



Novel coronavirus (COVID-19) standard operating procedure:

Usage of lateral flow devices for asymptomatic staff testing at vaccination sites

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 the public is accurate.

Overall aim

Our aim is to provide testing to all staff working on behalf of the NHS at vaccination sites – including those on a voluntary basis – using lateral flow devices (LFDs) on nasal swab samples. This standard operating procedure (SOP) excludes staff who are part of any other testing programme or pilot. Alongside a quantitative reverse transcription polymerase chain reaction (qRT PCR) test, this will improve virus detection, with the overall aim of preventing further transmission and spread.

What is a vaccination site?

In this document we refer to ‘vaccination sites’ as the place where vaccination services are provided. These comprise hospital hubs, vaccination centres and local vaccination services (LVS). LVS sites comprise primary care network (PCN)-led sites (run by GP practices) and community pharmacy-led sites.

Objectives

The key objectives will be to:

- protect patients
- protect staff and volunteers providing NHS services
- support vaccination sites in their infection control risk reduction strategy
- reduce vaccination sites’ staff COVID-19 absence by reducing transmission between staff, and therefore improve resilience within vaccination site settings
- support both COVID-19 and non-COVID-19 clinical pathways over the winter period/third 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, produces results in 30 minutes and can be self-administered.

Summary of key points

	PCN-led and community pharmacy-led local vaccination services	Hospital hubs and vaccination centres
How do NHS staff (including temporary staff) working at vaccination sites undertake testing?	Test at home twice weekly following the primary care SOP	Test at home twice weekly following the secondary care SOP
How do volunteers working at vaccination sites undertake testing?	Tested at the vaccination site on arrival for duty (to a maximum of twice per week)	Tested at the vaccination site on arrival for duty (to a maximum of twice per week)
How do NHS staff working at vaccination sites record their results?	On the NHS Digital self-reporting platform	On the host trust's recording system. Where a trust system is not available, record on the NHS Digital self-reporting platform
How do volunteers and temporary NHS staff working at vaccination sites record their results?	On the NHS Digital self-reporting platform	On the host trust's recording system. Where a trust system is not available, record on NHS Digital self-reporting platform

Lateral flow antigen testing

All staff at vaccination sites should be provided with access to testing using LFDs. The approach to using lateral flow antigen testing in vaccination sites is as follows:

It is recommended that staff are observed by a trained colleague the first time they administer the test. This is to identify early on if additional support is going to be required, or if they are unable to perform the test for any reason.

NHS staff with existing contracts

NHS staff will already have access to LFDs through their employer and should refer to the relevant SOP for their setting:

- Primary care: www.england.nhs.uk/coronavirus/publication/asymptomatic-stafftesting-for-covid-19-for-primary-care-staff/
- Secondary care: www.england.nhs.uk/coronavirus/publication/asymptomatic-stafftesting/.

NHS staff should carry out testing in line with their organisation's arrangements and following the guidelines of the appropriate SOP.

Positive results will need to be confirmed by qRT PCR tests as per the arrangements for the staff member's employing organisation.

Volunteers and temporary NHS staff

Volunteers and temporary NHS staff working at a vaccination site should also be provided with access to LFD testing at or via the vaccination site they are supporting.

Primary care network and community pharmacy-led local vaccination services

- **NHS staff on temporary contracts** should be provided with a box of 25 tests, in line with the approach for other NHS staff. The same twice-weekly testing guidelines should be followed, as described in the [primary care SOP](#).
- **Volunteers** should be tested at the vaccination site at the beginning of the shift (to a maximum of twice per week). This can be as observed self-testing or testing by trained vaccination site staff. The results of the test (positive, negative or invalid) should then be recorded immediately on the [NHS Digital platform](#), as this is a statutory requirement.

The vaccination site will need to ensure it has adequate supplies of LFDs on site to facilitate this testing.

Hospital hubs and vaccination centres

- **NHS staff on temporary contracts** should be provided with a box of 25 LFD tests in line with the approach to other NHS staff and follow the same twice-weekly testing guidelines as described in the [secondary care SOP](#).
- **Volunteers** should be tested at the vaccination site at the beginning of the shift (to a maximum of twice per week). This can be as observed self-testing or testing

by trained vaccination site staff. The results of the tests (positive, negative or invalid) should be recorded using the host trust's recording system immediately, as this is a statutory requirement.

A Health Education England (HEE) [instruction video](#) shows how to undertake the test, how to interpret the results, how to dispose of waste, and where and how the box containing the test should be stored.

There are also [written instructions](#) for staff in different settings about how to carry out the test.

Positive results for NHS staff on temporary contracts and for volunteers should be confirmed through qRT PCR tests – as per the arrangements for the vaccination site's supporting organisation. This may need to be via pillar 2 if the supporting organisation does not have access to qRT PCR testing.

Individuals with a positive test result should immediately self-isolate and follow the [national infection control guidelines](#). Where the confirmatory qRT PCR is negative, the individual can return to duties unless they are displaying any symptoms of COVID-19.

LFD testing is not suitable for people with symptoms. Symptomatic people should obtain a qRT PCR test through www.gov.uk/get-coronavirus-test.

Technology assessment

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

Implementation and methodology

Logistics

For PCN and community pharmacy-led vaccination sites, tests for staff and volunteers should be ordered through the primary care contractor(s) supporting the centre. There is an ordering and delivering process managed by Primary Care Services England (PCSE). For more information, including how to order tests see:

www.england.nhs.uk/coronavirus/publication/asymptomatic-staff-testing-for-covid-19-forprimary-care-staff/.

LFDs for hospital hubs and vaccination centres can be ordered through the respective hospital trust or lead workforce hub provider. For more information, including on how to order tests, see: www.england.nhs.uk/coronavirus/publication/asymptomatic-stafftesting/.

Lateral flow device – storage and box contents

Space will need to be made available for storage of the 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 mL buffer solution
- 25 extraction tubes and 25 tube caps
- 25 sterilised swabs for nasal sample collection
- manufacturer instructions for use of the device.

Note that the box does not come with the [NHS staff instruction leaflet](#). This will need to be printed out and given to staff when they receive their box of tests.

Where the tests are being performed at a vaccination site, the tests should be disposed of as clinical waste (1st option: Unmarked yellow neutral container/bag, 2nd option: White/clear container/bag, 3rd option: Tiger bag).

Where tests are undertaken at home, staff 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 of 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 are included in the box and are detailed and very technical. **These do not need to be followed**, as vaccination site staff are using the test

in a slightly different way, and so should follow the [NHS staff instruction leaflet](#) instead, which has been agreed with experts and discussed with the Medicines and Healthcare products Regulatory Agency (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 (ie how the test is performed and the results interpreted) is the same as set out in the manufacturer's instructions.

Please report any of the following incidents:

- 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
- if any adverse incident with the test occurs.

Primary care contractors should report this information to the MHRA via their reporting portal: <https://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.

Reporting of results and qRT PCR testing

NHS staff should use the reporting mechanism put in place by their employer and set out in the SOP for their setting.

Volunteers and temporary NHS staff should record the results from the device 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.

For local vaccination services, and hospital hubs and vaccination centres without access to a hospital/trust system to record tests:

The results from the LFD test should be recorded using the NHS Digital online platform via www.gov.uk/report-covid19-result.

Volunteers and temporary NHS staff should select 'Testing for staff delivering NHS services in England, Wales or Northern Ireland' and 'Other services commissioned by the NHS in England, Wales or Northern Ireland'. By following the link, people 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.

Staff should input their personal information including:

- | | |
|-------------------------------------|--|
| • Name | • Date of test(s) performed |
| • NHS number, if known | • Time test performed |
| • Gender | • Serial number of test strip (found on the test device) |
| • Ethnicity | |
| • Date of birth | • Result – recorded as positive, negative and invalid |
| • Address and postcode of residence | • If invalid, confirmation that a repeat test has been performed |

Test results recorded on the NHS Digital online platform are shared with Public Health England, in line with requirements to report identifiable diseases.

For hospital hubs and vaccination centres with access to a hospital/trust system to record tests

Test results should be entered on the host trust's system for recording and reporting test results. Where a trust system is not available, the test results should be recorded on the NHS Digital online platform via www.gov.uk/report-covid19-result.

What staff and volunteers should do following the LFD result

1. In the event of a negative result, the staff member will need to record their test result in line with the supporting organisation's arrangements and attend work as normal. [Infection prevention and control \(IPC\) guidance](#) must continue to be followed.

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 www.gov.uk/get-coronavirus-test.

Similarly, if a staff member or volunteer 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 volunteer or staff member should immediately:
 - report the positive test result to their supervisor at the vaccination site (with contact tracing as per the arrangements for the host organisation)
 - self-isolate, together with their household, in line with [government guidelines](#)
 - record their result in line with the supporting organisation's arrangements.
3. If the test indicates an invalid result (see below) the staff member or volunteer will need to repeat the test with a new test kit.

The supporting organisation should ensure staff or volunteers who are participating in LFD testing are informed of how to perform the test, how to report results and what to do if the test is positive.

Training staff members in the use of the device

(NB we recommend that volunteers are observed self-testing or are tested by trained vaccination site staff.)

For most vaccination site staff, the [HEE instruction video](#) and [written instructions](#) describing 'how to self-test' will be sufficient for staff to become proficient in self-testing independently. Staff who need extra support – and/or those for whom English is not their first language – may require or request practical assistance, including hands-on demonstrations/training.

It is possible that some members of staff or volunteers may not be willing or able to use the device. LFD testing is entirely voluntary.

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 or volunteer 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 or volunteers 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 or volunteers who are recovering from having had the virus. However, any staff member or volunteer who does test positive for the virus and this 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 the training video and simple written instruction materials, and other nationally and locally available information on COVID-19 symptoms and actions.

Sample type and compliance

Some staff/volunteers will not tolerate the regular use of nasal swabbing. Where possible, staff should be encouraged to report any difficulties they are experiencing to england.covidlfd@nhs.net. Over time, the rollout of further technologies will help to mitigate this.