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Novel coronavirus (COVID-19) standard operating procedure

NHS England and NHS Improvement rollout of lateral flow devices for asymptomatic staff testing for COVID-19 in primary care

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 1, 11 December 2020

Overall aim

To expand the roll out of regular COVID-19 testing to all patient-facing asymptomatic primary care staff who are delivering NHS services, using lateral flow assay devices (LFDs) on nasal swab samples. This, together with qRT PCR, will improve virus detection within primary care with the overall aim to prevent further transmission and spread

Objectives

The key objectives will be to:

- Support NHS primary care in its infection control risk reduction strategy
- Reduce primary care staff COVID-19 absence by reducing transmission between staff, and therefore improve resilience within primary care settings
- Support both COVID-19 and non COVID-19 clinical pathways over the winter period/second wave.

Background

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. However, studies to date suggest that 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 different settings, 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.

In parallel, focused efforts to introduce other technologies such as LAMP (Loop-Mediated Isothermal Amplification) continue, as well as efforts to increase testing capacity and capability across the different testing technologies in NHS pathology networks (and across the devolved administrations).

Lateral flow antigen testing

The approach to using lateral flow antigen testing in primary care is as follows

- Testing of asymptomatic patient-facing staff delivering NHS services in primary care initially using the Innova lateral flow antigen device will take place twice weekly, using self-administered nasal swabbing.
- Staff should conduct the test at home and not on NHS premises, twice a week, to fit with their working patterns, and record their results on the [NHS Digital platform](#). Staff should be asked to conduct the test before the start of work, leaving enough time to alert their employer who may need to arrange cover, should their lateral flow test be positive – for example the night before or a couple of hours before. Any member of staff who requires or wishes it should have the opportunity to be observed by a trained colleague the first time they take the test. Contractors should provide ongoing support for the testing process for any member of staff who requires it.
- Positive results will need to be confirmed by qRT PCR tests. Primary care staff can access qRT PCR tests via their organisation's usual route.
- An HEE [instruction video](#) and [written instructions](#), including on interpretation of results, are available for staff to learn to self-administer their test.
- Recording of all results (positive, negative, invalid) from lateral flow devices is a statutory requirement. Staff should be asked to record their results on the NHS Digital online platform. Primary care employers are encouraged have regular conversations with their staff who are undertaking these tests to ensure that the available test kits are used and results reported in the correct way in order to ensure that all statutory requirements are met.
- Lateral flow antigen testing is not suitable for symptomatic staff, who should instead access qRT PCR testing through the normal access routes for testing and self-isolate, together with their household, in line with government guidelines.

Technology assessment

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>

Implementation and methodology

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

Logistics

Lateral flow devices will be delivered to primary care locations through an ordering and delivering process managed by Primary Care Services England (PCSE), as agreed with NHS England and NHS Improvement.

Roll out of ordering and delivering will take place during a defined window and primary care organisations will be contacted with instructions about how and when to order test kits through the PCSE online portal. Primary care contractors should ensure that they have enough room for storing the kits. Kits should be handed to staff as soon as possible after they are received.

Any member of staff who requires or wishes it should have the opportunity to be observed by a trained colleague the first time they take the test. Contractors should provide ongoing support for the testing process for any member of staff who requires it.

In assessing which staff should be offered test kits, primary care contractors should count all of their patient-facing staff delivering NHS services. This should include any temporary patient-facing staff who provide NHS services through the contractor but are employed through an agency or other kind of temporary arrangements (e.g. locums).

Lateral flow device – storage and box contents

Space will need to be made available for storage of devices at between 4°C and 30°C. The testing kits will arrive in boxes. The dimensions of each box are: 7 by 4.5 by 5.5 inches.

Each box contains 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 is available [here](#) and will need to be printed and handed to staff members alongside the box.**

This simple to use written guide for healthcare staff self-testing has been developed nationally and 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. If primary care contractors or their staff have any queries related to the use of devices, reporting or outcome of results they should email england.covid-ld@nhs.net

As staff are required to conduct the test at home, they can safely dispose of the test items in their normal household waste but should pour any residual buffer solution away first. Even if the test is positive, the test kit can be disposed as normal household 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.

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 are using the test in a slightly different way and should follow the NHS staff instruction leaflet instead, which has been agreed with experts and discussed with the MHRA. The manufacturer has been 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.

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. Primary care contractors should report this information to the MHRA via their reporting portal: coronavirus-yellowcard.mhra.gov.uk

Healthcare professionals using the device are also encouraged to report issues 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 work patterns and leave requirements – for example, Wednesday and Sunday, or Monday and Thursday. Staff may continue to swab whilst on annual leave of longer than a week, but it is not a requirement. If staff – including ancillary staff – are participating in research studies where the frequency of testing is not weekly (e.g. every two weeks or monthly) they should undertake twice-weekly LFD self-testing. If staff have received a positive COVID-19 qRT PCR test result, they should pause LFD testing for 90 days.

Staff should be asked to perform the test before attending work leaving enough time before the start of their shift to alert their employer who may need to arrange cover, should their lateral flow test be positive.

Reporting of results and qRT PCR testing

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.

The results from the lateral flow antigen test will be documented at home by the individual using the NHS Digital online platform.

Staff can access the NHS Digital platform on www.gov.uk/report-covid19-result

Once on the web page primary care staff should:

- Go to the URL where they will be guided through a set of questions to enable them to identify which part of the NHS they are working for; this includes options for primary care contractor groups.
- Input their personal information including:
 - Name
 - NHS number if known
 - Gender
 - Ethnicity
 - Date of Birth
 - Address and postcode of residence
 - Date of test/s performed
 - Time test performed
 - Serial of number of test strip (found on the test device)
 - Result – recorded as positive, negative and invalid
 - If invalid, confirmation that a repeat test has been performed

Test results recorded on the NHS Digital online platform by staff are shared with Public Health England, in line with requirements to report identifiable diseases. There is no action from primary care employers on reporting results, as these will be reported by each member of staff individually. Primary care contractors are, however, encouraged to have regular check in conversations with their staff members to ensure that they are testing twice weekly and reporting their results.

What staff should do following the LFD result

(1) In the event of a negative result, the staff member will need to record their test result on the NHS Digital online platform and attend work as normal.

If a staff member records a negative result but begins to display symptoms of COVID-19, they should follow government guidance and obtain a qRT PCR test through the established testing routes.

Similarly, if a staff member has been advised by Test and Trace or the COVID-19 app to self-isolate, they should follow the advice and continue to self-isolate, even if they get a negative LFD test result.

(2) In the event of a positive result, the individual staff member should immediately:

- report the positive test result to their employer – this will normally be to their line manager or in line with any local organisational protocol.
- request a confirmatory qRT PCR test, through current established testing routes.
- self-isolate, together with their household, in line with [Government guidelines](#).
- record their result on the NHS Digital online platform.

If the result of the confirmatory qRT PCR test comes back as negative, the staff member would be able to attend immediately for duties, ceasing self-isolation for them and their household.

A staff member who tested positive following their confirmatory qRT PCR test – or any other qRT PCR test they have undertaken – they would recommence home testing 90 days after their positive test was taken. The staff member will

need to liaise with their employer to track the date at which the retesting should start.

(3) If the test indicates an invalid result (see below) the staff member will need to repeat the test with a new test kit.

The NHS staff instruction leaflet includes information on what to do when a positive, negative or invalid result is observed. However, information on how to report the result of a test on the [NHS Digital online platform](#) is set out here and on the primary care FAQ.

NHS primary care contractors should ensure staff who are participating in lateral flow testing are informed on how to perform the test, how to report results and what to do if the test is positive - including who to inform - and how they can access a confirmatory qRT PCR. NHS primary care contractors should also have regular check in conversations with staff who are testing to ensure they are testing twice weekly and reporting the results accordingly.

Training staff members in the use of the device

A HEE [instruction video](#) and [written instructions](#), including on interpretation of results, are available for staff to learn to self-administer their test.

For the majority of NHS staff, the HEE training video 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.

Asymptomatic COVID-19 testing, including lateral flow antigen testing, of NHS primary care staff by other NHS primary care staff will be covered under the Clinical Negligence Scheme for Coronavirus (CNSC)

It is possible that some members of staff may not be willing or able to use the device. LFD testing is entirely voluntary. Numbers of staff who do not use the device should be documented and recorded.

Risks

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 of 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 COVID-19 infection. The instruction booklet is clear that, if the staff member has returned a negative result but is symptomatic, they should follow government guidelines, self-isolate and obtain a qRT PCR swab test.
3. Positive or negative 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 qRT PCR molecular tests. Hence, they will not detect staff members who are recovering from having had the virus. However, 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 video and simple written instruction materials, and 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 to england.covid-lfd@nhs.net The roll out of further technologies will help over time to mitigate this.

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