



Novel coronavirus (COVID-19) standard operating procedure

Use of lateral flow devices for asymptomatic staff testing

For SARS CoV-2 in all NHS Staff

2 July 2021, **Version 1**

This guidance replaces the previous standard operating procedures (SOPs) for lateral flow device (LFD) use in acute trusts and primary care and should be referred to for all tests ordered from 5 July 2021.

Staff using existing LFD kits boxed in 25s (distributed by NHS England and NHS Improvement to employers for their staff) should be instructed to use these before ordering more tests. Staff should also refer to the previous SOP for either [trusts \(Nov 2020\)](#) or [primary care \(Jan 2021\)](#).

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.

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Overall aim

Asymptomatic staff testing is an important component of the infection prevention and control (IPC), which all organisations and staff have a duty to adhere to. Continued efforts are required to keep staff and patients safe from potential transmission of COVID-19 in healthcare settings by ensuring that all staff continue to participate in this important programme.

This SOP is part of our work to provide an integrated testing approach and resilience in NHS staff testing for asymptomatic NHS staff using LFDs on self-swab samples, in parallel with the deployment of loop-mediated isothermal amplification (LAMP) technology for use on saliva samples, together with quantitative real time polymerase chain reaction (qRT PCR).

Objectives

The key objectives of asymptomatic testing are to:

- protect patients
- protect staff
- 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 future waves.

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 around 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).

In parallel, focused efforts to introduce other technologies such as LAMP continue, as well as efforts to increase testing capacity and capability across the different testing technologies in NHS pathology networks.

Over the 27 week period from 26 October 2020 to 9 May 2021, 37,300 healthcare workers registered a positive result using LFDs. These individuals were either detected before they became symptomatic, or would never have become symptomatic, the intervention provided by this core IPC measure reduced the transmission risk among colleagues, patients and other close contacts.

Lateral flow antigen testing

The approach using lateral flow antigen testing is as follows:

- Based on testing characteristics such as sensitivity and modelling data, testing of NHS staff using LFDs should take place twice weekly, using self-administered tests.
- Staff should self-administer the test in line with manufacturer's instructions which are issued with a box of tests (this will differ slightly depending on the manufacturer). Confirmation of positives by PCR test will be through the employing organisation's local procedure.

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.

Efficacy of the tests

Technology assessment

The government has published [research on LFD tests](#) and [analysis of lateral flow tests](#).

Lateral flow device provision

From July 2021 all NHS staff will be able order testing kits directly from www.gov.uk/order-coronavirus-rapid-lateral-flow-tests.

Staff should follow the instructions and select yes to the question 'Do you work for the NHS in England and take part in their staff testing programme?' Staff are

encouraged to create an account when they place their first order. This should only take a few minutes and will retain ordering information making it quicker to order future tests. Staff can also use the same account to register results. It is possible to order and report tests without creating an account.

When staff receive their box of tests, if any of the items supplied are missing, broken, or 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. Users should report this information directly to the Medicines and Healthcare products Regulatory Agency (MHRA) via their reporting portal: coronavirus-yellowcard.mhra.gov.uk.

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.

Asymptomatic staff testing is a core component of the [national infection control guidelines](#), which all organisations have a duty to adhere to.

If a member of staff is unable to perform the test for whatever reason, NHS organisations should enable testing either by LFD or by other available technologies, such as the LAMP technology if it is available to the local NHS organisation. Where testing is not possible, the organisation should have mitigations in place

Staff should be asked to perform the test first thing in the morning, preferably before attending work to fit with shift patterns and leave requirements – for example, Wednesday and Sunday, or Monday and Thursday. In the event of a positive result, they 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/void result the staff member will need to repeat using a new LFD test.

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. 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 asymptomatic home testing 90 days after their PCR 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.

Further information, including a video showing how to do the test can be found www.gov.uk/guidance/COVID-19-self-test-help#self-test-instructions. Please be aware that the directions of use in each box may differ, so instructions should be read carefully and followed each time a new box is received.

A step-by-step guide for COVID-19 self-testing is available in a number languages at: www.gov.uk/guidance/COVID-19-self-test-help#self-test-instructions.

If required, translation services are available by calling 119. The translation services available at 119 are available to support people throughout the testing process and can access around 200 languages and British Sign Language (BSL).

Reporting of LFD test results and PCR testing

It is a statutory duty that all test results **must** be reported, whether they are positive, negative or invalid/void. This must happen every time an LFD test is completed. Organisations may wish for their staff to follow an established local reporting procedure, in which results are submitted by the individual to their organisation, who then collate and submit all results weekly to NHS Digital's Strategic Data Collection Service (SDCS).

Alternatively, staff can report their results at www.gov.uk/report-COVID19-result. Staff should only report the results through one route to avoid double counting and it is the employing organisation's responsibility to confirm to staff which route they must follow.

NHS England and NHS Improvement is working with NHS Digital, Test and Trace, and regional testing leads to develop a suite of management information to enable NHS organisations to support staff to order and report tests, and to assure themselves that their staff are routinely testing as part of their infection prevention and control practice.

Reporting an LFD test on the GOV.UK website (for staff who are not reporting via their local trust system).

1. Click on the following link www.gov.uk/report-covid19-result and follow the steps below.
2. Select who you are reporting the result for, either 'myself' or 'someone else'.
3. If you haven't already, it is advised you create an account, you will only have to do this once and it will remember your personal details. You may also report without an account if you wish.
4. Select the date you took the coronavirus test.
5. Enter or scan your test ID number. You will find the ID number under the QR code on the LFD.
6. Select the result of the test whether that be 'positive', 'negative' or 'invalid/void'. Check your answers.
7. Receive confirmation of registration via email.

If there are any problems with reporting an LFD test via this route, call 119. If any staff member cannot complete the online form for reporting via this route, they can either:

- Call 119 and select option 1
- Ask someone else to register on their behalf (provided they have written consent to do so and can obtain personal details required to complete the form).

The results from the device should be recorded by the staff member after the time set out on the manufacturer's instructions. 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/void 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 LFD test.

All positive results using an LFD will be followed up by standard qRT PCR testing in the local designated COVID-19 testing laboratory. The request should be made following each NHS organisation's local protocol. If the result is positive, the information will be reported through to Public Health England (PHE) second generation surveillance system (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 PCR swab test.

Implementation

NHS organisations are asked to undertake the following:

- Work with regional testing leads to ensure that all existing boxes of 25s delivered to the NHS are used in the most efficient fashion.
- Provide information to staff on how to obtain tests via www.gov.uk/order-coronavirus-rapid-lateral-flow-tests from July 2021 when boxes of 25s are used.

- Provide their staff with details on the requirements for reporting results – either through the national reporting platform or for an individual organisation’s local reporting route if preferred.
- Ensure staff members know what to do if they test positive and where they will get their swab test for confirmatory qRT PCR. In addition, ensure staff understand that they do not need to self-test using an LFD for 90 days after any positive result is confirmed by qRT PCR.

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.
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.
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 SOP.

Some staff will not tolerate the regular use of swabbing. Where possible, staff should be encouraged to report any difficulties they are experiencing via the helpline/assistance point by calling 119.

Further information

For queries and further information relating to LFD tests boxed in 25s, these should be directed to england.covid-lfd@nhs.net or in writing to the **NHS Testing Programme** at the address below. For queries about LFD kits ordered from the GOV.UK website, please call 119.

Contact us:

NHS England and NHS Improvement

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