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## **INTERIM Novel coronavirus (COVID-19) standard operating procedure**

### **Rollout of lateral flow devices for asymptomatic testing of healthcare workers for SARS CoV-2**

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*This Standard Operating Procedure (SOP) has been developed for use by Healthcare Workers in NHS Scotland and by Primary Care Independent Contractors and is based on the initial SOP developed for the rollout of lateral flow devices for asymptomatic staff testing by NHS England. It is correct at the time of publishing. However, as it is subject to updates, please use the hyperlinks to confirm the information you are disseminating to your staff is accurate.*

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**Version Control**

Version	Author	Summary of Changes	Reviewed By	Date
1.0	Scottish Government	Draft interim SOP	Scottish COVID Testing Clinical Governance Group	07//12/20
1.1	Scottish Government	V1.1 following comments from COVID Testing Clinical Governance Group	Expanded Healthcare Worker Testing Programme Board	08/12/20
1.2	Scottish Government	V1.2 following comments from Expanded Healthcare Worker Testing Programme Board	Scottish COVID Testing Clinical Governance Group	09/12/20
1.3	Scottish Government	V1.3 updates to wording following comments from Programme Board in relation to: <ul style="list-style-type: none"> <li>•Change to isolation requirements</li> <li>•Update on waste disposal</li> <li>•Clarify requirement for LFD testing if already undergoing weekly PCR testing</li> <li>•Expanded scope to include COVID-19 vaccinators</li> </ul>	Pathway lead for expanded healthcare worker testing	18/12/20

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1.4	Scottish Government	<p>V1.4 update to wording following comments from Programme Board members in relation to:</p> <ul style="list-style-type: none"> <li>• Further emphasis placed on importance of following IPC measures and national guidelines even if you receive a negative result.</li> <li>• Recognition of other emerging studies on efficacy of LFD tests.</li> <li>• Updated link to Oxford University research on sensitivity.</li> <li>• Further clarity for staff partaking in PCR and LFD tests Simultaneously. These groups would have one LFD test and one PCR test per week.</li> <li>• Lot numbers are case Sensitive, staff need to be aware of this when inputting data. Update to contact tracing policy. Contact tracing will now commence from the positive LFD test result.</li> <li>• MHRA Coronavirus Yellow Card reporting site added.</li> <li>• Expansion of in-scope</li> <li>• Healthcare workers</li> </ul>	Pathway lead for expanded healthcare worker testing	05/02/21
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1.5	Scottish Government	<p>Update to wording following expansion of pathway to include primary care independent contractor workforce including:</p> <ul style="list-style-type: none"> <li>• Advice regarding waste disposal in primary care setting</li> <li>• Clarification of testing arrangements for care home visiting professionals</li> <li>• Information regarding delivery mechanism of LFD test-kits to primary care premises</li> <li>• Data gathering requirements for primary care context</li> <li>• Expectations regarding supporting staff monitor 90 day period following positive PCR test in primary care setting <ul style="list-style-type: none"> <li>• Training and adverse event contacts for primary care added</li> </ul> </li> <li>• Amendment of NHS Board to Employer where appropriate. Amendment of NHS staff to staff where appropriate</li> </ul>	Pathway lead for expanded healthcare worker testing	15/02/21
1.6	Scottish Government	V1.6 Update to wording following comments from NSS IRIC in relation to the Scottish process for alerting to incidents.	Pathway lead for expanded healthcare worker testing	17/02/21

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<p>1.7</p>	<p>Scottish Government</p>	<p>V1.7 Update to wording following review and comments from Design Authority</p> <p>Update to include hyperlinks to online portal following user feedback. Update to include contact details for NES and new mailbox for support for primary care independent contractors.</p> <p>Updated to wording following review and comments from Scottish COVID Testing Clinical Governance Group</p> <p>Updated to include additional information regarding distribution of test-kits to primary care independent contractors.</p>	<p>Pathway lead for expanded healthcare worker testing</p> <p>Scottish COVID Testing Clinical Governance Group</p>	<p>08/0/21</p>
<p>1.8</p>		<p>V1.8 Updated to include information on the use of latex in PCR test swabs</p>	<p>Pathway lead for expanded healthcare worker testing</p>	<p>1.8</p>

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1.9	Scottish Government	<p>V1.9 Updated to include expansion of pathway to all NHS Scotland healthcare workers.</p> <p>Updated information on the use of latex in PCR test swabs.</p> <p>Primary care information updated re: access to testing for locums, practices that have opted out of testing, and NSS mailbox.</p>	Pathway lead for expanded healthcare worker testing	29/03/21
1.10	Scottish Government	<p>V.10 Updated to reflect the transition in LFD testing product from Innova 25s to Orient Gene 7s.</p> <p>Updates to reflect transition of primary care testing to BAU.</p>	Pathway lead for expanded healthcare worker testing	16/08/21
1.11	Scottish Government	<p>Updated to highlight the change in policy from twice weekly testing to daily LFD testing and the move to OG20 LFD test kits. Change to exemption to LFD testing within 90 days of a positive PCR test</p>	Pathway lead for expanded healthcare worker testing	16/12/21

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**Approval**

Cell Name / Role	Review / Approval	Version Reviewed / Approved	Date
Scottish COVID Testing Clinical Governance Group	For review on 7 December	1.0	07/12/2020
Healthcare Worker Testing Programme Board	For review on 8 December	1.1	08/12/2020
Scottish COVID Testing Clinical Governance Group	For approval on 9 December	1.2	09/12/2020
Pathway lead for expanded healthcare worker testing	For review and approval on 18 December	1.3	18/12/2020
Pathway lead for expanded healthcare worker testing	For review and approval on 05 February	1.4	05/02/2021
Pathway lead for expanded healthcare worker testing	For review and approval on 15 February	1.5	15/02/2021
Pathway lead for expanded healthcare worker testing	For review and approval on 15 February	1.6	15/02/2021
Scottish COVID Testing Clinical Governance Group	For review and approval on 08 March	1.7	08/03/2021
Pathway lead for expanded healthcare worker testing	For review and approval on 15 March	1.8	15/03/2021



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Pathway lead for expanded healthcare worker testing	For review and approval on 29 March	1.9	29/03/2021
Pathway lead for expanded healthcare worker testing	For review and approval on 16 August	1.10	16/08/21
Pathway lead for expanded healthcare worker testing	For review and approval on 16 December	1.11	16/12/2021

## Introduction

This is the Standard Operating Procedure (SOP) for daily testing of all asymptomatic healthcare staff in NHS Scotland using lateral flow devices (LFDs) on nasal swab samples.

The scope of the pathway has been expanded to include all healthcare workers employed directly by NHS Scotland.

The scope of the pathway also includes patient-facing staff in primary care independent contractors - general practice, dentistry, optometry and pharmacy. Please note primary care staff currently are required to be patient-facing in order to access testing.

The aim of this programme is to identify staff members infected with the virus who do not have symptoms, and allow them to self-isolate, so reducing the risk of infecting colleagues and patients. LFD tests are less sensitive than PCRs, and will not detect every infected individual. It is therefore essential to stress that a negative LFD test does not guarantee an individual is virus-free. Existing Infection Prevention and Control (IPC) measures - including the use of PPE, the extended use of face masks, physical distancing, symptom vigilance, increased environmental cleaning, and good hand and respiratory hygiene – all remain critical to minimise the risk of transmission of COVID-19.

For more information about Infection Prevention and Control and PPE please see:

- National Infection Prevention and Control Manual  
<http://www.nipcm.hps.scot.nhs.uk/>
- Training materials via TURAS  
<https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-yourworkplace-environment>

This SOP must be used as described; any reasonable minimal adaptations where appropriate for localised service delivery must be subject to local clinical governance scrutiny and these changes must be documented. The SOP is designed for safe implementation of approved processes. Any major proposed changes or innovations to this SOP must be approved by the Scottish COVID Testing Clinical Governance Group and the Expanded Healthcare Worker (HCW) Testing Programme Board before implementation.

## Governance

Clinical governance is the mechanism through which healthcare services are held accountable for continuously improving their quality and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. Effective clinical governance ensures that risks are mitigated, adverse events are rapidly detected and investigated openly, and lessons are learned. It is

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an umbrella term for a framework of activities that help sustain and improve high standards of clinical care.

Effective clinical governance requires:

- A supportive environment and organisational culture that recognises the importance of good clinical governance
- Effective systems, processes and information flows to assess, monitor and improve the quality and safety of services provided, including application of evidence-based practice
- Sufficient numbers of suitably qualified, competent and experienced staff to deliver care to the required standard
- Risk and incident management systems setting out the management of safety concerns, safety incidents and risk mitigation
- In addition, rigorous audit will help reduce the risk of errors and where this occurs it will help identify them quickly and manage them effectively and sensitively.

The Scottish Government is responsible for providing national level guidance and Frequently Asked Questions (FAQs) and ensuring that appropriate training materials are available nationally from NHS Education for Scotland (NES). The Scottish Government has established a national Programme Board to oversee the delivery of asymptomatic lateral flow testing of staff in NHS Scotland for SARS CoV-2.

### **NHS Scotland Boards**

NHS Scotland Boards are responsible for ensuring successful delivery and implementation of this testing programme at a local Board level in line with this SOP. In addition, Boards are responsible for ensuring there is effective local clinical governance of the testing programme and that there is a local quality management and assurance system in place. Boards must ensure there is a consistent approach to quality and safety, and that risks are mitigated, adverse events are rapidly detected, appropriately reported, investigated openly, and lessons are learned. Boards should also take the SOP through their own local governance groups.

A quality management system could cover the following (non-exhaustive list):

NHS Board Quality Assurance requirements:

- Operational checklist
- Workflow reviews
- Staff competence and training checks
- Staff sign off form
- Testing supervision where necessary

NHS Board Monitoring:

- Kit lot numbers and allocation to staff - ensure the information set out at **Appendix 1** is recorded when LFD test kits are issued to staff
- Invalid test rates
- Operator-specific audit trail

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- Reporting errors
- Serious incidents monitoring
- Risk and mitigation plans
- Performances against qRT-PCR – comparative analysis to be developed nationally

National Quality Assurance of test-kit:

- Quality assurance batch acceptance of the test kits will be agreed and managed nationally
- As detailed later on in the SOP, if there are concerns about the safety or performance of the test kits, an adverse event must be recorded on the local Board adverse event reporting system. This will enable the responsible manager to investigate and identify mitigating actions.

Boards should designate an appropriate individual to act as Quality and Governance Lead – this could be your existing appointed LFD Testing Lead - who will have accountability for the clinical quality and risk management of the service within the context of a non-laboratory environment. This person will undertake the following:

- Implement appropriate quality assurance – i.e. monitoring the LFD tests being issued, LFD test results, voids and confirmatory PCR tests
- Implement a quality & safety incident and risk reporting system
- Maintain a risk register, develop and implement mitigation plans
- Report on quality assurance, incidents, risks and mitigations
- Review staff sign off forms stating that they are able/competent and understand instructions for use of LFD tests
- Ensure the promotion of good quality practice across the service delivery
- Undertake quality audits, identifying where there are repeat inconclusive tests

### **Primary Care Independent Contractors**

Primary Care Independent Contractors are responsible for ensuring successful delivery and implementation of this testing programme in line with this SOP. They should ensure effective governance and reporting processes are in place as appropriate and proportionate to their circumstances.

Contractors are responsible for distributing test kits to staff and ensuring appropriate training is provided to staff, supported by resources developed and made available by NHS Education for Scotland (NES) and detailed further below. Contractors have been provided with a mailbox ([PrimaryCareLFD@gov.scot](mailto:PrimaryCareLFD@gov.scot)) to which they must escalate clinical or serious incidents or concerns. Requests for further support with training should be directed to NES (at [hai@nes.scot.nhs.uk](mailto:hai@nes.scot.nhs.uk)).

### **Risk and incident management**

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

- identify the risk;

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- assess the frequency and severity of the risk;
- mitigate the risk;

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

Clinical or serious incidents and recurring spurious results are managed through local service delivery governance processes; LFD test Leads within Boards must be informed (Primary Care Independent Contractors have been provided with details of a mailbox to contact – [PrimaryCareLFD@gov.scot](mailto:PrimaryCareLFD@gov.scot)) to enable appropriate escalation. If appropriate, the Pathway lead will ensure the Scottish COVID Testing Clinical Governance Group are notified to ensure local, programme and national implications are understood and required action is taken. Any suspected side effects to medical devices used in coronavirus treatment, or issues relating to spurious results, should also be reported to [NSS IRIC](#) to ensure safe and effective use. More information on the process for incident reporting is on page 16.

Please note that the manufacturer's Instructions for Use included in the Orient Gene 7s LFD test kits directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify [NSS IRIC](#).

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

**Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy.** A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test.

Both the Innova and Orient Gene swabs (LFD kits) are latex free. The swabs are also supplied in sterile packaging, labelled as sterile, to protect from exposure to latex within the external environment. This means that if testing staff handling the test kit are wearing latex gloves there should be no impact on the swab itself. If any part of the swab packaging looks damaged in any way, staff should not use the test and should report this via the incident reporting process outlined on page 15.

Some PCR testing swabs - while not containing latex – may have been manufactured in areas that have previously handled latex. This applies to those kits that have been distributed via the Department of Health and Social Care (DHSC) across care at home/housing support services.

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The PCR kits affected will have a warning clearly stating this and we advise, although the risk is minimal, that staff who have a latex allergy do not use these kits. Where this arises we suggest that staff contact their employer in the first instance. Alternative LFD kits can be provided.

### **Overall aim**

To roll out daily testing of all asymptomatic healthcare workers using lateral flow assay devices (LFDs) on nasal swab samples with immediate effect. This, together with qRT PCR, will provide an integrated testing approach and resilience in asymptomatic NHS staff testing.

### **Objectives**

The key objectives will be to:

- Reduce the potential spread of COVID-19 in healthcare settings
- Reduce staff COVID-19 absenteeism by minimising risk of transmission between staff as previously unidentified asymptomatic positive staff members will self-isolate following positive test result
- Support both COVID-19 and non COVID-19 clinical pathways over the winter period/second or future waves.

### **Lateral flow antigen testing**

Lateral flow antigen testing detects the presence of the COVID-19 viral antigen from a swab sample. The test is administered by handheld devices producing results in up to 30 minutes and can be self-administered, following provision of training materials. Studies to date suggest that lateral flow antigen tests are sensitive at higher viral loads, but with a lower sensitivity than qRT PCR. As such, they may be more practical for detecting individuals who are infectious, rather than individuals who may have had COVID-19 in the recent past but are no longer infectious (qRT PCR will detect both). However, this also means that Lateral Flow antigen tests are more likely to miss people with current infection at lower viral loads who may be infectious or go on to become so. Staff should remain vigilant to the development of symptoms that could be due to COVID-19 and continue to follow existing Infection Prevention and Control (IPC) measures.

Since lateral flow antigen test kits are available for immediate deployment, expanded testing of all asymptomatic healthcare workers will commence with this testing methodology.

The approach to using lateral flow antigen testing is as follows:

- Based on testing characteristics, such as sensitivity and modelling data, testing of in-scope staff (as outlined above) using the Innova or Orient Gene lateral flow antigen device will take place daily, using self-administered nasal swabbing (with confirmation of positives by PCR via the Board's local designated COVID-19 laboratory).

- The Healthcare worker pathway is now transitioning from Innova to Orient Gene lateral flow antigen devices. Existing supplies of Innova 25 LFD test kits remain valid for use until their expiry date and any stocks should be depleted before staff are issued with Orient Gene test kits.
- Testing will be rolled out via training resources developed and made available by NHS Education for Scotland (NES) via [TURAS](#).
  - For Innova test kits this will include an instruction video and written instructions; this will include instructions on the interpretation of results. The MHRA have advised that the LFD training video can be used as the observed test for the purposes of the competency assessment. This will ensure that each member of staff who will be self-testing has received information and support (including access to training resources either online or in person) and, where necessary, has been observed by a trained healthcare professional the first time that they undertake the test.
  - For Orient Gene 7 test kits, the manufacturer's Instructions for Use are included in the test kit and are also available [here](#). Please however note the following important departures from the IFU for the healthcare worker pathway in Scotland.
    - The Orient Gene IFU directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify NSS [IRIC](#).
    - When recording test results on the online portal, please ensure staff enter the lot number provided on the outer cardboard packaging of the test kit, **not** the ID Number printed on the individual test cassette.
  - For Orient Gene 20 test kit, electronic Instructions for Use (eIFU) will replace the Manufactures' Instructions for Use, which should be disregarded, and an instructional video will be available online. In addition, a one page summary IFU (to be issued with the boxes of kit to end users), and a poster of the differences between all test kits used by HCWs to date will be given to staff. OG20s are approved for use as 'assisted-testing' kits, however we are able to use these tests as self-testing kits for health and social care staff. A range of training materials and an eIFU will be available to guide support HCWs to use OG20 LFD test kits. However, staff are encouraged to request supervision for their first OG20 test if they are unsure or would like extra support.
    - Please note Health Boards/ Primary Care Independent Contractors will be asked at point of ordering OG20s to confirm that all staff have completed the required training for using the lateral flow test supplied.

- Employers must provide information related to whom the staff member should contact for any issues (e.g. their line manager); who to inform if they record a positive result and the need to self-isolate at that point; and what they need to do to get a confirmatory qRT PCR. Employers must make a Privacy Notice available to their staff. Employers must also clarify with staff members where their results should be recorded, and how frequently these should be submitted for collation.
- A digital solution has been developed allowing for results of LFD tests to be captured via a [digital portal](#). Data captured from the digital portal will flow to NHS National Service Scotland for use in reporting and any required systems integration. The portal is available via a web link ([www.covidtestingportal.scot](http://www.covidtestingportal.scot)) so that anyone can use their own or a workplace device to record the results. Guidance on how to use the portal is included in the instruction guide developed by NES. Further communications will be issued by the Directorate for Health Performance and Delivery in relation to weekly performance monitoring.
- **Symptomatic staff should not use lateral flow tests and must not attend work.** They must access a qRT-PCR test as per usual symptomatic testing channels within their Board.
- Similarly, staff working in clinically vulnerable areas who are already being regularly tested for COVID, or who are participating in studies such as SIREN, should continue their current method of testing via qRT PCR testing in line with local guidance and/or study protocols. However, in line with advice from the national COVID-19 Clinical Cell, these members of staff **should be offered the opportunity to also access LFD testing** to ensure they are being tested daily. This would result in a staff member testing once with a qRT PCR test and on the others days of the week with a LFD test.
- **Staff who are negative on LFD testing must not regard themselves as free from infection** – the test could be a false negative – they may also go on to acquire the virus in the period before the next test. They should remain vigilant to the development of symptoms that could be due to COVID-19 and existing Infection Prevention and Control (IPC) measures must be followed.

## Methodology

The following are key elements of the rollout which are either provided nationally or determined locally.

### **Lateral flow device provision to Health Boards**

The Orient Gene LFD test will be supplied to NHS Boards to meet the requirements of the staff testing population and to an agreed ordering schedule with NHS National Procurement. Remaining supplies of Innova 25 LFD test kits remain valid



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for use until their expiry date and any stocks should be depleted before staff are issued with Orient Gene test kits.

Space will need to be made available for storage of devices and instructions drawn up in local NHS Boards for the collection and issue of the devices alongside the distribution of the NHS staff instruction leaflet.

### **Lateral flow device provision to Primary Care Independent Contractors**

The testing scheme is currently available to patient-facing primary care healthcare workers only. Retail workers in primary care settings are only eligible for LFD testing under this scheme if they are directly involved in the provision of healthcare services, for example pharmacy counter staff.

All primary care independent contractors will receive supplies of Orient Gene 20 LFD test kits based on an estimate of patient-facing staff numbers. Existing supplies of Innova 25 and Orient Gene 7 LFD test kits remain valid for use until their expiry date and any stocks should be depleted before staff are issued with Orient Gene test kits. Test kits will be provided directly to individual premises for onwards distribution to staff.

If insufficient test kits are provided, NHS National Services Scotland (NSS) should be contacted by phone on 0800 008 6587 or by email at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) to arrange additional supplies. In due course it is intended that contractors will access LFD test kits via PECOS, where available.

The 22 February 2021 deadline for contractors to opt-out of receiving test kits following consultation with all patient-facing staff has passed. Contractors who have previously opted-out but now wish to participate in the programme can do so by contacting [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot). If any eligible staff subsequently wish to participate in routine testing, we expect contractors to support them in doing so. Staff can also contact [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) directly to access testing if necessary.

For reassurance, information on individuals choosing to participate or not participate in testing is protected under data protection however business level information about whole practices who decide not to participate maybe subject to an FOI request.

If contractors receive kits that they cannot (or do not wish to) use they can return kits by contacting NSS on 0800 008 6587 or at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) who will arrange for a return label to be send out. Alternatively excess kits can be retained for future use by current staff or for use by visiting locums, students etc.

### **Primary Care Locums**

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In the first instance primary care locums should access testing via a practice or pharmacy with which they have an ongoing relationship. Contractors can order test kits from [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) specifically to provide to locums if necessary. Where the locum works in an Out of Hours Hub or Community Assessment Centre, in addition to within primary care, they will be able to access supplies of test kits within these environments.

Optometry, General Practice and Dentistry locums have been contacted by the relevant Health Board to outline the process for locums to access LFD testing in their Health Board area. Pharmacy locums should contact NSS directly at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) to access LFD testing, providing their GPhC number, name and postal address.

### **Lateral flow device information**

#### ***Innova Test Kits***

Tests can be stored in typical warehouse conditions; they do not need refrigeration and must be brought to room temperature (15–30 °C) before use. They must be kept out of direct sunlight and not be exposed to heat.

The testing kits will arrive in boxes containing the following:

- 25 foil pouches containing the test cartridge and a desiccant
- two vials of 6 mls buffer solution
- 25 extraction tubes and 25 tube caps
- 25 sterilised swabs for sample collection
- The manufacturer's instructions for use of the device (IFU).
- **NB: you will receive instructions for healthcare workers separately from the box, and it is these that staff should follow instead.**

The manufacturer's instructions for use (IFU) are included in the box and are detailed and very technical. These do not need to be followed as healthcare workers will use the test in a slightly different way, which has been agreed with experts, discussed with MHRA, and the manufacturer informed. This is particularly in relation to use of the test for asymptomatic people, self-administration of the test, and the use of nasal swab inside the lower part of both nostrils. The rest of the process (i.e. the way the test is performed, and the results are interpreted) is the same as set out in the manufacturer's instructions.

**A simplified written guide for staff self-testing has been developed nationally by NES, it includes how to undertake the test, how to interpret the results, how to dispose of waste, and where they should store the box containing the test.**

#### ***Orient Gene Test Kits***

The Orient Gene 7s LFD devices and reagents can be stored at room temperature or refrigerated (between 2-30°C). Do not freeze any of the test kit components. The LFD devices and reagents should be used at room temperature (between 15°C and 30°C). If the kit has been stored in a cool area, leave it to reach normal room temperature before using.

The Orient Gene testing kits will arrive in boxes containing the following:

- x7 Sterile swabs inside a sealed wrappers
- x7 Test cassette in a sealed pouches
- x7 Extraction tubes with buffers
- x7 Nozzle caps
- x7 Plastic waste bag
- x1 extraction tube holder (reusable, not to be discarded)
- The manufacturer's Instructions for Use of the device (IFU).

Please note that for Orient Gene test kits, the manufacturer's Instructions for Use should be followed by healthcare workers. However, please note that the manufacturer's Instructions for Use included in the Orient Gene LFD test kits directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify [NSS IRIC](#).

The Orient Gene 20s LFD devices and reagents can be stored at room temperature or refrigerated (between 2-30°C). Do not freeze any of the test kit components. The LFD devices and reagents should be used at room temperature (between 15°C and 30°C). If the kit has been stored in a cool area, leave it to reach normal room temperature before using.

The Orient Gene testing kits will arrive in boxes containing the following:

- x20 Sterile swabs inside a sealed wrappers
- x20 Test cassette in a sealed pouches
- x20 Extraction tubes
- x2 Bottles of buffer solution (buffer solution contained in the 2 bottles are required to be portioned across all 20 tests)
- x20 Nozzle caps
- x1 extraction tube holder (reusable, not to be discarded)
- The manufacturer's Instructions for Use of the device (IFU).

Please disregard the IFU issued in the box and use the electronic instructions for use (eIFU) hosted on the Scottish Government web page and TURAS.

**Local information will need to be provided by Boards, for example, numbers to call for any queries or concerns related to the use of devices and outcome of results. Primary care independent contractors may wish to consider appointing a member of staff to deal with testing queries in the first instance, where it is proportionate to do so. They can also contact NES (at [hai@nes.scot.nhs.uk](mailto:hai@nes.scot.nhs.uk)) for further support with training.**

### **Waste disposal**

#### ***At Home:***

Negative LFD tests can be disposed of in domestic waste as normal. Positive tests should be double bagged and held for 72hrs before disposal in domestic waste.

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Regardless of whether the test is negative or positive, it should not be disposed of as clinical waste (i.e. in an orange bag) due to the presence of the test chemicals.

***In clinical settings:***

Staff are encouraged to test at home to allow self-isolation to begin immediately should a positive result be received.

Any swabs, cartridges and devices associated with LFD testing are likely to be contaminated with liquid chemicals. This waste is not clinical, neither is it infectious waste, therefore it must not be placed in an orange bag, nor disposed of via the clinical waste route.

Due to the liquid chemical content it must be treated by municipal incineration i.e. 'Energy from Waste' from waste facilities. It is necessary for this waste to remain 'visible' in the waste management chain in order to prevent mis-handling or inappropriate treatment (for example, landfill); therefore, where possible, it should be placed in a clear bag.

Where clear bags are not available you should speak to your local waste management team to agree an appropriate approach to achieve the desired treatment route (i.e. incineration). You will need to speak to the general waste contractor and ensure that this segregated waste is taken to energy from waste facilities, this may require separate arrangements to be made from other waste you produce. This may mean agreement to use another type of non-clinical waste bags such as white, black or other bags, as long as it is labelled as non-hazardous, chemically contaminated waste.

As set out in the manufacturer's safety instructions, the buffer solution is not hazardous; however, if accidentally ingested, a medical practitioner should be informed.

***In primary care settings:***

For primary care and independent contractor practices, the number of staff undertaking daily testing in situ should be taken into account. If only very small numbers of staff are undertaking the test on site, tests should be disposed of in the normal domestic waste stream, as per the At Home waste disposal guidance above. Staff are encouraged to test at home to allow self-isolation to begin immediately should a positive result be received.

**Risk and incident management**

**Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy.** Further details are provided above. A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is not a latex issue if the person is being tested with a lateral flow device (LFD) test.

Suitable pre-use checks should be carried out on the packaging and contents of the test kits. If there are quality concerns, e.g. items are missing, broken or damaged, the test kits should be rejected and returned to the supplier. If there are concerns about the safety or performance of the test kits, e.g. the device is damaged, breaks during use, or if the user has any concerns about the safety or performance of the test, **an adverse event must be recorded on the local adverse event reporting system. This will enable the responsible manager to investigate and identify mitigating actions. In primary care settings, adverse events should be notified to NHS National Services Scotland at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) if related to deliveries (e.g. items are missing, broken or damaged) or to [PrimaryCareLFD@gov.scot](mailto:PrimaryCareLFD@gov.scot) for other concerns.**

Arrangements must also be in place with LFD testing Lead to rapidly notify complaints to National Procurement and adverse events to [NSS IRIC](#), which is responsible for prompt onward notification of Scottish incident data to MHRA.

Please note that the manufacturer's Instructions for Use included in the Orient Gene LFD test kits directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify [NSS IRIC](#).

Further advice on quality control processes will be issued nationally if required.

### **Process for testing asymptomatic staff**

Staff should test themselves daily. Staff should continue to test themselves during periods of leave so that, in the event of a positive test, they can begin their period of self-isolation at that point.

**Following provision of training materials, the LFD test can be self-administered by staff at home or in the workplace.** Some staff are likely to require more support and may prefer to test themselves in the workplace. This should be taken into account in local delivery plans.

Staff working in clinically vulnerable areas who are already being regularly tested for COVID, or who are participating in studies such as SIREN, should continue their current method of testing via qRT PCR testing in line with local guidance and/or study protocols. However, in line with advice from the national COVID-19 Clinical Cell, these members of staff should also be offered the opportunity to access LFD testing to ensure they are being tested daily (one qRT PCR test and one LFD test when not accessing a qRT PCR test.)

Primary care staff who may previously have used other Pathways to access testing such as "Healthcare Worker" or "Care Home – Visiting Professional" should no longer do so from 22 February 2021. From this date, primary care staff should select

“Primary Care including Independent” on the [online portal](#) as the most relevant reason for taking the test. They should then select the area of independent and general practice they work in from the drop down list.

In the event of a positive result, the staff member must self-isolate immediately (along with their household) in line with government guidance, inform their manager and occupational health department (if available), and arrange to have an urgent confirmatory qRT PCR test performed; swabs will be taken in accordance with their organisational protocols and sent to their local designated COVID-19 laboratory for testing.

**Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy.** A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test.

The positive result of a LFT test will now be used to initiate contact tracing. On receipt of the test result, NHS National Services Scotland will feed this result into the Case Management System which contains all the positive test case information. This system is used to undertake contact tracing. The person who has tested positive will be advised to undertake a confirmatory PCR test result.

Should this test result confirm a false positive on the LFT, then local Health Protection/Test and Protect teams will be informed so that they can conduct a risk assessment to decide whether or not to reverse the contact tracing process. A person who is LFD pos/PCR neg should not stop self-isolation and should not resume usual duties unless told to do so following a HPT risk assessment. Contact tracing for that person will also continue until HPT decide it should stop. Should no confirmatory PCR be received within 48 hours, then the case will continue to be considered a positive case and where applicable relevant authorisation codes for the protect.scot app will then be sent.

If symptoms develop subsequently, then the staff member must restart their period of isolation from start of symptom onset, in line with Government guidance. Staff must continue to isolate until they have the results of the PCR test.

In line with existing government guidance, the symptomatic staff member must remain in isolation for 10 days from symptom onset, or longer if certain symptoms persist. The rest of their household must also being their period of isolation (in line with government guidance) from symptom onset in the symptomatic person, even if they don't have symptoms themselves.

**Please be advised that there has been a change to the guidance on exemption from LFD testing within 90 days of a positive PCR test. HCWs should continue to LFD test daily within 90 days of a positive PCR result. If HCWs have a positive LFD result or have new symptoms, they should isolate and get a PCR test.**

Staff who are negative on LFD testing must **not** regard themselves as free from infection – the test could be a false negative – they may also go on to acquire the virus in the period before the next test. They should remain vigilant to the development of symptoms that could be due to COVID-19 and existing Infection Prevention and Control (IPC) measures - including the use of PPE, the extended use of face masks, physical distancing, increased environmental cleaning, and good hand and respiratory hygiene – all remain critical to minimise the risk of transmission of COVID-19.

**Staff should not be at work if they have symptoms of COVID 19.** If staff have coronavirus (COVID-19) symptoms they must self-isolate as per Government advice and book a qRT-PCR test as per usual symptomatic testing channels within their Board: <https://www.nhsinform.scot/illnesses-and-conditions/infections-andpoisoning/coronavirus-covid-19/test-and-protect/coronavirus-covid-19-testing>

The LFD testing programme, and ongoing need for other IPC and no pharmaceutical interventions (NPI) measures, also applies to staff who are participating in the vaccination programme. Staff who have been vaccinated should still partake in daily LFD testing, preferably prior to their shift and adhere to existing IPC measures. The need for testing will be in place until we better understand the degree of protection, and duration, that the vaccination provides, including importantly whether it is possible to still transmit the virus if you've been vaccinated. The vaccination will not impact the LFD test result.

#### **For Innova LFD Test Kits:**

A simple-to-use written guide for healthcare staff LFD self-testing has been developed nationally and will be made available electronically to local teams for provision to staff members. This includes information on what to do when a positive, negative or invalid result is observed, and how the outcome of the test should be recorded, alongside the lot number of the test kit and any comments related to the performance of the device. An instructional video is also available.

#### **For Orient Gene LFD Test Kits:**

For OG7s the manufacturer's Instructions for Use are included in the test kit and are also available [here](#).

For OG20s please access the electric Instructions of Use (eIFU) via TURAS and Scottish Government webpages (from 20 December 2021), please do not use the manufacturer's Instructions for Use.

When recording the result of Orient Gene test kits please ensure staff enter the lot number provided on the outer packaging of the box, **not** the ID Number printed on the individual test cassette. Please note that this is contrary to the instructions provided in the manufacturer's Instructions for Use.

Staff should currently enter the results of Orient Gene test kits on the online portal only as a registered user or through the single test registration form. Please do not record Orient Gene test results via the bulk upload option.

Boards must provide staff with information on who to contact for queries, further training and assistance. Primary care independent contractors can contact NES (at [hai@nes.scot.nhs.uk](mailto:hai@nes.scot.nhs.uk)) for additional support with training, for example Webinars. They can also contact [PrimaryCareLFD@gov.scot](mailto:PrimaryCareLFD@gov.scot) for additional support if necessary.

**When issuing the LFD test kits to staff, NHS Boards need to ensure the information set out at Appendix 1 is recorded.** Primary care independent contractors should consider recording this information if it is proportionate to their setting to do so. When issuing LFD test kits, employers must also provide information related to whom the staff member needs to inform if they record a positive result, and what they need to do to get a confirmatory qRT PCR test. Employers must also clarify with staff members where their results should be recorded (i.e. via the [online portal](#)), and how frequently these should be submitted for collation (see section below on reporting of results).

## Isolation exemption

### Self-isolation for Social Care Staff

Within the healthcare workforce a high number of staff isolating would put additional pressure on already fragile services, therefore, we would like to emphasise that current guidance for healthcare staff should still be applied with one important addition. See [DL\(2021\)24 - Update on isolation exemptions for Health and Social Care staff \(scot.nhs.uk\)](#) for further details.

This existing isolation policy for staff who are household or passing contacts of covid-19 positive cases, exempts them from the requirement to self-isolate for 10 days when they:

- are double-vaccinated;
- are asymptomatic and remain asymptomatic,
- undertake PCR test (which returns a negative test result before returning to work), and;
- Undertake daily LFD testing for the remainder of the 10 day period.

### An important addition to this is that staff must be

- double vaccinated and had their booster

LFD test kits from this pathway (**not** the universal offer) should be used to support the requirement for daily LFD testing for 10 days following last exposure. If additional LFD tests are required, staff should contact their Board LFD Lead. Primary care staff should contact NSS by phone on 0800 008 6587 or by email at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) to order additional kits if necessary.

## Reporting of results and PCR testing



The results from the LFD test will be documented by the individual staff member via an [online portal](#). Data captured from the digital portal will flow to NHS National Services Scotland for use in reporting and any required systems integration. The portal is on a web link ([www.covidtestingportal.scot](http://www.covidtestingportal.scot)) so that anyone can use their own device or a workplace device to record the results. Guidance on how to use the portal is included in the instruction guide developed by NES. Further communications will be issued by the Directorate for Health Performance and Delivery in relation to weekly performance monitoring.

The results from **Innova** devices must be recorded digitally by the staff members after 30 minutes has passed via the [online portal](#). The timing is critical, as leaving the test for longer than 30 minutes can lead to false positive results and the test will need to be repeated.

For **Orient Gene** devices the results must be recorded digitally by the staff member after 15 minutes have passed via the [online portal](#). The timing is critical, as leaving the test for longer than 20 can void the test result, and the test will need to be repeated.

**It is critical that staff note the difference in development time between the Innova and Orient Gene testing products.**

Results must be recorded in line with the following:

- **Negative:** The presence of only the control line (C) and no test line (T) within the result window indicating a negative result.
- **Positive:** The presence of the test line (T) and the control line (C) within the result window, regardless of which line appears first, indicating a positive result. The presence of any test line (T), no matter how faint, indicates a positive result.
- **Invalid result:** If the control line (C) is not visible within the result window after performing the test, the result is considered invalid.

When an **invalid result** is observed, **the test should be repeated with a new test kit**. If this issue persists and an individual continue to get invalid results, they should request to be observed by a trained healthcare colleague whilst they administer the test to identify if additional support or training is required. The test kit should also be replaced in case there is an issue with the batch in question. In addition, an incident report should be sent to [NSS IRIC](#).

All positive results on the lateral flow antigen device will be followed up by standard qRT PCR testing in the local designated COVID-19 testing laboratory. The request should be made following NHS Board protocols. The result from the qRT PCR test will be returned as per NHS Board protocols with clear instructions to staff members to speak to their line manager with any questions. Staff with a positive LFD test result must isolate (along with their household) until a confirmed PCR result is available.

If a staff member records a negative LFD test result but begins to display symptoms of SARS CoV-2, they must self-isolate in line with government guidance and obtain a PCR test in line with existing national guidance.

**Please be advised that some qRT-PCR tests are not suitable for those with a latex allergy.** A latex warning is present on affected qRT-PCR test packaging. This can include symptomatic, asymptomatic and confirmatory qRT-PCR tests. There is **not** a latex issue if the person is being tested with a lateral flow device (LFD) test.

### **Training staff members in the use of the device and providing ongoing support**

NHS Boards will identify members of staff to support training in self-administered LFD testing where required and to deliver training to those staff within their Boards who require support, according to a locally agreed roll out timetable. Primary care independent contractors should ensure that staff are trained in self-administered LFD testing, and provide support as appropriate to their setting and number of staff. Primary care independent contractors can contact NES (at [hai@nes.scot.nhs.uk](mailto:hai@nes.scot.nhs.uk)) for additional support with training, for example Webinars.

Training materials will be made available at the following link:

<https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-yourworkplace-environment>

It is recommended, but not required, that staff are observed by a trained healthcare colleague the first time they administer the test to identify early on if additional support is going to be required, or if they are unable to perform the test for whatever reason. Employers should use their discretion as to which staff may require training or additional support. Any staff member who needs support undertaking the test should be provided with appropriate support and training and observed on the first occasion, if possible. If a staff member is unable to perform the test, employers should enable testing by other technologies where possible.

For the majority of staff, the NES training materials and, for Orient Gene 7s test kits only, the manufacturer's Instructions for Use describing 'how to self-test' will be sufficient for staff to undertake self-testing independently. Some staff, where English is not their first language, or who have dexterity or other issues, will require practical support which may include hands-on demonstrations/training. Please note that the Orient Gene Instructions for Use are available in a number of languages [here](#).

For the majority of staff, the NES training materials and, for Orient Gene 20s test kits only, the electronic Instructions for Use (the manufacturer's Instructions for Use should not be used and destroyed), describing 'how to self-test' will be sufficient for staff to undertake self-testing independently. Staff should be aware that they should make it clear when picking up boxes of OG20s they feel comfortable being able to self-test and follow the instructions to self-test using OG20s.

Testing of staff is offered on a voluntary basis, however we would strongly encourage all eligible staff to undertake the testing. If staff members are not able to use the device, Boards must provide further support and training. Primary care independent contractors are encouraged to provide as much staff support and training as is reasonably practicable in their setting.

The national NES team will support Boards and independent contractors with training as needed, including webinars if required. Requests by employers should be made by Board LFD Leads via the Programme Manager of the Expanded HCW Testing Programme Board in the first instance. All NHS Boards must agree a local point of contact to assist their staff with any queries relating to the use of the device, and to support with further training if necessary. Primary care independent contractors may wish to consider appointing a member of staff to deal with testing queries in the first instance, where it is proportionate to do so.

Training materials for Innova branded LFD test kits are available digitally via TURAS - <https://learn.nes.nhs.scot/28079/coronavirus-covid-19/protecting-yourself-and-yourworkplace-environment>.

Training materials for Orient Gene 7s LFD test kits are available [here](#). Please note

- The manufacturer's Instructions for Use included in the Orient Gene LFD test kits directs users to contact the MHRA via the yellow card scheme if they are harmed by a lateral flow device. In Scotland the appropriate pathway is to notify [NSS IRIC](#).
- Contrary to the instructions provided in the manufacturer's Instructions for Use, healthcare workers should record positive, negative and inconclusive LFD test results via [NSS testing portal](#). Healthcare workers should only enter Orient Gene results as a registered user or through the single test registration form.
- Please do not record Orient Gene test results via the bulk upload option.
- When recording test results on the online portal, please ensure you enter the lot number provided on the outer cardboard packaging of the test kit, not the ID Number printed on the individual test cassette.

Training materials for Orient Gene 20s LFD test kits will be available digitally via TURAS and Scottish Government websites from 20 December 2021. Please note the manufacturer's Instructions for Use should be disregarded and the electronic Instructions of Use available on the above webpages used in their place.

## **Implementation**

### **NHS Boards**

NHS Boards will need to provide NHS National Procurement with details of delivery addresses for supplies and will need to provide adequate room for storage of test kits. An internal distribution location will be required for issue of devices to all (eligible) staff members, printed copy of the instruction guide and any other written instructions including local information.

### **Primary Care Independent Contractors**

The testing scheme is currently available to patient-facing primary care healthcare workers only. Retail workers in primary care settings are only eligible for LFD testing under this scheme if they are directly involved in the provision of healthcare services, for example pharmacy counter staff.

All primary care independent contractors will receive supplies of LFD test kits based on an estimate of patient-facing staff numbers. Existing supplies of Innova 25/Orient Gene 7 LFD test kits remain valid for use until their expiry date and any stocks should be depleted before staff are issued with Orient Gene test kits. Test kits will be provided directly to individual premises for onwards distribution to staff. If insufficient test kits are provided, NHS National Services Scotland (NSS) should be contacted by phone on 0800 008 6587 or by email at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) to arrange additional supplies. In due course it is intended that contractors will access LFD test kits via PECOS, where available.

The 22 February 2021 deadline for contractors to opt-out of receiving test-kits following consultation with all patient-facing staff has passed. Contractors who have previously opted-out but now wish to participate in the programme can do so by contacting [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot). If any eligible staff subsequently wish to participate in routine testing, we expect contractors to support them in doing so. Staff can also contact [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) directly to access testing if necessary.

For reassurance, information on individuals choosing to participate or not participate in testing is protected under data protection however business level information about whole practices who decide not to participate maybe subject to an FOI request.

If contractors receive kits that they cannot (or do not wish to) use they can return kits by phone on 0800 008 6587 or by email at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) who will arrange for a return label to be send out. Alternatively excess kits can be retained for future use by current staff or for use by visiting locums, students etc.

### **Primary Care Locums**

In the first instance primary care locums should access testing via a practice or pharmacy with which they have an ongoing relationship. Contractors can order test kits from [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) specifically to provide to locums if necessary. Where the locum works in an Out of Hours Hub or Community Assessment Centre, in addition to within primary care, they will be able to access supplies of test kits within these environments.

Optometry, General Practice and Dentistry locums have been contacted by the relevant Health Board to outline the process for locums to access LFD testing in their Health Board area. Pharmacy locums should contact NSS directly at [nss.PrimaryCareLFDOrderKits@nhs.scot](mailto:nss.PrimaryCareLFDOrderKits@nhs.scot) to access LFD testing, providing their GPhC number, name and postal address.

### Each employer will need to:

- Identify staff trainers (where necessary) and facilities to enable staff to be observed (if required) when they first collect and use the device
- Oversee staff the first time they undertake the test (if required)
- When issuing the LFD test kits to staff, ensure the information set out at **Appendix 1** is recorded, where it is proportionate to do so
- Establish a point of contact for staff members having difficulty performing the self-administered test
- Ensure staff are aware of and can access the [online portal](#) for recording results
- Provide information for staff members on what to do if they test positive and where they will get their swab test for confirmatory qRT PCR; *Primary Care independent contractor employers may wish to consider establishing a similar system where it is proportionate to do so.*
- Agree who is the designated laboratory for confirmatory qRT PCR testing
- Boards should develop a mechanism for recording and reporting results for statutory purposes in line with this document.
- Provide staff with privacy information.

### Key risks

This is not an exhaustive list but includes:

Test limitations:

1. Failure to follow the instructions for sample taking, test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. The likelihood of this happening will be reduced by adequate training, initial observed performance of those staff who require it, ongoing support as required, and ongoing access to training materials and, for Orient Gene test kits only, the manufacturer's [Instructions for Use](#).
2. A negative test result may occur if the specimen was collected or extracted from the swab incorrectly. **A negative test result will not eliminate the possibility of SARS-CoV-2 infection and all staff must continue to adhere to strict Infection Prevention and Control (IPC) measures, including appropriate use of PPE, extended use of face masks, physical distancing and symptom vigilance.** Additionally, the instruction booklet is clear that, if the staff member has returned a negative result but is symptomatic, they must follow government guidelines and obtain a PCR swab test.
3. Positive test results do not rule out co-infections with other pathogens and therefore staff members may also have other respiratory infections, such as Influenza A or B.

4. Lateral flow devices are less likely to detect non-infectious virus during the later stages of viral shedding that might be detected by PCR molecular tests. Hence, they are less likely to detect staff members who are recovering from having had the virus.

These limitations will be mitigated, as far as possible, by the actions outlined in this document, particularly related to training, simple written instruction materials and with an organisational help line, and by other nationally and locally available information on COVID 19 symptoms and actions.

### **Switching to different device**

Any switching to a different LFD will be carefully planned and managed with further training materials and written instructions prepared and distributed.

### **Sample type and compliance**

Some staff will not tolerate the regular use of nasal swabbing. Where possible, staff should be encouraged to report any difficulties they are experiencing via the local support contact identified by their Board or to their line manager.

### **Appendix 1 – Data to be collected when LFD tests are issued to staff**

Employers, including independent contractors, should establish local processes to ensure the following information is collated when the LFD test kits are issued to staff members:

- LOT number (written on the test kit)
- Number of LFD kits distributed
- Date of distribution
- Site / event distributed