



INTERIM Novel coronavirus (COVID-19) standard operating procedure

Rollout of lateral flow devices for asymptomatic testing of patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the Scottish Ambulance Service and all COVID-19 Vaccinators for SARS CoV-2

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Reviewed by: Expanded Healthcare Worker Testing Programme Board

Reviewed by: Scottish Covid Testing Clinical Governance Group

This Standard Operating Procedure (SOP) has been developed for use in NHS Scotland 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.

Contents

Document Control and Approval	3
Introduction	4
Governance	4
Overall aim	6
Objectives	6
Lateral flow antigen testing	7
Methodology	8
Lateral flow device provision	
Waste disposal	
Risk and incident management	
Process for testing patient-facing asymptomatic staff	
Reporting of results and PCR testing	12
Training staff members in the use of the device and providing ongoing support	
Implementation	13
Key risks	
Test limitations	
Switching to different device	
Sample type and compliance	

Document Control and Approval**Version Control**

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Approval

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Introduction

This is the Standard Operating Procedure (SOP) for twice weekly testing of all asymptomatic patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the Scottish Ambulance Service and all COVID-19 Vaccinators using lateral flow assay devices (LFDs) on nasal swab samples.

The aim of this programme is to identify patient-facing 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 PCR, 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.

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 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 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 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

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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 patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the Scottish Ambulance Service (SAS) and all COVID-19 Vaccinators for SARS CoV-2.

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, and investigated openly, and lessons are learned. Boards should also take the SOP for the asymptomatic testing of patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the SAS and all COVID-19 Vaccinators 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
- 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-kit 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:

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- 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

Risk and incident management

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

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

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 are managed through local service delivery governance processes; LFD test Leads within Boards must be informed and the Scottish COVID Testing Clinical Governance Group and the HCW Testing Programme Board must also be notified to ensure local, programme and national implications are understood and required action is taken. More information on the process for incident reporting is on page 10.

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.

Overall aim

To roll out twice weekly testing of all asymptomatic patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the Scottish Ambulance Service and COVID-19 Vaccinators 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:

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- Support the NHS in reducing 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 30 minutes and can be self-administered, following provision of training materials. Lateral flow antigen testing has a lower sensitivity than qRT PCR. However, studies to date suggest that these lateral flow antigen tests are more sensitive at higher viral loads, hence 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).

Since lateral flow antigen test kits are available for immediate deployment, expanded testing of all asymptomatic patient-facing staff in NHS Scotland hospitals, COVID-19 Assessment Centres, the Scottish Ambulance Service and COVID-19 Vaccinators will commence with this testing methodology.

The approach using lateral flow antigen testing is as follows:

- Based on testing characteristics, such as sensitivity and modelling data, testing of in-scope patient-facing staff (as outlined above) initially using the Innova lateral flow antigen device will take place twice weekly, using self-administered nasal swabbing (with confirmation of positives by PCR via the Board's local designated COVID-19 laboratory).
- This will be rolled out via training resources developed and made available by NHS Education for Scotland (NES) via TURAS, including an instruction video and written instructions; this will include instructions on the interpretation of results. 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. A simple-to-use written guide for healthcare staff self-testing has been developed nationally and will be made available electronically to local teams for provision to staff members. NHS Boards must provide information related to whom the staff member should contact for any issues; 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. NHS Boards 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 which will mean that reporting of results for LFD tests will be captured via a digital portal. Data captured from the

digital portal will flow to NHS Scotland for use in reporting and any required systems integration. The portal is available via a web link 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 twice weekly, every three to four days.
- **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

The Innova 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.

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.

Tests can be stored in typical warehouse conditions; they do not need refrigeration and must be brought to room temperature 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 NHS staff 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 NHS staff 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. 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.

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. 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:

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 ex. 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 other 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.

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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.

Risk and incident management

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

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

Process for testing patient-facing asymptomatic staff

Staff should test themselves twice a week – every three to four days – to fit with shift patterns – for example, Wednesday and Sunday, or Monday and Thursday. We advise that staff 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. Boards should take this into account in their 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 twice weekly, every three to four days.

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, 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. Students on clinical placements should also advise their University.

Until the PCR result is confirmed, the staff member must self-isolate in line with government guidance. At the point the confirmatory PCR test result is known, and this is positive, test results will, as normal, be referred to Test and Protect so that full contact tracing can commence. If the PCR result is negative, the staff member would be able to attend immediately for duties.

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 be in their period of isolation (in line with government guidance) from symptom onset in the symptomatic person, even if they don't have symptoms themselves.

A staff member who has tested positive via PCR should not commence/recommence regular COVID testing until 90 days after their positive test was taken. The staff member will need to liaise with their NHS Board to track the date at which the retesting should start. However, as above, if the staff member develops COVID-19 symptoms during that 90 day period, they must self-isolate in line with government guidance and arrange 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-and-poisoning/coronavirus-covid-19/test-and-protect/coronavirus-covid-19-testing>

The LFD testing programme, and ongoing need for other IPC and non-pharmaceutical interventions (NPI) measures, also applies to staff who are participating in the vaccination programme. Staff who have been vaccinated should still partake in twice weekly LFD testing 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.

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, and Boards must provide staff with information on who to contact for queries, further training and assistance.

When issuing the LFD test kits to staff, NHS Boards need to ensure the information set out at Appendix 1 is recorded. When issuing LFD test kits, NHS Boards 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. NHS Boards 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).

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 Scotland for use in reporting and any required systems integration. The portal is on a web link 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 the device must be recorded digitally by the staff member 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. 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 seek advice and support from their manager and the Board point of contact for LFD testing.

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.

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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 patient facing staff within their Boards who require support, according to a locally agreed roll out timetable. Training materials will be made available at the following link:

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

It is recommended 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. Boards 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 a staff member is unable to perform the test, NHS Boards should enable testing by other technologies where possible.

For the majority of NHS staff, the NES training video and information leaflet 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.

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. Numbers of staff who do not use the device should be documented and recorded.

The national NES team will support Boards with training as needed, including webinars if required; all requests 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 staff with any queries relating to the use of the device, and to support with further training if necessary.

The training video and written instruction materials will be made available digitally via TURAS.

Implementation

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.

In addition, each NHS Board 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
- 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; *NB remind them they should not self-test with the LFD for 90 days after any positive result is confirmed by qRT PCR. Boards should agree an alert system so staff know when to restart testing.*
- Agree who is the designated laboratory for confirmatory qRT PCR testing
- Develop a mechanism for recording and reporting results for statutory purposes in line with this document

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 an instruction booklet and video.
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 Influenzae 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. Nonetheless, any member of staff who does test positive for the virus which is confirmed by qRT PCR should not self-test for a further

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90 days from the point of becoming positive.

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.

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

NHS Boards should establish local reporting processes to ensure the following information is collated when the LFD test kits are issued to staff members:

- Staff name
- Date staff member received their box of tests
- Lot number of test kit issued
- Date staff member will require their next box (approx. 12 weeks)
- Staff contact details
- Staff are aware of how to access training materials