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The Queen Elizabeth Hospital King's Lynn
NHS Foundation Trust

Novel coronavirus (COVID-19) standard operating procedure

NHS England and NHS Improvement rollout of lateral flow devices for asymptomatic staff testing for SARS CoV-2 (phase 2: trusts)

This guidance 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.

Version 2, 16 November 2020

Overall aim

To roll out regular testing of all asymptomatic NHS staff using lateral flow assay devices (LFDs) on nasal swab samples with immediate effect, in parallel with the deployment of LAMP technology for use on saliva samples. This, together with qRT PCR, will provide an integrated testing approach and resilience in NHS staff testing.

Objectives

The key objectives will be to:

- Support the NHS in its infection control risk reduction strategy
- Reduce staff COVID-19 absenteeism
- Support both COVID-19 and non-COVID-19 clinical pathways over the winter period/second wave.

Background

An NHS asymptomatic staff testing pilot of 1,200 staff members in five NHS trusts has recently concluded, with a final report due soon. This pilot has demonstrated the feasibility and acceptability of regular testing of staff members, particularly using the collection of saliva samples. This was undertaken as a comparative technology assessment including to qRT PCR.

This pilot established that Direct LAMP technology with saliva samples can, on the basis of the observed specificity and sensitivity, be successfully used for NHS asymptomatic staff testing to identify infectious individuals. Deployment has begun across the NHS pathology networks in England and across the devolved administrations of the UK. However, due to the need to establish dedicated laboratories with a trained workforce, this will take some time to be fully functional at the capacity required to undertake all NHS staff testing.

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. Lateral flow antigen testing has a lower sensitivity than qRT PCR and LAMP technology. However, studies to date suggest

that, similar to LAMP, these tests are better at returning positive results for individuals who are infectious rather than individuals who may have had COVID-19 recently and are no longer infectious (qRT PCR will detect both).

Pilots are currently taking place to improve our understanding of the use of these devices in practice, for example in universities and schools, adult social care settings and as well as part of mass city testing. In the latter the Innova lateral flow assay device has been used.

Since lateral flow antigen test kits are available for immediate deployment, NHS staff testing in England will commence with this testing methodology. In parallel, focused efforts will continue to introduce LAMP and other technologies, and to increase testing capacity and capability across the different testing technologies in NHS pathology networks (and across the devolved administrations). The approach using lateral flow antigen testing is as follows

- Based on testing characteristics such as sensitivity and modelling data, testing of NHS staff initially using the Innova lateral flow antigen device will take place twice weekly, using self-administered nasal swabbing (with confirmation of positives by PCR by the local designated COVID-19 laboratory).

- This will be rolled out by cascade training delivered by trained trainers and supported by an HEE instruction video and written instructions, including on interpretation of results. This should ensure that each member of staff who will be self-testing has received training and, where necessary, observed by a trained healthcare professional the first time that they undertake the test. Each trust will provide a support package which will also include staff access to helpline/further training and, if deemed necessary, on-site training arrangements.

- In an interim period until a digital solution is available, staff will be asked to document their results. NHS organisations will be asked to collate these and upload to PHE's POCT portal on a weekly basis.

- Symptomatic staff and other staff working in clinically vulnerable areas, or who are participating in studies such as SIREN, should continue their current method of testing and will access qRT PCR testing in line with local guidance and/or study protocols. Depending on the frequency of testing in

studies, these staff members may also need to undertake twice-weekly LFD testing. This is especially relevant to the SIREN study, where a comparative analysis will be undertaken between the LFD testing with the qRT PCR testing performed every two weeks.

Methodology for the sites

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

Technology assessment

As this will be the first use case of testing NHS asymptomatic staff with an LFD, and as part of the roll out of other COVID-19 rapid antigen tests, a service evaluation will run alongside this deployment. A plan will be developed, and support provided if required from the NHS Test and Trace team.

Emerging sensitivity and specificity data has been published on the Government website https://www.gov.uk/government/news/oxford-university-and-phe-confirm-high-sensitivity-of-lateral-flow-tests

Lateral flow device provision

The Innova LFD test will be supplied to NHS organisations in England to meet the requirements of the staff testing population and to an agreed ordering schedule with NHS England and NHS Improvement.

Space will need to be made available for storage of devices at between 4^0C and 30^0C, and instructions drawn up in local NHS organisations for the collection and issue of the devices alongside the distribution of the NHS staff instruction leaflet available on the NHS England and NHS Improvement web pages.

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 nasal sample collection
- manufacturer instructions for use of the device (IFU).

- **Note that the box does not come with the NHS staff instruction leaflet; this will need to be printed and handed to staff members alongside the box.**

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 (ie the way the test is performed, and the results are interpreted) is the same as set out in the manufacturer's instructions

A simple to use written guide for healthcare staff self-testing has been developed nationally, 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, will be provided electronically for printing to distribute with each set of testing kits. Local information will need to be provided on, for example, numbers to call for any queries related to the use of devices and reporting and outcome of results. Staff can safely dispose of the test items in their normal household waste but should pour any residual buffer solution away first. 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.

If any of the items in the boxes of devices supplied are missing, broken or damaged, if the device is damaged or breaks during use, if the user of the test has any concerns about the performance of the test, or if any adverse incident with the test occurs, then these incidents should be reported. NHS organisations should report this information to MHRA via their reporting portal: coronavirus-yellowcard.mhra.gov.uk

Healthcare professionals using the device are also encouraged to report directly to the MHRA which is outlined clearly in the instruction guide.

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

Testing patient-facing asymptomatic staff

Staff should test themselves twice a week – every three to four days – to fit with shift patterns and leave requirements – for example, Wednesday and Sunday, or Monday and Thursday. If they are participating in research studies where the frequency of testing is not weekly (eg every two weeks or monthly) they should undertake twice-weekly LFD self-testing. For example, staff members participating in the SIREN study and having qRT PCR testing every two weeks should also be part of the twice-weekly LFD testing if they are a patient-facing member of staff.

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. If this is the case, NHS organisations should enable where possible testing by other technologies, such as the LAMP technology when it is available to the local NHS organisation.

Staff should be asked to perform the test first thing in the morning, preferably before attending work. In the event of a positive result, the individual staff member should immediately follow their local organisational protocol for reporting a positive test result – this will normally include contacting their line manager and occupational health department. If the test indicates an invalid result (see below) the staff member will need to repeat the test with a new test kit.

For any positive result, the staff member should have an urgent confirmatory qRT PCR testing performed, with swabs taken in accordance with their organisational protocols and sent to their local designated COVID-19 laboratory for testing. Until the result is confirmed the staff member should self-isolate in line with Government guidelines. If the result comes back as negative, the staff member would be able to attend immediately for duties.

A staff member who tested positive would recommence home testing 90 days after their positive test was taken. The staff member will need to liaise with their NHS organisations to track the date at which the retesting should start.

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. 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 . NHS organisations should provide information related to who the staff member needs to contact for any issues, for who to inform if they record a positive result, and what they need to do to get a confirmatory qRT PCR. NHS organisations should also clarify with staff members where their results should be recorded, and how frequently these should be submitted for collation.

An instructional video is available, and a local help line should be made available for queries, further training and assistance.

Reporting of results and PCR testing

The results from the lateral flow antigen test will be documented at home by the individual using the guidance provided in the staff instruction booklet This should be returned to the staff member's organisation for collation into the reporting template spreadsheet; a weekly return is recommended in the first instance. All NHS organisations will be required to collate and submit these returns to Public Health England via a data upload to its POCT portal on a weekly basis. NHS organisations will also be required to report number of tests distributed and staff absence as a result of a positive test via NHS sitrep processes.

Organisations which do not currently have access to this portal should send an email to POCT.Contact@phe.gov.uk. Users will then receive an email with a registration link. Once registered they can use the web app to upload the reporting template spreadsheet, which will be made available to participating organisations.

When the self-reporting results digital service becomes available, further instructions for staff to report results will be issued.

The results from the device will be recorded by the staff member after 30 minutes. The timing is critical, as leaving the test for longer can lead to false positive results and the test will need to be repeated. Results should 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 will be repeated with a new test kit.

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 organisational protocol. If the result is positive, the information will be reported through to PHE/SGSS via the standard route. PHE will compare results from lateral flow devices and PCR tests to ensure that there is no double counting of an individual's positive result.

The result from the qRT PCR test will be returned as per organisational protocols with clear instructions to staff members to speak to their line manager with any questions.

If a staff member records a negative result but begins to display symptoms of SARS COV 2, they should follow government guidance and obtain a swab test. This is clearly set out in the instruction booklet.

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

NHS organisations will identify members of staff to become trainers in self-administered LFD testing and to deliver training to patient facing staff within their organisation according to a locally agreed roll out timetable. It is recommended that staff are observed by a trained healthcare colleague the first time they administer the test.

For the majority of NHS staff, the HEE training video (described below) and information leaflet describing 'how to self-test' will be sufficient for staff to become proficient in 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. It is possible that some members of staff may not be willing or able to use the device. Numbers of staff who do not use the device should be documented and recorded.

The national team will support training of the trainers and will hold regular webinars. All NHS organisations will need to establish a local helpline/drop-in location to assist staff with queries which they may have with the use of the device, and to support with further training if necessary.

An HEE eLearning for health video is available https://learninghub.nhs.uk/self-swab to support training the trainers. A separate short video will also be available aimed at supporting individual staff members to perform the test at home.

Written instruction materials and FAQs will be made available nationally.

Implementation

Identification of early adopter sites linked to a phased roll out

In conjunction with NHS regional teams, expressions of interest were gathered from organisations to become early adopter sites. These sites are now live, NHS regional teams should plan the roll out of LFD testing to all NHS organisations within their geography, building on the lessons from the early adopter sites.

Logistics

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

In addition, each NHS organisation will need to:

- Identify staff trainers 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 (recommended if required)
- Establish a help line or drop-in assistance point for staff members having difficulty performing the self-administered test
- Establish a mechanism for staff to return their weekly results sheets
- 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 and to remind them they do not need to self-test with the LFD for 90 days after any positive result is confirmed by qRT PCR
- 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 test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results. The likelihood if this happening will be reduced by initial observed performance of those staff who require it, ongoing support as required, and 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. The instruction booklet is clear that, if the staff member has returned a negative result but is symptomatic, they should 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 do not detect non-infectious virus during the later stages of viral shedding that might be detected by PCR molecular tests. Hence, they will not detect staff members who are recovering from having had the virus.

Any member of staff who does test positive for the virus which is confirmed by qRT PCR will not have to self-test for a further 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 helpline/assistance point. The roll out of LAMP technology used with saliva will help over time to mitigate this.

Appendix 1 - Staff reporting template

A staff reporting template is included in the staff instruction booklet. NHS organisations should arrange for collection and collation of these forms from staff. Fields to be collected are as follows:

- Name
- Job role
- Department/ward
- NHS number if known
- Gender
- Ethnicity
- Date of birth
- Address and postcode of residence
- Date of test/s performed
- Time test performed
- Lot number of test strip (found on outside package of test device)
- Result – recorded as positive, negative and invalid
- If invalid, confirmation that a repeat test has been performed
- Comments, eg experience of using test.

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This publication can be made available in a number of other formats on request.

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