

# Novel coronavirus (COVID-19) standard operating procedure

## Rollout of lateral flow devices for asymptomatic staff testing for COVID-19 in the independent sector

Version 2, 29 April 2021

**Following communication with independent sector providers on 21 April 2021, the process for accessing lateral flow testing kits has now changed.**

**From 29 April 2021, all orders should be directed to [NHS Test and Trace](#).**

**This standard operating procedure is only relevant to lateral flow testing kits (containing 25 individual tests), ordered from NHS England and NHS Improvement before this date.**

**There is new guidance for all testing kits ordered from [NHS Test and Trace](#).**

## Overall aim

Our aim is to provide testing to all staff providing NHS services in the independent sector using lateral flow assay devices (LFDs) on nasal swab samples. This, together with qRT PCR, will improve virus detection in the independent sector, to prevent further transmission and spread.

## Objectives

The key objectives are to:

- protect staff providing NHS services and patients
- reduce independent sector staff COVID-19 absence by reducing transmission between staff, and therefore improve resilience in independent sector settings
- support both COVID-19 and non COVID-19 clinical pathways.

## Background

Lateral flow antigen testing detects the presence of the COVID-19 viral antigen from a swab sample. The test is administered using handheld devices and gives results in 30 minutes and can be self-administered. It 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).

Lateral flow tests have been made available to patient-facing staff across the NHS. They are part of effective infection control protocols and enable the identification of COVID-19 positive asymptomatic individuals.

## Lateral flow antigen testing

The lateral flow antigen testing approach for staff providing NHS services in the independent sector is:

- Asymptomatic patient-facing staff delivering NHS services in the independent sector using the Innova lateral flow antigen device will take place twice weekly, using self-administered nasal swabs.
- Staff should conduct the test at home and not at their work place, twice a week to fit in 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 of a positive result and for their employer to arrange cover if necessary – for example, the night before or a couple of hours before. Any staff member who requires or wishes it should have the opportunity to be observed by a trained colleague the first time they take the test. Organisations should provide ongoing testing process support for any staff member who requires it.
- It is a statutory requirement and imperative that staff record all their results (positive, negative, invalid) from lateral flow devices. Staff should be asked to record their results on the NHS Digital online platform.
- To ensure that all statutory requirements are met, independent sector employers are encouraged to communicate regularly with their staff who are tested to ensure that the available test kits are being used and results reported in the correct way.
- Positive results need to be confirmed by qRT PCR tests. Independent sector staff can access qRT PCR tests via their organisation's usual route.
- A Health Education England (HEE) [instruction video](#) and [written instructions](#), including on interpretation of results, are available to help staff learn how to self-administer the test.
- Lateral flow antigen testing is not suitable for symptomatic staff. They should instead access qRT PCR testing through the normal routes for testing and self-isolate, together with their household, in line with [government guidelines](#).

## Technology assessment

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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 the key elements of the rollout and are either provided nationally or determined locally.

### Logistics

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To order lateral flow tests, independent sector providers should contact their commissioner detailing the number of patient-facing staff in their organisation who are delivering NHS services; the commissioner should raise through their regional testing lead. Queries can also be directed to the NHS England and NHS Improvement national team via [england.covid-LFD@nhs.net](mailto:england.covid-LFD@nhs.net).

To assess how many test kits they need to order, independent sector providers should count all their patient-facing staff delivering NHS services. This should include any temporary patient-facing staff who provide NHS services through the organisation but are employed through an agency or other kind of temporary arrangements.

Deliveries will be made using a courier service to a single agreed delivery address for each organisation. Organisations will be notified in advance of the delivery schedule.

Kits should be distributed to staff as soon as possible after they are received.

## Lateral flow device – storage and box contents

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The testing kits will arrive in boxes and space will be needed to store these at between 4°C and 30°C. The dimensions of each box are: 7 x 4.5 x 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 using the device (IFU).

**Note that boxes do not contain the NHS staff instruction leaflet; this is available [here](#) and will need to be printed and handed to staff members along with 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 the box of tests should be stored. If independent sector providers or their staff have any queries about using the of devices, or result reporting or outcome, they should email [england.covid-ld@nhs.net](mailto: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 first pour away any residual buffer solution. They should do this even if the test is positive. 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 by NHS commissioned independent sector staff. They will be using the test in a slightly different way from that designed by the manufacturer, and should instead **follow the NHS staff instruction leaflet**, 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 and the use of a 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.

The following incidents should be reported:

- missing, broken or damaged items in the boxes of devices supplied
- any device that breaks during use
- test user has any concerns about the performance of the test
- any other adverse incident with the test occurs.

Independent sector providers should report this information to the MHRA via their reporting portal: [coronavirus-yellowcard.mhra.gov.uk](https://coronavirus-yellowcard.mhra.gov.uk)

Healthcare professionals using the device are also encouraged to report issues directly to the MHRA, as outlined clearly in the instruction guide.

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

## **Testing patient-facing asymptomatic staff**

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Staff should test themselves twice a week – every three to four days – to fit in with their work patterns and leave requirements – for example, Wednesday and Sunday, or Monday and Thursday. Staff may continue to swab while on annual leave of longer than a week, but this is not a requirement. If staff – including ancillary staff – are participating in research studies where the frequency of testing is not weekly (eg every two weeks or monthly), they still need to undertake twice-weekly LFD self-testing. If staff receive 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 and sufficiently in advance of this to give them time to alert their employer of a positive result and for their employer to arrange cover if necessary.

## Reporting of results and qRT PCR testing

The staff member needs to record the result from the device 30 minutes from the start of the test. 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) in the result window indicates a negative result.
- **Positive:** The presence of the test line (T) and the control line (C) in the result window, regardless of which line appears first, indicates 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 in 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.**

Staff must document each lateral flow antigen test result at home using the NHS Digital online platform. Staff can access the NHS Digital platform on [www.gov.uk/report-covid19-result](https://www.gov.uk/report-covid19-result)

Once on the web page staff should:

- Go to the URL where they will be guided through a set of questions to identify which part of the NHS they are working for. They should select 'Testing for staff delivering NHS services in England or Northern Ireland', followed by 'Other services commissioned by the NHS in England or Northern Ireland'.
- 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 staff record on the NHS Digital online platform are shared with Public Health England (PHE), in line with requirements to report identifiable diseases. There is no action from independent sector providers on reporting results as this is the responsibility of each individual staff member. Independent sector providers are, however, encouraged to communicate regularly with their staff members to ensure that they are testing twice weekly and reporting their results.

The only exception to this is where large independent sector providers have already begun using the PHE POCT portal. In this case, providers should continue submitting data in this form as directed by PHE.

## What staff should do following the LFD result

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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 – would continue isolation in line with government guidance. 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. Information on how to report the result of a test on the [NHS Digital online platform](#) is set out here and in the [independent sector FAQs](#).

Independent sector providers should ensure staff who are participating in lateral flow testing are informed about 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. Independent sector providers should communicate regularly with their staff who are testing to ensure they are testing twice weekly and reporting the results accordingly.

## **Training staff in the use of the device**

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An 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 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.

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

## 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 influenza 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 after having had the virus. However any staff member 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 by referring to the training video and simple written

instruction materials, and other nationally and locally available information on COVID-19 symptoms and actions.

## **Switching to different device**

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Any switching to a different LFD will be carefully planned and managed, and appropriate training materials and written instructions prepared and distributed.

## **Sample type and compliance**

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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](mailto:england.covid-lfd@nhs.net) The rollout of further technologies will help over time to mitigate this.

