request for Information (as defined in the Freedom of Information Act 2000 or the Environmental Information Regulations 2004 as relevant) related or otherwise connected to this Agreement.

10.3 In such time as will enable the Notifying Party to comply with regulatory timescales, the Collaborating Party shall give the Notifying Party full co-operation and information needed so that the Notifying Party can comply with any Freedom of Information Act or Environmental Information Regulations request.

10.4 The Notifying Party may consult the Collaborating Party to help it decide whether to publish information under this clause 10. However, the extent, content and format of the disclosure is the Notifying Party's decision, which does not need to be reasonable.

11 Liability

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

11.2 Nothing in this clause 11 shall limit or exclude either party's liability for:

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

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

11.3 Subject to clauses 11.1 and 11.2, the total liability of Sheffield Hallam to DHSC under or in connection with this Agreement, whether in contract, tort (including negligence) or otherwise, shall in no circumstances exceed the greater of £100,000 and the value of any applicable insurance held by Sheffield Hallam.

12 Costs

12.1 DHSC will pay reasonable labour and incidental costs incurred by Sheffield Hallam directly as a result of carrying out the Event ATS Testing in the Designated Area only under this Agreement subject to Sheffield Hallam providing written evidence of such costs. Any and all costs and expenses which Sheffield Hallam wishes to recover from DHSC in accordance with this clause must be agreed in advance and in writing with DHSC.

12.2 Save as set out in clause 12.1, each party shall bear its own costs in relation to the Event ATS Testing and carrying out its responsibilities under this Agreement.

13 Termination

13.1 Either party may immediately terminate this Agreement by issuing a notice in writing to the other party if the other party is in material breach of any obligation in this Agreement which is either incapable of remedy or, where capable of remedy, that breach is not remedied within 48 hours of receiving notice specifying the breach and requiring it to be remedied.

13.2 DHSC may immediately terminate this Agreement (or suspend compliance with its obligations under clauses 6 and 7) by issuing a notice in writing to Sheffield Hallam if Sheffield Hallam is not carrying out the Event ATS Testing in accordance with SOP or applicable law and regulation.

13.3 On termination or expiry of this Agreement, Sheffield Hallam shall return to DHSC at DHSC's request, all other equipment, materials and property, including the DHSC Supplies which Sheffield Hallam has not used, that DHSC had supplied to Sheffield Hallam specifically in connection with the Event ATS Testing.

13.4 The termination of this Agreement shall be without prejudice to the rights and remedies of a party which may survive or may have accrued at the date of termination.

13.5 Any term of this Agreement which expressly or by implication is intended to continue in force on or after termination or expiry of this Agreement shall remain in full force and effect.

14 Change in applicable law or guidance

14.1 Neither party shall be liable to the other party for any delay in performing, or failure to perform, its obligations under this Agreement (other than a payment of money) to the extent that such delay or failure is a result of changes in applicable law and/or government guidance which mean that the Event ATS Testing cannot be carried out (in all material respects) without such laws and/or government guidance being breached, or if Sheffield Hallam can demonstrate that despite all reasonable endeavours it is unable to secure non-Covid-19 infected staff (including sub-contractor staff) to provide the Event ATS Testing due to the levels of Covid-19 infections in the population of the United Kingdom.

14.2 Notwithstanding the foregoing, each party shall use all reasonable endeavours to continue to perform its obligations under this Agreement to the extent possible (in accordance with applicable laws and guidance), which may include only providing part of the Event ATS Testing.

15 Publicity

15.1 Subject to clause 15.2, neither party shall make any press announcement in relation to, or publicise, this Agreement or any part of this Agreement in any way, without the prior written consent of the other party.

15.2 DHSC may publicise the involvement of Sheffield Hallam in the Event ATS Testing, in order to inform Event Test Subjects of the availability of the Event ATS Testing at Sheffield Hallam's Facility provided always that DHSC shall only publicise such details

relating to access to the Event ATS Testing at the Facility as have been approved by Sheffield Hallam.

16 Governing Law and Jurisdiction

16.1 This Agreement shall be considered as a contract made in England and shall be subject to the laws of England.

16.2 Both parties agree that the courts of England and Wales shall have exclusive jurisdiction to hear and settle any action, suit, proceeding or dispute in connection with this Agreement and irrevocably submit to the jurisdiction of those courts.

17 General

17.1 This Agreement constitutes the entire agreement between the DHSC and Sheffield Hallam, and supersedes and extinguishes all previous agreements, promises, assurances, warranties, representations and understandings between them, whether written or oral, relating to its subject matter.

17.2 In the event of the transfer of all or a substantial part of DHSC's activities to one or more government bodies, DHSC's rights and obligations shall, notwithstanding any provision to the contrary in the agreement, automatically transfer to such other government body.

17.3 Except as provided elsewhere in this Agreement, a person who is not a party to the agreement shall not have any rights under or in connection with it.

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

17.5 Any variation to this Agreement should be agreed in writing between the parties.

17.6 Notices shall be sent to such address as the relevant party may give notice to the other party for the purpose of service of notices under this Agreement.

Signed by the authorised representative of THE SECRETARY OF STATE FOR HEALTH AND SOCIAL CARE

Name:	[redacted]	Signature	[redacted]
Position:		Date	16/04/21

Signed by the authorised representative of Sheffield Hallam University

Name:	[redacted]	Signature	[redacted]
Position:		Date	15 April 2021

Schedule 1

SOP

Department of Health & Social Care

Department of Health and Social Care (DHSC) SARS-COV-2 Response

NHS Test and Trace

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

Version 4.1

HIGHER EDUCATION INSTITUTIONS (HEI): ROUTINE ASYMPTOMATIC TESTING

Date of publication: 09/04/2021

Authorised by: Dr Tom Fowler and Dr Peter Marks, NHS Test and Trace Health Protection and Public Health Leads

The HEI SOP is based on a variation of the Clinical Master Template Standard Operating Procedure (SOP) for LFD asymptomatic testing.

Contents

Version Control

The file and table below contains a summary of the changes contained in the most recent version of this template


Version Control.pdf

Version	Author	Summary of Changes	Reviewed By	Date
4.1	HEIs Team	Updated to reflect the MASTER SOP v4.1 • Updated site staff testing to align with national policy of twice per week testing offer (section 7.2) • Added workforce outbreak management guidance (section 7.2.1) • Added a reference to over sleeves for staff that cannot have bare e bows (section 11.3) • Added a poster with key information about testing to be posted near registration points to help inform the Subjects when giving informed consent for testing. This is a requirement for all sites to implement by 16/04. (Appendix F)	National Testing Programme Health Protection and Public Health Leads	26/03/21

Lateral Flow Device SOP Scope Summary

1. Lateral Flow Device

Innova SARS-Cov-2 Antigen Test IFU ☒

2. Situation in which LFD will be used

Post pilot rollout – external clinical responsibility ☒

3. Testing frequency

2 tests per week

4. Population Tested

Symptomatic ☐

Asymptomatic ☒

5. Sample Type

Throat Swab only ☐

Double nasal swab only ☐

Throat and Nose Swab (where possible) ☒

Saliva ☐

6. Sample Collection Method

Assisted ☐

Self-Implemented ☒

7. Sample preparation, application to LFD and results interpretation

Assisted ☒

Self-Implemented ☐

Glossary of terms

Term	Definition
SOP	Standard Operating Procedure
Devolved Administrations	Wales, Northern Ireland, Scotland

DHSC	Department of Health and Social Care
HEI	Higher Education Institution
LFD	Lateral Flow Device
PCR	Polymerase chain reaction
ATS	Asymptomatic testing site
LA	Local Authority
T&T	Test and Trace
NHS	National Health Service
MHRA	Medicines and Healthcare products Regulatory Agency
PHE	Public Health England
FAQs	Frequently Asked Questions
ID	Identification
IFU	Instruction for Use
PPE	Personal protective equipment
URN	Unique reference number

1 Introduction

This is the standard operating procedure (SOP) for mass testing for SARS-COV-2 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.

For the purpose of this document, a Higher Education Institution (HEI) is defined as a university or college providing Higher Education, which is defined as the continuation of study post the age of 18.

1.1 Purpose of this document

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

This document will be shared with key program stakeholders including the HEIs in the United Kingdom, NHS, Public Health bodies, Local Resilience Forums (LRF) and the Devolved Administrations.

1.2 Scope of the SOP

This clinical SOP can be used as such, or with reasonable minimal adaptations where appropriate, for localised service delivery with adequate clinical/public health review. The clinical SOP is designed for safe implementation of approved processes. Major changes or innovations to this SOP must pass through the DHSC approval process before implementation.

As part of the implementation of this SOP, the following external stakeholders should be engaged:

- Each respective HEI's leadership team
- Each respective HEI's Student Union body
- Local Directors of Public Health
- Devolved Authorities, where required.

2 Clinical Governance

2.1 What is clinical governance and why is it important?

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

2.2 Accountabilities and quality lead role

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

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

2.3 Clinical governance processes needed prior to start testing

Each testing site is responsible for ensuring:

- Premises meet all relevant legislative, certification and validation inspections and requirements including health & safety.
    - Premises must be accessible, clean, secure, suitable for purpose, properly used, social distancing measures in place, properly maintained and appropriately located for the purposes for which they are being used
    - Risk assessments are undertaken if the premises used mean that hygiene standards are more difficult to maintain (e.g. carpeted flooring)
- Sufficient numbers of suitably trained, competent, skilled and experienced persons must be deployed in order to meet the requirements of the service and persons employed by the service must:
    - Receive such appropriate support, training, professional development including update training, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,
    - Be enabled where appropriate to obtain further qualifications appropriate to the work they perform
    - Where such persons are health care professionals or other professionals, they will be registered with a health care or social care regulator

- Clear escalation and decision mechanisms in place to support the Quality Lead and ensure staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally where appropriate.
- Process in place to ensure lessons are learned and systemic problems and themes are identified so that an action is taken as a result of investigations when things go wrong.
- Creating clear clinical governance processes prior to the start of the testing, which should include the following:
    1. Training:
        - Knowledge assessment at the end of on-line training- this is done as part of online training
        - A dry run as a team during mobilisation or on first day
    2. Observing testing process:
        - Daily/weekly clinical quality audits by site supervisor. A sample quality checklist template is provided below:

        
        QUALITY CHECKLIST.pdf

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

        
        Recorder Competency Assessm

        
        Test Processor Competency Assessm

        
        Testing Assisstant Competency Assessm

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

2.3.1 Risk assessment

All HEIs will need to have a risk assessment, covering health and safety as well as operational delivery related risks, in place prior to sign off. Any deviations from the SOP, including hygiene standards, should be included in the risk assessment. The assessment should be completed jointly by the HEI and various service providers involved in the delivery of testing. HEIs should define their ongoing risk and incident management accountabilities.

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

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

Additional guidance on risk assessment can be found in the Asymptomatic Testing Guidebook

(Design Section)

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

Example Risk Assessment.docx

2.3.2 Incident management and reporting

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.

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

2.3.3 Clinical effectiveness

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

2.3.3.1 Internal Quality Assurance

Internal Quality Assurance 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 selected HEI sites, to ensure they are performing at the right level. This will involve sites running known samples at periodic intervals.

If the testing service site is asked to engage with the internal quality assurance process, they must follow the instructions given and report as required.

2.3.3.2 Quality assurance on-going evaluation

Dual swabbing at a selection of sites will be enacted for the purpose of quality assurance ongoing evaluation. This will be delivered by the HEI team under the guidance of PHCO. Analysis will be performed at an aggregate level for the archetype as a whole, and not for individual sites. This will be designed centrally by PHCO who will coordinate with the HEI team to provide detailed work instruction to the sites in scope for this process.

2.3.3.3 MHRA reporting and lessons learned

Sites will have a process in place to ensure lessons are learned and systemic problems and themes are identified so that an action is taken as a result of investigations when things go wrong.

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

2.4 Care Quality Commission

The law has now changed which makes COVID-19 testing activity that falls outside the scope of registration with the Care Quality Commission (CQC). It is therefore not a requirement for Use Cases to register with the CQC to provide COVID-19 diagnostic and screening services. 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.

3 Testing Rationale

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

The specific public health aims of this programme are to support setting up sustainable asymptomatic testing capability within HEIs to:

1. Find active cases – identifying asymptomatic positive cases of SARS-CoV-2 within the HEI population quickly and ensuring they self-isolate to break the chain of transmission.
2. Enable return – support return to normal life on campus, reducing the risk of HEI outbreaks and spread of infection to the wider local community.
3. Provide surveillance – proactively monitor the incidence and prevalence of SARS-CoV-2 in the HEI population for timely identification of emerging hotspots, for targeted public health response in collaboration with the local Directors of Public Health and Health Protection teams.

The PHCO team is a key customer of the HEIs evaluation. Interim updates and outcome reports, along with lessons learnt during the testing will be formally submitted to the Test and Trace Public Health and Clinical Oversight to help iterate future versions of the DHSC master clinical SOP and to inform the national policy and implementation of NHS Test and Trace.

The evaluation of this programme will reach across the following key lines:

- Operational feasibility
- The tolerability of the LFD test
- The acceptability of the testing regime
- The operational performance (time to test, number of tests, % uptake)
- Communication and engagement with HEI population
- Public health effectiveness
- The incremental case-finding ability of routine weekly asymptomatic LFD testing
- The uptake and continuity of regular weekly testing
- Reduction in onward transmission and symptomatic case rates in the HEI population
- Reduction in HEI- linked community COVID outbreaks

4 Lateral Flow Antigen Test Devices (LFD)

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

The test kit is a hand-held device with an absorbent pad at one end and a reading window at the other. Inside the device is a strip of test paper that changes colour in the presence of

SARS-CoV-2 proteins (antigens). The device detects a viral protein (antigen) produced in greatest quantity at its most infectious stage.

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

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

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

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

4.1 Instructions for use

The manufacturer's instructions for use (IFU) can be found here: Click for 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 document and ATS Guidebook for more detail). The key roles outlined in the document required to operate a 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 Lead / Site Manager**	**Responsible for the overall on-site operations at the test site, including day-to-day workforce management.** 1. Running day-to-day operations including on-site workforce management, managing site health & safety and receiving and managing stock 2. Point of escalation for any issues on site, and escalates to local public health officials as appropriate 3. Ensure adherence to SOP and clinical guidance is maintained throughout operations 4. Responsible for safety and security of the site

		5. If Subjects raise any data privacy concerns, directs Subjects to the Data Privacy Notice which explains how we will use their data (https://www.gov.uk/government/publications/coronavirus-covid-19-testing-privacyinformation)
Quality Lead / Testing Supervisor	**Dedicated role or a designated team member**	1. Supporting the team leader in ensuring the requirements set out in the Quality, Risk and Issue Management section of the Asymptomatic Testing Guidebook p151-158 2. Implementing an appropriate quality assurance system 3. Ensuring he promotion of good quality practice across the service delivery 4. Implementing a quality and safety incident and risk reporting system 5. Maintaining testing staff training records and undertaking testing staff performance reviews
Site Operative	**Queue Coordinator**	**Ensures orderly entry of Subjects onto the testing site.** 1. Ensures crowd control and social distancing is maintained in Subject queueing areas 2. Monitor Subjects in the queue who are showing symptoms of COVID and acts accordingly if they are 3. In case of long queue, encourages people in line to start registering online 4. Supports general site set up, including appropriate signage to manage Subject flow
	Registration Assistant	**Responsible for ensuring Subjects have registered and distributing test kits on arrival.** 1. Greets Subject at arrival, asks them to sanitise hands and ensures the subject is eligible for asymptomatic testing 2. Provide the Subject with key messages for testing, including definition of the test hat no test is perfect and a negative test does not guarantee that they do not have coronavirus 3. Aids the Subject in registering for the test if they are unable to 4. Provides assistance for people who might not have the relevant digital information such as phone number and email address 5. Guides people who are coming and for a valid reason need to test anonymously 6. 'Drip feeds' Subjects into testing area, ensuring testing area does not exceed maximum capacity 7. Communicate to test Subjects the purpose of participating in testing at your site and the testing journey.
	Test Assistant	**Provides guidance to Subjects on swabbing as requested, and ensures cleaning of booths or sample collection station.** 1. Directs Subject to available testing stations and directs them to the exit when they are finished 2. On hand to provide Subject with additional verbal instruc ions if required 3. Provides regular cleaning to testing stations throughout day (Subjects are also asked to self-clean between each test)
Testing Operative	**Processing Operative**	**Prepares test sample for analysis and interprets result.** 1. Sets up sample for analysis, and pipettes reagent to sample 2. Times the sample analysis 3. Await and read result displayed, and mark it on device 4. Provides to Results Recorder to upload to digital platform
	Results Recorder	**Collates results from Processing Operatives and uploads to digital solution.** 1. Reads test result outcome (marked by Processing Operative) 2. 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 & Trace)

An appropriate training package is in place for operators to be trained and able to conduct the test in a safe and effective manner including IPC and PPE requirements for their role and activities - this should include the approach to supervising swabbing. Refer to the ATS Workforce document and ATS Guidebook for detailed training instructions and content. The training package should include regular audits of performance and overall testing process.

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 dependent on type of setting, numbers tested and area of testing place used. While the specific staffing requirements are dependent on the testing service, 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

More details can be found in the Guidebook which shows how sites should be set up, the materials to use, and how to enforce social distancing on-site.

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
- This may be performed at adjacent sites, and/or in multiple lanes, using a one-way system
- PPE required, as in line with the latest clinical guidelines
- The clinical guidelines on personal, spatial hygiene and access to hand hygiene products
- Washrooms for test samples are not appropriate due to the potential of contamination of equipment/test etc.
- 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 HEI should complete a local 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 disinfect

- All surfaces should be de-cluttered of equipment that is not required to run the testing
- Sufficient room for storage
- Perimeter fencing or an enclosure restricting access to the site may be required

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 and described in the waste management section
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 SARS-COV-2 symptoms
    iv. a spillage

We recognise that HEIs 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. On non-testing days, ATS can be used for BAU activities given appropriate cleaning has taken place to make the site/location clean and ready for the ATS sites to be used for those activities (in line with the cleaning guidance in the SOP).
8. 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.
9. The LFD devices and reagents need to be stored between 15 and 30^{o}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 emergencies and staff sickness

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 SARS-CoV-2 symptoms should alert their relevant team leader and site lead or colleagues and arrange to travel home and follow the latest government guidance on treatment (this may involve contacting the prescribed emergency number where necessary). 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.

6.1.1 Ventilation requirements for sites

In poorly ventilated areas the amount of virus in the air can build up, increasing the risk of spreading the virus, the more fresh air is brought into the site, the quicker any airborne virus will be removed from the room. Each site should do a risk assessment of areas where staff work with to ensure mechanical or natural ventilation i.e. opening windows, doors or vents. For more information, please refer to: Ventilation of indoor spaces to stop the spread of coronavirus (COVID-19) - GOV.UK (www.gov.uk)

6.2 Testing site set-up

Please refer to the Guidebook for site 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).

Each sample collection station with 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. HEI, community hall, church hall, event / 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 station requirements:
    - Sample collection stations will be arranged as appropriate for each test site. Please refer the Guidebook for layout examples.
    - Testing sites are intended to be set-up at fixed locations indoors in a dedicated separate area within another complex. The principles of testing site design are described in the Guidebook.
    - Sample collection station (testing booth or open plan) requires at a minimum: a table, healthcare waste bins (separate bins for chemical e.g. used PPE, wipes, used test kits), a supply of surface combined wipes (where the wipe has a detergent and disinfectant combined) and alcohol-based hand rubs, and laminated instructions. A sick bowl will be placed near the front of the sample collection station so that they remain accessible to the Subjects if needed. Optionally, a chair and mirror can be provided.
        I. The stations should be constructed in such a way as to maintain 2m social distancing. For open plan collection stations, more space will be required to maintain social distancing.
        II. The stations should be constructed in such a way as to allow a one-way system around the test site for entry and exit.
    - Testing booth (optional): a dedicated testing booth will comprise of the above features and 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 plastic screen with an open slot where the Subject can pass their sample through. The booths are intended to offer privacy from other Subjects. Local risk assessments need to be in place to ensure ventilation is adequate given the room dimensions (i.e. ceiling height).
    - Minimum build / 'desktop' screen (optional for open plan stations): a screen is clinically and operationally recommended 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. It is recommended that the equipment adheres to the following criteria:

d) 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.
e) Prepping space: area where Processing Operatives work
f) Cleaning area
g) Demarcated exit route
h) 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 bin: these bins should be 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 the Infection Prevention and Control Section) 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 a suitable disinfectant wipe 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.

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

Frequent of testing

The routine testing frequency for the LFD to ensure active case finding in people without symptoms of SARS-COV-2 is two tests per week i.e., three-four days apart, every week.

For students residing in halls of residence, HEIs must make arrangements to ensure that appropriate isolation facilities are available for asymptomatic cases and their contacts identified during the course of testing.

7.1 Eligibility

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

- The Subject can be a member of staff or a student at the HEI
- 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

* A Subject is considered to be symptomatic if they are experiencing any of the symptoms listed in the latest government guidance. If they are experiencing any of these symptoms they should go to the gov.uk site and register for a test offered for symptomatic patients.

People with additional needs might not be able to self swab. If the person has the capacity to consent, they should be asked if they will allow someone to help them do the test, or to allow someone to do the test for them. Each case should be assessed on a case by case basis.

7.2 Staff testing

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

Site staff outbreak management

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

7.3 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 from a consultee, in line with the Mental Capacity Act 2005. A consultee may be a parent or guardian, or a carer, and the individual must be fully informed to make a decision.

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

7.4 Information about testing

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

- COVID-19 tests detect parts of the coronavirus and if it detects it then it is likely you are infected with the virus. The test involves taking a swab of the inside of your nose and the tonsils area.
- No test is perfect. A negative result does not guarantee that you don't have coronavirus. A positive result does not always mean you are infectious. Though this is less likely, false positive results may occur.
- Keep following advice about how to avoid spreading COVID-19 – including social distancing, avoiding mixing, regular handwashing, and wearing a face covering where recommended.
- Rapid antigen tests (also known as "lateral flow devices") detect proteins (antigens) that are present when a person has COVID-19. These are less sensitive than PCR tests and we know that they will not identify everyone with coronavirus, but the majority of infectious individuals will be found.

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

7.5 Face coverings

Individuals are required to arrive at the test site wearing a face covering, unless they are exempt or have 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 with 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 Administrations.

7.6 Testing people with additional needs

People with additional needs (this could be physical or mental disability) might not be able to selfswab. If the person has the capacity to consent, they should be asked if they will allow

someone to help them do the test, or to allow someone to do the test for them. If the person does not have the capacity to consent, a parent or guardian can consent on their behalf. Carers or other accompanying

individuals should only be asked to assist or test the person if this falls into their normal responsibilities and they feel comfortable and confident on doing so.

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

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

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

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

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

If it is not possible to swab their tonsils, both nostrils can be swabbed instead. (Note: The result may be less accurate than a nose and throat swab).

7.7 Pre-registration

HEIs should define an approach which works best for the institution and its students and staff. Some options include:

- Calendar booking model: Allow students and staff to book an appointment at a time that suits their schedule. Narrower appointment windows (15-30 minutes) can help manage flow better.
- Cohort booking model: Define cohorts of students who are then given specific appointment windows. Attend at your convenience

- Allow students and staff to get tested whenever they like as long as they adhere to the desired testing frequency. It is imperative to consider crowd management if pursuing this model.
- Testing reminder emails: twice weekly scheduled reminders either based on scheduled appointments or as mass emails.

7.8 Registration, 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 operator
   c) Prepare for testing run through
5. Check-in: Confirm if Subjects have a booking and appropriate ID
   a) Check Subject is wearing face covering.
   b) Ask Subject if they are experiencing any SARS-CoV-2 symptoms. If they are, explain that this site is for asymptomatic individuals only and direct them to the nearest Local Testing Site.
   c) Confirm booking (if relevant) and HEI ID.
6. Registration: Subjects link their personal details to barcode provided
   a) Hand Subject a Test Registration Card with the barcodes (these come in sets of 3 or 4) with matching ID numbers
   b) Explain that the test registration process ensures they can receive the results of the test by linking the barcode given to them to the result of the test once it is completed
   c) Ask them to scan the QR code and enter the details requested on the Registration website: https://gov.uk/enter-lateral-flow-test
   d) Once registered, direct subject to testing / waiting area
7. Carrying out the throat and 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 nasal swab test
   d) Subject will be required to place their swab directly into the prepared extraction tube on the processing area or hand over the swab to testing assistant (depending on local process).
   e) Subjects respect all hygiene and social distancing rules
   f) Subjects exit the facility
8. 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. Tray must be kept horizontal.

9. Sample matching and results notification
    a) Results will be captured by the Results Recorder
    b) Results of LFD will be shared with the NHS Test and Trace programme
    c) Results matching will be completed, and notifications issued to the Subject directly – results will only be issued to the Subject, not to the host institution
10. Follow up of results
    a) The employer or host institution and Subject will follow Public Health guidelines and procedure on follow up

7.9 Detailed testing process

7.9.1 Self-swabbing sample collection procedure:

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

Before commencing swabbing, the Test Assistant will explain the process to the Subject. The Subject will also be informed that the swab may sometimes make them gag and they should use a sick bowl for any expectoration or vomit and guidance will be given regarding what to do with this if used.

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

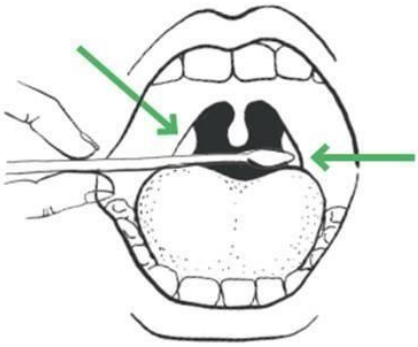


Figure 1 Swab rubbing the tonsil

5. The Subject should identify the soft, fabric tip of the swab its sealed, sterile packaging, peel open the packaging and gently remove the swab whilst taking care to not touch the soft, fabric tip of the swab
    a) The swab must be kept dry before taking a sample from the back of the throat and therefore it must not touch any surfaces including the teeth, gums, tongue, cheek or any other surfaces when conducting the test.
    Please note: The swab will be invalid if it touches these parts during or after sampling and it must be put in healthcare waste container and a fresh swab selected. The swab will also be invalid if the soft, fabric tip is touched by the Subject's hands.
6. Holding the swab between fingers, the Subject should open their mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been) at the back of the throat with good contact at least 4 times on each side (a mirror can be used to ensure the tonsils are being swabbed). If the Subject cannot take a throat swab, this step should not be taken and the Subject should swab both nostrils (see point 7). Carefully remove the swab stick from the back of the throat taking care to ensure that it does not come into contact with any other structure or surface.
7. The Subject should then insert the same swab into one nostril. The swab tip should be inserted until there is a slight resistance up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab firmly around the inside of the nostril, making 10 complete circles along the mucosa to ensure that both mucus and cells are collected.
8. If the Subject has a nose piercing, swab the other nostril. If pierced on both sides, remove the piercing on one side before swabbing.
9. Note: if nasal swabbing is not possible because the Subject has unhealed wounds or fresh piercings on both nostrils, throat only swabbing can be used.
10. Note: In children, adults and the very elderly where throat swabbing is more difficult or they have a very sensitive gag reflex that prohibits the throat swab from being completed successfully, double nasal swabbing can be used.
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 anti-viral wipes
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.

7.9.2 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 selfswab section above)
2. The Processing Operative then removes the LFD device from the pouch and applies a barcode to the underside of the LFD cartridge.
    a) LFD cartridges should be used without a long delay after opening the pouches in which they are supplied.
3. The Processing Operative sets up the extraction tube by following these steps:
    a) Place the extraction tube in the tube rack with the opening facing up
    b) Open the extraction solution bottle and hold the cap with the free hand. Do not put the cap down on the table while adding extraction solution to the tube as this would increase the risk of contamination
    c) Press the extraction solution bottle to drip 6 drops of extract solution into the extractor tube without touching the edge of the tube. **Do not let the buffer bottle touch the edge of the tube**. The buffer bottle should be decontaminated with antiviral using wipes between samples to prevent cross-contamination. The Processing Operative should check the label and, if damaged, they should dispose of the buffer bottle.
        i. Manufacturer's note: guidance should be followed for the 6 drops of extraction solution to be added to the tube. However, results with 4 to 7 drops have been validated and accepted.
    d) The extraction tube will be left in the tube rack on the processing bench next to the window for the Subject to place the swab
4. The Subject will place the swab sample into the prepared extraction tube (as described in self-swab section above) located on the table at the window (to potentially prevent the swab from drying out)
5. The Processing Operative then takes the swab and commences the following steps:
    a) Extract: Hold and press the swab head against the wall of the tube with force while rotating the swab for about 10 seconds to release the antigen into the extraction solution from the swab head

b) Remove swab: Squeeze the swab head by squeezing the lower end of the tube while removing the swab in order to remove as much liquid as possible from the swab as shown in Figure 2
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 extraction solution into the sample well of the LFD cartridge
   - Manufacturer's note: guidance should be followed for the 2 drops of extraction solution to be loaded on the cartridge. However, results within 2 to 4 drops have been validated and accepted.

   Record the time of test (Drop @ XX: XX) in marker on the LFD and make sure you have set a timer to read the results at 30 minutes
f) Re-check that the liquid can be seen seeping through the cartridge (to ensure the drop was not an air bubble). Refer to the section below on Reading and interpreting LFD results for details on the control C line to ensure the test is valid
g) If the cartridge appears dry, the Subject will need to be recalled for a further sample to be taken.
h) If needed move the cartridge to a defined processing space for reading and leave for between 20-30 minutes as below. Please note the LFD movement should be kept to a minimum and where it is required to be moved, keep horizontal using a tray.

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

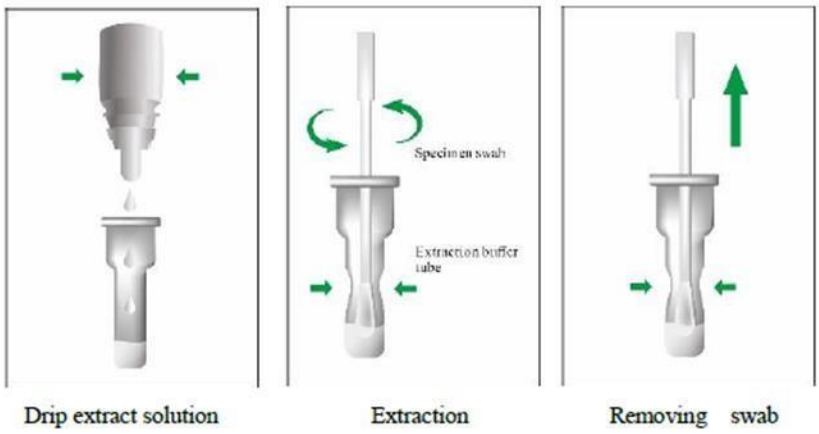


Figure 2 Extraction buffer preparation

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

The Subject can leave the test centre and await results communication after loading. It is at the HEIs discretion whether to allow the Subject to wait for the results. The waiting area should follow the physical requirements outlined earlier in the document. Each employer or host institution is responsible for administering this process.

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.

7.9.3 Reading LFD result

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

- Strong positive results can be reported at 20 minutes, however, negative results must be reported at 30 minutes
- a positive signal appears after 30 minutes, it should not be reported as positive

7.9.4 Interpreting LFD result

1. Results should be interpreted as follows:

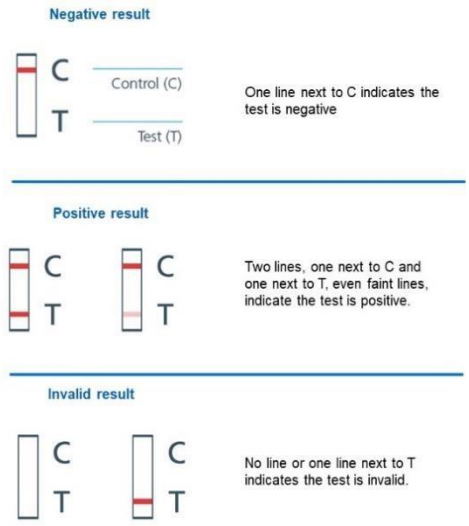


Figure 3. Result interpretation taken from IFU

Valid results:

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

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

Invalid results:

- There is no coloration on line C. The test is invalid or an error in operation occurred.
- The operator cannot differentiate whether a T line is discernible or not.

The control C line is designed to indicate that the test strip does not have a mechanical

fault. It is not designed to confirm if the sample applied to the test strip is a valid sample. Therefore, it is vital that the instructions for collection and preparation of the Subject's sample are followed precisely.

2. Tests are marked with a black permanent pen and removed from the desk. A symbol system should be used to avoid confusion:
   - '+' mark for positives – removed any time before 30min
   - 'V' mark for invalid – removed 30min after "drop"
   - '- 'mark for negatives – removed 30min after "drop"
3. The LFD may now be moved to a different area for data logging/result recording
4. The area where the device was situated is then cleaned after it has been removed

7.9.5 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
5. Once result has been logged, the LFD are disposed of as per the requirements outlined in the waste management section

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

1. Login to the results application
2. Select the test site location
3. Scan the LFD barcode as per digital results recording process with the iOS mobile application and digitally record the applicable result
4. After entering the result of the test, take a 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
6. Once result has been logged, the LFD are disposed of as per the requirements outlined in the waste management section.

Please see the HEIs Asymptomatic Guidebook page 71 for further detailed guidance on setting up site IDs and Logging 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.

7.9.6 Communication of results

The testing site will analyse the sample and upload the test results linked to the barcode to

NHS Test & Trace digital system. To protect privacy and confidentiality, the testing site 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 latest national guidance published by the NHS.

7.9.7 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.

	Positive	**Negative**	**Void**
Assisted LFT	Yes	No	No
Self-report LFT	No	No	No

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.

7.9.8 Negative results

Individuals who have a negative test result do not need to self-isolate unless,

a) they are symptomatic (they will need to book a different test),
b) someone they live with tests positive (or has symptoms and has not been tested yet)
c) they have been traced as a contact of someone who tested positive

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

7.9.9 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.
- 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/getcoronavirus-test and choose home testing (do not choose a test site)

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

7.9.10 Positive results

People who return a positive LFD result and everyone in their household must self-isolate immediately for 10 days. This includes the day of your test and the next 10 full days.

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

7.9.11 Confirmatory testing:

Following a decrease on the national COVID-19 prevalence (the proportion of false positives compared to all cases increases as prevalence decreases), the temporary suspension of the

requirement for routine confirmatory PCR for positive LFD results has been lifted.

For test sites in England with assisted-processing testing

From the reinstatement of confirmatory PCR in all test sites in England offering assisted-processing testing (where results are logged by a member of the ATS using Log results portal/app):

- **The legal duty to self-isolate and tracing period will be triggered by the positive LFD test result. A positive LFD result will also trigger access to the Test and Trace Support Payment (for those eligible), notwithstanding that it will not be possible to recover the payment where there is a subsequent negative PCR result and those notifications are rescinded**
- Subjects with a positive LFD result must take a different follow-up test on the same day (or as soon as possible). 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 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. The Subject can leave their home for the follow-up test.
    - If the follow-up test is negative from a test taken within 2 days of the positive LFD result, the Subject and everyone in their household can stop self-isolating. Self-isolation notifications and the tracing process will halt.
    - If the follow-up test is positive, the Subject and everyone in their household will need to self-isolate for 10 full days from the time of the positive LFD test or when symptoms start.
    - If the test is not taken within 2 days, the Subject and everyone in their household will need to self-isolate for the full 10 days.

For all other situations

In situations where confirmatory PCR was not temporarily suspended, the requirement will remain unchanged. Scotland, Wales and Northern Ireland's requirement for confirmatory PCR will also remain unchanged, in accordance with the decisions of their Chief Medical Officers.

In the situations above where confirmatory PCR was not temporarily suspended:

- **The legal duty to self-isolate and tracing period will 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 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. The Subject can leave their home for the follow-up test.
    - If the follow-up test is negative, the Subject and everyone in their household can stop self-isolating.
    - If the follow-up test is positive, the Subject and everyone in their household will need to self-isolate for 10 full days from the time of the positive test.

7.10 Contacts of a case

Close contacts must continue to self-isolate for a period of 10 days even if they test negative on LFD test. They need not do the twice weekly LFD testing during self-isolation period. They should order a PCR test if they develop symptoms.

7.11 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
- When travelling home, social distancing measures should be strictly observed, keeping at least 2m away from other passengers, keeping windows open, wearing a face covering, facing away from other passengers, avoiding touch points, washing their hands before and after the journey, and using hand sanitiser at regular intervals during the journey.
- Asymptomatic contacts of positives cases should go home as they would normally do. If the contact becomes symptomatic, they should follow same travel advice as positive cases.
- It is especially important that people follow Government guidance on hygiene, including hand washing before leaving, throughout the process of attending a testing site.

7.12 Repeat testing

Subjects that have tested positive by PCR for SARS-COV-2 are exempt from routine re-testing by PCR or LFD tests within a period of 90 days from their initial illness onset or test (if asymptomatic) unless they develop new SARS-COV-2 symptoms.

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

https://www.gov.uk/government/publications/covid-19-stay-at-home-guidance/stay-at-home-guidancefor-households-with-possible-coronavirus-covid-19-infection

8 PPE

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

	Gloves[2]	**Apron**	**Fluid Resistant Surgical Mask (FRSM)**	**Eye/face protection[4]**
Processing operative	Wear only during sample analysis Single use	Wear only during sample analysis Check notes for use[3]	Wear FRSM at all times Sessional use	During Sample analysis Sessional use
Cleaning staff	Wear only during cleaning Change between cleaning tasks[2] /if cleaning a spillage, and if visibly contaminated	Wear only during cleaning Change between cleaning tasks and if cleaning a spillage	Wear FRSM at all times Sessional use	During cleaning Sessional use
Test assistant	Only if assisting a Subject with a test, otherwise not required	Only if assisting a Subject with a test, otherwise not required	Wear FRSM at all times Sessional use	Not required

	Single use	Single use		
Site coordinator /Team Leader	Not required	Not required	Wear FRSM at all times Sessional use	Not required
Registration Assistant	Not required	Not required	Wear FRSM at all times Sessional use	Not required
Results recorder	Only if required to intervene and handle a device Single use	Not required	Wear FRSM at all times Sessional use	Not required
Queue coordinator	Not required	Not required	Wear FRSM at all times Sessional use	Not required

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. 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**
3. Use of aprons for processing operatives:
    - Aprons to be put on just prior to processing
    - Aprons to be put on just prior to processing
    - Once PPE is put on, if the individual needs to move to another area, the apron is removed and hand hygiene is performed
    - A local assessment is undertaken to review the throughput in the testing site. Change of aprons will fluctuate depending on the throughput of individuals for testing
    - Sites should review throughput and if the throughput is low, i.e. one test every 10mins, then the apron is removed, hand hygiene is performed, and a fresh apron is put on when the new cartridge is being processed
    - If the throughput is high, i.e., several tests being processed either in batches or one after the other with no movement of staff, the apron is to be removed once the task is completed, and hand hygiene to be performed
    - When leaving the testing area for a break/comfort break the apron should be removed, and hand hygiene is performed
4. A local risk assessment should be undertaken for the use of eye and face protections (visor and goggles), worn when there is risk from splashing of secretions (including respiratory secretions) (Gov.UK 2020), when there is a risk of contamination of the eyes from splashing such as aerosol generating procedures (HSE 2020), and when there is a perceived risk that blood and/or body fluids or chemicals may splash into the eyes. Eye or face protection can be achieved using any of the following items:
    - A surgical face mask with an integrated visor
    - A full face visor or shield
    - Goggles
    - Please note, eye protection spectacles are not recommended, as they do not meet the required EN 166 standard when interacting with suspected or confirmed SARS-COV-2 cases.

Further instructions on PPE:

1. 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.

2. PPE should be changed if protective properties are compromised or if contaminated, or if suspected to be contaminated.
3. 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.
4. 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.
5. This is enabled and supported by frequent cleaning of testing stations and high touchpoint areas.

Where private providers are assuming clinical responsibility for the testing, they will also be responsible for quality assurance component. **HEI should have clear escalation and decision mechanisms in place to support the Quality Lead.**

Record keeping:

A quality 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.

9 Supply & equipment

DHSC support team will provide sample collection kits and lateral flow antigen test devices to the employer or host organisation. At DHSC's discretion, DHSC may provide the organisation with materials and resources to enable testing activities, including but not limited to PPE and hygiene products.

DHSC will provide:

- Sample Collection Kits (all types)
- Lateral Flow Devices (all types)
- Digital Devices for results submission

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 (including fire extinguishers, defibrillator)
- Healthcare Waste (including bins, bags, containers)
- General Waste (including bins, bags, containers)
- Miscellaneous (laptops, whiteboards, printers, tools)

Note: A detailed list of all the entire site inventory will be issued to the organisation

10 Data management

10.1 Data control

Within the scope of the process outlined in section: Process Overview, 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.

HEIs must make sure that they obtain the appropriate consent from persons who are unable to give implied consent due to age and mental capacity, and that the person who obtains the consent has the necessary knowledge and understanding of the test and its implications.

If a 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.

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 town, institution
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

It is essential that all staff follow this SOP to prevent potential transmission of SARS-CoV-2 to themselves and others. Any non-compliance will be escalated through existing 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 SARS-COV-2:

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-infection-prevention-andcontrol

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

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

11.2 Cleaning policy

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

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

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

The following cleaning guidelines must be followed:

1. All surfaces that the Subject has come into contact with must be cleaned and disinfected, including all potentially contaminated and frequently touched areas such as handles, light switches, telephones, and the surfaces that the Subject may have had contact in between each individual that is tested
2. Use disposable cloths or paper roll and disposable mop heads, to clean all hard surfaces, floors, chairs, door handles and sanitary fittings – think one site, one wipe, in one direction.
3. Any cloth and mop heads used for cleaning must be disposed of as healthcare waste (offensive waste/tiger bag)
4. Surfaces will require to be cleaned at the end of the session before the next session starts
5. Surfaces will require to be cleaned at the end of the session before the next session starts i.e. in between test group batches of Subjects

Use one of the options below:

- A combined detergent and disinfectant at a dilution of 1000 parts per million (ppm) available chlorine (ppm av.cl) Referred to as a stage one process, as the area is cleaned and disinfected at the same time. The area must be left to air dry, to enable the disinfectant to have the required contact time.
- A household detergent followed by disinfection (1000 ppm av.cl). Follow manufacturer's instructions for dilution, application and contract times for all detergents and disinfectants. . This is referred to as a two-stage process, the area needs to be cleaned with a detergent, rinsed and dry, then the disinfectant can be applied and left to air dry, to achieve the correct contact time required.
- If an alternative disinfectant is used 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.

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

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

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

11.3 Hand hygiene guidance

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

To aid hand hygiene staff must:

- Follow the principles of bare below the elbow, while in the testing zone. Ensuring wrists and forearms are exposed, removing any items that may hinder the process for hand hygiene including wrist watches, rings with stones in (a single, plain metal finger ring is permitted but should be removed (or moved up) during hand hygiene, bracelets, friendship bands, long sleeved clothing*.
- Ensure fingernails are clean and short, and do not wear artificial nails or nail products
- Any cuts and abrasion on the hands or arms must be covered with a waterproof dressing
- Any skin condition such as boils, abscesses, eczema or psoriasis must be reported to the organisational Occupation Health

*If the exposure of arms is not acceptable due to religious reasons, disposable over-sleeves, elasticated at the elbow and the wrist, may be used and must be put on and discarded in the same way as disposable gloves. Sleeves must not be loose or dangling. Sleeves must be able to be rolled or pulled back and kept securely in place during hand washing and direct patient/subject activity. Sites should contact central supply to order stock of disposable over-sleeves.

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 Clinical Standard Operating Procedure (ATS LFD) 46 wipes followed by alcohol-based hand rub, and must wash their hands at the first opportunity (NHSE/I 2019)

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

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

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

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

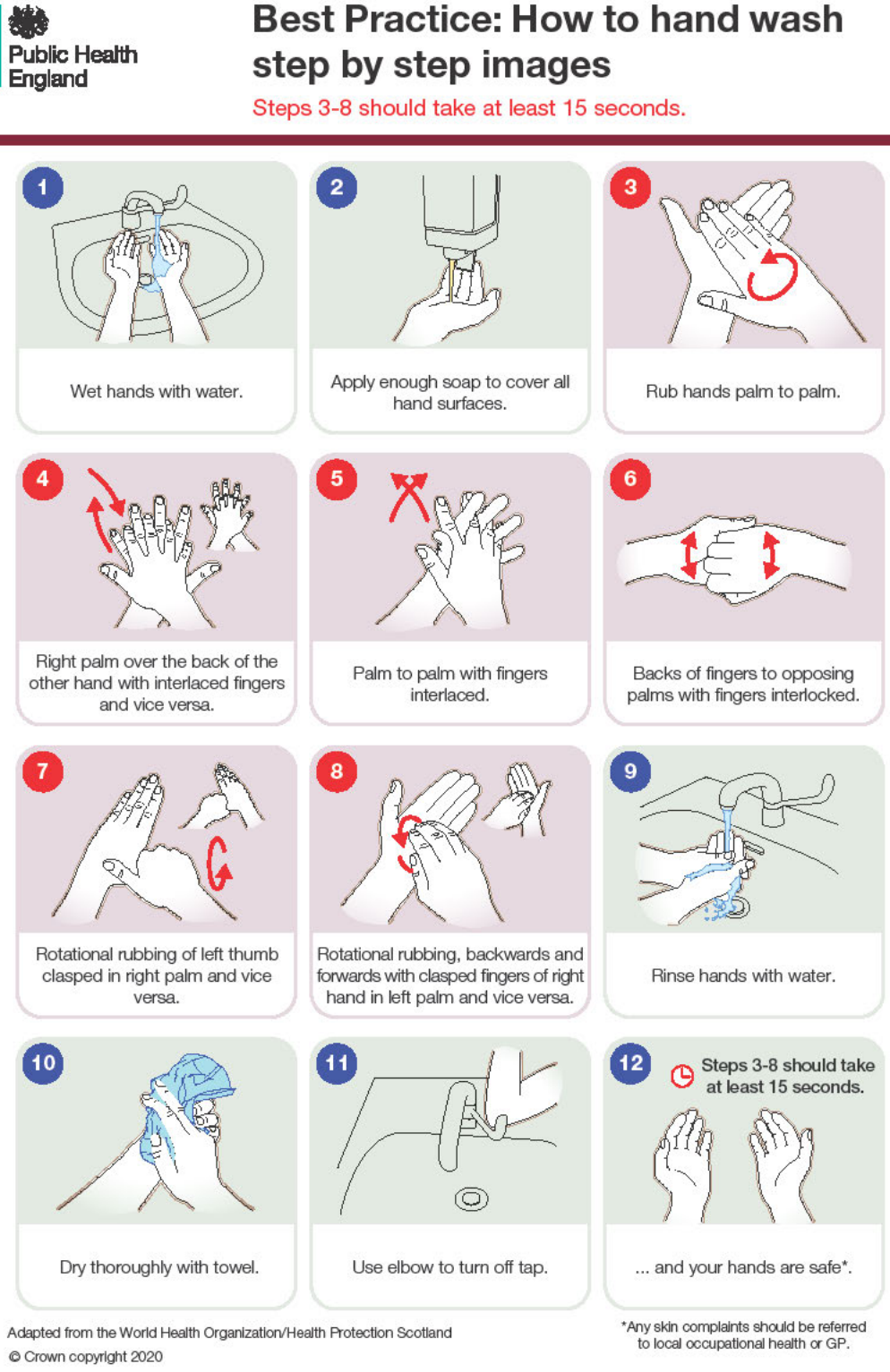
Alcohol based hand rub: It is critical for Test Sites to ensure that guests and staff are maintaining regular hand sanitisation as prescribed in this document and the testing procedures. Testing booths or sample collection areas should be equipped with hand sanitiser dispensers for use throughout the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

Best practices techniques for hand rub and hand wash can be found in the schematics below:

Public Health England

Best Practice: How to handrub step by step images

Adapted from the World Health Organization/Health Protection Scotland



11.4 Body fluid spillage guidance

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

There are several types of spill kits available specifically developed to deal with body fluid spills.

If you have access to a body fluid spillage kit, follow the manufactures instructions, and ensure you are wearing appropriate PPE and the area has been cordoned off. Staff who deal with a spillage must report to their line manager to ensure that the spillage kit is replaced after it is used.

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

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

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

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.

Please also refer to the Guidebook for further information.

12.1 Classification

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

While the testing sites are regarded as healthcare settings in England and Wales, in Scotland they are viewed as municipal sites. In either scenario the waste that is generated should be segregated at source and should not be over classified as clinical waste. With the increased testing availability in the NHS Test and Trace programme, there is a requirement to fully understand the responsibilities of healthcare waste management at a local level. Investigation is on-going in Northern Ireland. All areas have a waste management 'Duty of Care' and are responsible for undertaking a local WM3 assessment for the classification of the waste that they will generate (if not identified in the table below), this assessment must be documented. A Duty of Care Waste Transfer Note must be completed before waste is removed from site and records kept for minimum of 2 years were applicable.

12.2 Regulatory Position Statement (RPSs) and Local Enforcement Positions (LEPs) C23

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

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 waste disposal facilities are available in the location that will accept 18 01 04 and 18 01 07 waste or if there is available capacity outside of the location how will the waste be transported in order to be safely received?
- Where there is no facility already permitted to transfer, incinerate, or landfill 18 01 04 and 18 01 047 wastes and reliance on a Local Enforcement Position or Regulatory Position Statement may be required, contact the waste contractor to confirm that they will accept the waste, understand in what form it needs to be delivered and that regulatory requirements are in place.

- Where incinerator or landfill operators are willing to accept the waste ensure that they obtain, or have already obtained, permission from the local Environmental Agency Officer and demonstrate that they can meet the conditions set out in the Regulatory Position Statements and corresponding Local Enforcement Position Statements.
- 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 classified or transported as clinical waste, UN3291)

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/biohazard) markings
- Yellow bag with a black strip (tiger bag)

12.7 Storage: 72 hours storage and reclassification is not acceptable

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

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

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

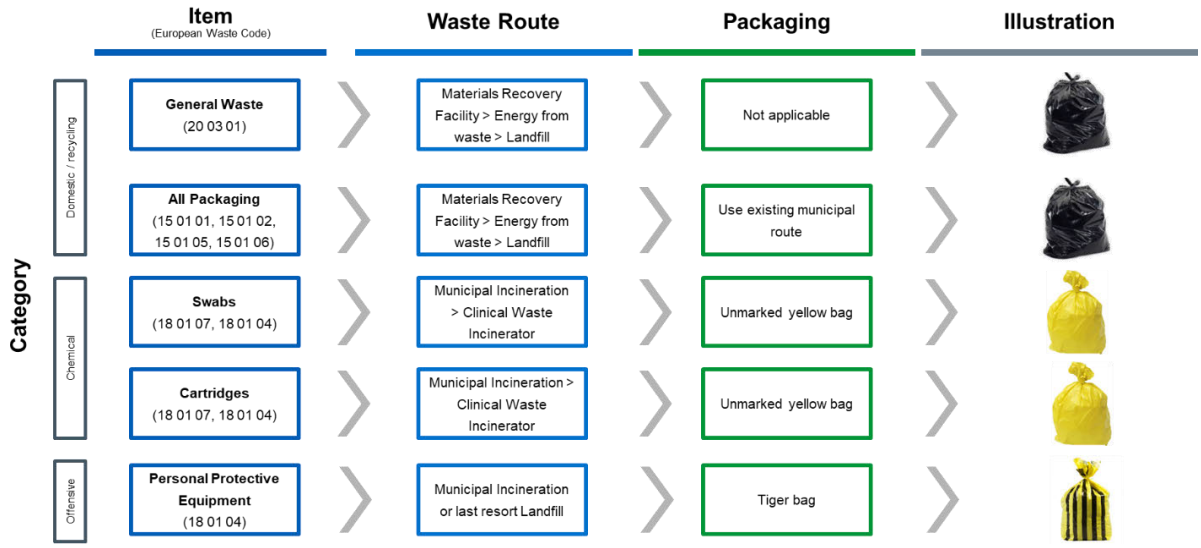
12.8 Waste streams for Asymptomatic Testing Site - Lateral Flow Testing

Item	Sample	Waste categorisation	European Waste Code (EWC)	Likely Management Route / Waste Hierarchy	Health Technical Memoranda (HTM) 07.01 Packaging
General Waste	Sandwich wrapper	Domestic/ recycling	20 03 01	1st Option: Materials Recovery Facility 2nd Option: Energy from waste 3rd Option: Landfill	Not applicable
All packaging	Outer packaging on equipment	Domestic / recycling	15 01 01 15 01 02 15 01 05 15 01 06	1st Option: Materials Recovery Facility 2nd Option: Energy From Waste 3rd Option: Landfill	Use existing municipal route
Swabs	Absorbent pads Vials Tissues	Chemical	18 01 07 Plus 18 01 04	1st Option: Energy from waste 2nd Option: Municipal incineration 3rd option: Clinical waste incinerator 4th option: Landfill (last resort)	1st Option: Unmarked yellow neutral container/bag 2nd Option: White / clear container/bag 3rd Option: Tiger bag **Do not use hazardous waste packaging**
Cartridges / Devices (i.e., Innova)	LFT cartridge	Chemical	18 01 07 Plus 18 01 04	1st Option: Energy from waste 2nd Option: Municipal Incineration 3rd Option: Clinical Waste Incinerator 4th option: Landfill (last resort)	1st Option: Unmarked yellow neutral container/bag 2nd Option: White / clear container/bag 3rd Option: Tiger bag **Do not use hazardous waste packaging**

Personal Protective Equipment	Apron Face mask Gloves	Offensive	18 01 04	Municipal Incineration or last resort Landfill	1st Option: Tiger bag

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

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



13 Appendix C: Self swabbing instructions

UK Government

NHS Test and Trace

Take swab sample

Step-by-step guide

Need help?

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

1

Remove your face covering.

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

You can use the mirror to help.

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

2

Gently blow your nose into a tissue

Throw the used tissue into the healthcare waste bin provided.

This is so that you get rid of excess mucus.

3

Use hand sanitiser to clean your hands.

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

4

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

Identify the soft, fabric tip of the swab.

5

Open the package and gently take out the swab.

This will be used for both tonsils and nose.

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

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

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

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

6

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

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

7

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

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

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

Be careful not to touch any surfaces with the swab.

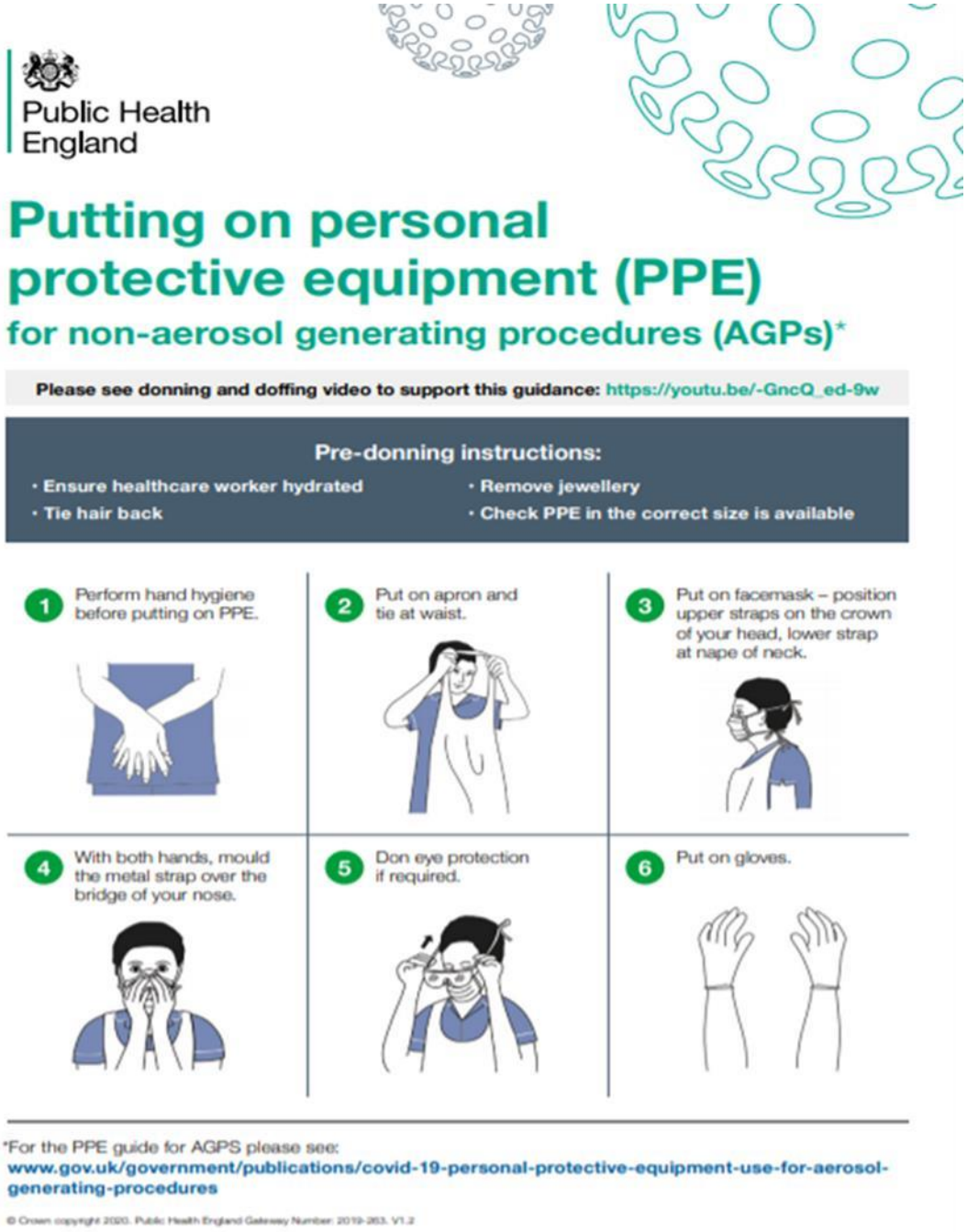
Put on your face covering.

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

Use hand sanitiser after handing in your sample.

14 Appendix D: PPE instructions – putting on and taking off

Putting on personal protective equipment (PPE) - standard infection control procedures (publishing.service.gov.uk)



Public Health England

Putting on personal protective equipment (PPE)

for non-aerosol generating procedures (AGPs)*

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

Pre-donning instructions:

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

1. Perform hand hygiene before putting on PPE.
2. Put on apron and tie at waist.
3. Put on facemask – position upper straps on the crown of your head, lower strap at nape of neck.
4. With both hands, mould the metal strap over the bridge of your nose.
5. Don eye protection if required.
6. Put on gloves.

*For the PPE guide for AGPS please see: www.gov.uk/government/publications/covid-19-personal-protective-equipment-use-for-aerosol-generating-procedures

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

15 Appendix E: Assisted swabbing instructions for testing Subjects with additional needs

UK Government

NHS Test and Trace

Assisted swab sample

Step-by-step guide

Need help?

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

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

You should wear a face covering throughout the process.

1

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

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

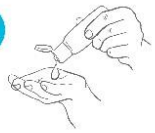
2

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

Throw the used tissue into the healthcare waste bin provided.

This is so that they get rid of excess mucus.

3



Use hand sanitiser to clean your hands.

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

4

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

5

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

Identify the soft, fabric tip of the swab.

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

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

6

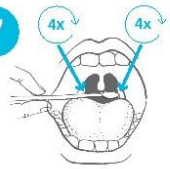
Open the package and gently take out the swab, holding it at the stick end.

This will be used for both tonsils and nose.

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

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

7



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

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

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

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

8

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

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

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

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

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

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

Use hand sanitiser after handing in their sample.

TC Jan 2021

16 Appendix F: Testing information poster

HM Government

NHS Test and Trace

Information about your test

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

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

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

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

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

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

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

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

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

17 Appendix G: About this document

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

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

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

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

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

What is the clinical standard operating procedure?

The clinical SOP document is part of the DHSC's testing framework describing how testing services can be delivered safely, efficiently, with quality output and uniformity of performance. It covers key areas such as testing procedures (how to use the device), infection control and quality assurance. The document has been developed from learnings captured across thousands of sites.

Why is it important for you to read the document?

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

How to use this document?

As a matter of good clinical governance practice, the framework and policies are being continually reviewed, so when changes are made it is critical that these are understood and implemented to maintain the quality of testing services, regulatory requirements and local health and safety.

Your continued support and efforts to combat the virus are essential to the national response.

Thank you,

Schedule 2

Bill of Materials

Approved on 23/02

4.2 Innova Lateral Flow Test Kit (Swab) Bill of Materials

Applicable for Universities, Public Industries, DPHs, Under-represented Groups, Community Testing, Devolved Administrations

Sample SKU	Item	Quantity	Notes
TK1573	Innova Swab Collection Kit	1 *	One coloured box contains enough materials to conduct 25 tests. This includes 25 throat / nasal swabs, 25 SARS-CoV-2 Antigen Test Cartridges, 25 extraction tubes, 2 bottles of extraction fluid, instructions for use and a QC card.
TC1660	Test Registration cards	25	
TC1683	LFD barcode	25	
PP1333	Face visors with foam	1.56	
PP1090	EN146683 Surgical Mask	3.65	Does not include additional supply for subjects that arrive without a mask
PP1013	Disposable Apron	3.13	
PP1014	Nitrile Disposable Gloves - Small	12.89	
PP1015	Nitrile Disposable Gloves – Medium	24.75	
PP1355	Nitrile Disposable Gloves – Large	11.34	
PP1220	Nitrile Disposable Gloves – Extra Large	2.58	

* 1 Innova Swab Collection Kit = 25 kits
PPE volumes above are in line with requirements of Master ATS SOP v3.0

Optional item for site set-up and ad hoc requests

Sample SKU	Item	ATS	Notes
TBD	Test Tube Rack	TBD	This will be determined by the number of testing booths at the test site

*This only includes the items that the SC&L team provides to testing sites in order to conduct a test, not the entire site set up

NHS Test and Trace

OFFICIAL – FOR INTERNAL USE ONLY

2

Schedule 3

Event Testing Dates and Operating Hours

Day	Event Testing Date	Operating Hours
1.	16 April 2021	9:00 – 17:00
2.	17 April 2021	9:00 – 17:00
3.	18 April 2021	9:00 – 17:00
4.	19 April 2021	9:00 – 17:00
5.	20 April 2021	9:00 – 17:00
6.	21 April 2021	9:00 – 17:00
7.	22 April 2021	9:00 – 17:00
8.	23 April 2021	9:00 – 17:00
9.	24 April 2021	9:00 – 17:00
10.	25 April 2021	9:00 – 17:00
11.	26 April 2021	9:00 – 17:00
12.	27 April 2021	9:00 – 17:00
13.	28 April 2021	9:00 – 17:00
14.	29 April 2021	9:00 – 17:00
15.	30 April 2021	9:00 – 17:00
16.	1 May 2021	9:00 – 17:00
17.	2 May 2021	9:00 – 17:00
18.	3 May 2021	9:00 – 17:00