



# Advanced service specification

## Advanced service – Community pharmacy COVID-19 lateral flow device distribution service

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Updates made to this document since version 1 (published September 2021) are highlighted in yellow.

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## 1. Background and service aims

### Background

- 1.1 COVID-19 lateral flow antigen tests allow the detection of people with high levels of the COVID-19 virus, making them effective in identifying individuals who are most likely to transmit the virus, specifically those not showing symptoms.
- 1.2 Research by NHS Test and Trace into mass testing shows participants prefer to access testing in the community. Pharmacists are trusted by their local communities and unfamiliar new points of access are less trusted.

### Service aims

- 1.3 The purpose of the Community Pharmacy COVID-19 Lateral Flow Device Distribution Service ('the Service') is to improve access to testing by making lateral flow device (LFD) test kits available at community pharmacies for asymptomatic people, to identify positive cases in the community and break the chain of transmission.
- 1.4 This Service will work alongside other NHS Test and Trace COVID-19 testing routes.
- 1.5 Tests will be administered away from the pharmacy. The pharmacy will not be involved in the generation or communication of results. Pharmacy teams will not be required to support the communication of results but should encourage results reporting and confirmatory testing as outlined in the Service pathway.

## 2. Service sign-up and setup

- 2.1 The community pharmacy COVID-19 LFD distribution service has been running since March 2021, with 97% of community pharmacies providing the Service. This version of the Service specification is a minor update to the version issued in September 2021, **that comes into effect on 1 January 2022**. Pharmacy contractors already providing the Service must adopt the new Service requirements from that date unless they decide to stop providing the Service (see paragraph 6.1 below).

- 2.2 Prior to provision of the Service, the pharmacy contractor must:
- a. be complying with their obligations under Schedule 4 of the Pharmaceutical Services Regulations (Terms of Service of NHS pharmacists) in respect of the provision of essential services and an acceptable system of clinical governance
  - b. sign up to the Service by completing a registration declaration through the NHS Business Services Authority (NHSBSA) [Manage Your Service \(MYS\) portal](#)
  - c. be satisfied that all pharmacy staff involved in the provision of the Service are competent to do so and have familiarised themselves with the appropriate guidance
  - d. have a suitable place away from members of the public to store test kits ordered from the wholesaler.
- 2.3 All pharmacy contractors will be automatically added to the [NHS Test and Trace Site Finder map](#) as a participating pharmacy once they sign up to provide the Service.
- 2.4 All details for pharmacy contractors on the Test and Trace Site Finder Map will be managed by the NHS Test & Trace team. If individual pharmacy contractors wish to manage their data for their sites on the map, they can request to do so by emailing [PharmacyCollect@dhsc.gov.uk](mailto:PharmacyCollect@dhsc.gov.uk). To manage their data on the map, pharmacy contractors will need to use a mobile phone as part of the logging in process, as the service employs two-factor authentication, sending a unique code to the registered mobile phone.
- 2.5 This Service will be reviewed to reflect developments in NHS Test and Trace policy.

### 3. Operational process

Annex A illustrates the end-to-end operational model for the Service, which is split into the following key areas:

#### **Supply of tests kits to the pharmacy contractor**

- 3.1 Pharmacy contractors will order cartons of test kits via a participating wholesaler in the normal way. A list of participating wholesalers can be found on the [NHSBSA website](#). Test kits will be supplied free of charge to pharmacies providing the Service as part of their standard deliveries from the wholesaler. Pharmacy contractors will need to be aware that stock ordered may not arrive with their next delivery and plan accordingly. Further information on wholesalers' service level agreement can be found on the [NHSBSA website](#).
- 3.2 Pharmacies must store the supplied test kits in line with the manufacturer's instructions. Information on test kits currently in use, including storage requirements and dimensions and quantities of kits per carton, is available on the [NHSBSA website](#).
- 3.3 To comply with Medicines and Healthcare products Regulatory Agency (MHRA) product recall provisions, on receipt of cartons from wholesalers, pharmacy contractors must make a record of the following, and that record must be retained for six months from the date on which the stock was delivered:
  - LOT Number (eg A1234567)
  - Quantity of cartons (xx Cartons)
  - Supplying wholesaler (variable)
  - Date of receipt (DD/MM/YY).

This data must also be entered into the MYS portal by the close of business on the pharmacy contractor's last trading day of the week (reports can be submitted more frequently than weekly, if the pharmacy contractor wishes to do so).

- 3.4 Pharmacy contractors should order and re-order appropriate quantities of cartons of test kits in line with the demand of the population they serve. The

expectation is that pharmacies will order up to a weekly limit of six cartons (one carton per day, assuming a six-day working week). The weekly order limit is subject to review by NHS Test and Trace and may be amended on a case-by-case basis if there is sufficient evidence to suggest that patient demand is consistently greater than available supply.

## **Stock control**

- 3.5 Pharmacy contractors should manage stock flow carefully, reordering stock in line with the regular demand they experience for test kits and generally only ordering another carton when the last carton has been opened.
- 3.6 The quantities of test kits ordered from wholesalers and those supplied to the public will be monitored by NHS Test and Trace.
- 3.7 Pharmacy contractors may be contacted by NHS Test and Trace if this data indicates a stockholding of more than three cartons. NHS Test and Trace reserve the right to withhold further deliveries from being made should it appear that excess stock is being held without reason.

**Pharmacy contractors that do not record stock supplied to citizens, or complete a nil return, on MYS as per the Service specification will be assumed to have given no stock out, and therefore any additional requests for stock will be seen as over-stocking.**

- 3.8 If a pharmacy contractor experiences a surge in demand that it cannot meet with the standard supply quantities, they can contact [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk), providing information on the cause of the surge and the approximate level of unmet demand.
- 3.9 In exceptional circumstances (eg closure of a pharmacy contractor or mutual aid for an unforeseen surge in demand), pharmacy contractors may move stock between pharmacies within or outside their company. They must email [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk) confirming the LOT numbers, quantities of cartons and the ODS codes of the pharmacies involved to support batch traceability and stock monitoring.
- 3.10 Any stock which cannot be accounted for when comparing records of stock received and supplies made to the public (eg where it is suspected as being

lost or stolen) must be notified to [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk) providing details of the quantity of test kits and their LOT numbers.

## Quality control

- 3.11 If any issues are identified on receipt of a carton of test kits, the pharmacy contractor should contact the wholesaler customer services team to address the issue.
- 3.12 The pharmacy contractor must inform [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk) of any test kits which are damaged while at the pharmacy contractor's premises, including stock which may have been compromised due to storage outside of the manufacturer's instructions. The pharmacy contractor should provide details of the quantity of affected stock, the LOT numbers and a description of how the stock was damaged or compromised.

## Supplying test kits to the public

- 3.13 The test kits must be provided free of charge to people requesting them and must only be distributed in line with this Service specification.
- 3.14 Pharmacy contractors can supply one pack of test kits per requesting individual. If the person is also collecting on behalf of another, a maximum of two packs can be provided per transaction. These quantities are subject to review and may be altered in line with changes in Government policy.
- 3.15 People requesting a test kit should register for a 16-digit collect code via [gov.uk/get-collect-code](https://gov.uk/get-collect-code) or 119 prior to making a collection from a pharmacy. A new 16-digit collect code must be requested for each transaction. The pharmacy contractor must ask the person collecting the test kits for their 16-digit collect code **which must be recorded** by the pharmacy contractor.
- 3.16 If the person collecting the test kits does not have a collect code, the pharmacy contractor must encourage them to register via [gov.uk/get-collect-code](https://gov.uk/get-collect-code) or 119 to obtain a code before collection. The pharmacy contractor should explain that obtaining a collect code provides additional patient safety (particularly in the event of a product recall) and allows for a greater understanding of test use. If the person collecting the tests does not wish to register, **the pharmacy contractor should still provide them with the required test kits and record this as an anonymous collection.**

3.17 For every **transaction**, including anonymous collections, the pharmacy contractor must record the following information:

- the 16-digit collect code (where provided)
- the LOT number for the test pack(s) handed out
- the number of test packs handed out
- the date of the collection.

The record of this information must be retained for six months from the date on which the supply was made.

This information must also be entered into MYS. **Daily** entry of data will support NHS Test and Trace to identify areas of COVID-19 testing demand, support traceability and enable stock management. As a minimum, pharmacy contractors **must enter each week's data by the close of business on the pharmacy contractor's last trading day of that week**. If no tests have been collected on a given date, pharmacy contractors must enter a nil return on MYS.

3.18 Pharmacy contractors' data and MYS reporting frequency will be regularly monitored. Further information may be requested as part of data reconciliation on stock levels and reported collections. Pharmacy contractors may be contacted by NHS Test and Trace should they fail to report on time each week to understand why reporting has not taken place. NHS Test and Trace reserve the right to withhold further deliveries of test kits should weekly reporting not be satisfactorily undertaken.

3.19 To comply with MHRA requirements, it is important for NHS Test and Trace to collect user data and the collect code must be recorded by pharmacy contractors when the user has obtained one. Monitoring of the number of anonymous collections will take place and any pharmacy contractor that is recording levels of anonymous collections that are significantly different to the local and national average will be approached by NHS Test and Trace to seek to understand the reasons for this.

Should the information provided by the pharmacy contractor be deemed as unsatisfactory, further action may be taken, including withholding further deliveries of test kits until the issue is resolved.



- 3.20 Collect codes will be analysed and matched with the database of those originally issued by NHS Test and Trace. Should a significant number of mismatches occur, pharmacy contractors will be approached by NHS Test and Trace to seek to understand the reasons for this. Should the information provided by the pharmacy contractor be deemed as unsatisfactory further action may be taken, including withholding further deliveries of test kits until the issue is resolved.
- 3.21 There is no minimum age for use of LFD test kits, but users should consult the Instructions for Use included in the test pack for guidance on the appropriate usage.
- 3.22 The NHS Test and Trace minimum recommended age for a person to collect LFD test kits is 16 years, but where necessary professional judgement can be applied by pharmacy contractors.
- 3.23 Tests must be conducted away from the pharmacy and results registered, online or via 119, as explained in the Instructions for Use inside the test kit. People undertaking a test can contact 119 for assistance with using the test kit or to register their result.
- 3.24 Pharmacy staff must ensure the person collecting the test kits is made aware of the following **key points**:
- i. The test kits help identify people who are positive for COVID-19 but do not have symptoms. If they have symptoms then the person should self-isolate, complete a PCR test and follow the guidance on GOV.UK.
  - ii. Instructions on how to use the test kit and report your results are inside the box.
  - iii. A negative result means that it's likely you were not infectious when the test was done. **It is important to continue following Government guidelines and restrictions.**
  - iv. A positive result means it's likely you had the Coronavirus when the test was done. You and anyone in your home must follow Government guidelines on self-isolation and confirmatory testing.
  - v. **It is important to report your results, whether positive or negative.** This is because reporting results helps the NHS identify areas where asymptomatic cases of COVID-19 are rising and declining, so we can all

keep each other safe. When you report your result, you will be provided with information on the next steps you need to take.

[If a person indicates that they have not previously reported their results, it is particularly important to reiterate the importance of doing so for the new test kits being supplied.]

- vi. You must make a note of the LOT number of the test kit used, in case you need to report any incidents related to the device, test instructions, harm or injury. The instructions inside the box give details on how you can report any incidents.

3.25 Should the Government messaging on testing change during the provision of the Service, pharmacy contractors should update the messaging used in the service pathway with any alternatives provided by NHS Test and Trace.

3.26 If a pharmacy contractor is contacted by a person with a query about the LFD device, test instructions, harm, injury or results, they should direct them to 119, and report any incidents as described in Section 7.

## **Recall process**

3.27 To comply with MHRA product recall requirements, in the event of a recall notice for LFD kits being issued, pharmacy contractors must:

- i. Respond in line with all instructions in the recall notice, particularly the requirement to respond and confirm that they have received and acted upon the recall notice (this could be via but not limited to email or an automated telephone system), while noting that the recall will include other instructions (eg the display of information regarding the recall to the public).
- ii. Quarantine any affected stock immediately and comply with follow-up instructions which could include returning or destroying affected stock.

## 4. Marketing

- 4.1 Pharmacy contractors may proactively inform customers of the availability of the service, including encouraging them to register for a collect code.
- 4.2 Marketing materials, including printable posters in a range of languages, are available to download from the [campaign resource centre](#).
- 4.3 Should the Government messaging on testing change during the provision of the Service, pharmacy contractors should update the displayed marketing materials with any alternatives provided by NHS Test and Trace.

## 5. Service availability

- 5.1 The pharmacy contractor must seek to ensure that the Service is available throughout the pharmacy's core and supplementary opening hours.
- 5.2 The pharmacy contractor must ensure the Service is accessible, appropriate, and sensitive to the needs of all service users. No eligible person should be excluded or experience difficulty in accessing and effectively using this Service due to their race, gender, disability, sexual orientation, religion or belief, gender reassignment, marriage or civil partnership status, pregnancy or maternity, or age.
- 5.3 The pharmacy contractor must have a standard operating procedure (SOP) for provision of the Service and all pharmacy staff involved in the provision of the Service must be familiar with the SOP.
- 5.4 If there is a problem with the Service, the pharmacy contractor should contact the NHS Test and Trace support team by emailing [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk).

## 6. Withdrawing from provision of the Service

- 6.1 Where a pharmacy contractor elects to withdraw from provision of the Service, or ceases trading, they must notify NHS Test and Trace by emailing [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk).
- 6.2 In the event that the pharmacy contractor elects to withdraw from provision of the Service, they should give four weeks' notice, to allow sufficient time for stock levels to be depleted.
- 6.3 Once a pharmacy contractor has given their notice to stop providing the Service, no further cartons of test kits should be ordered from the wholesaler. Pharmacy contractors should continue to provide the Service until the earliest of the following – distribution of all remaining stock or the expiration of their four week notice period. During this time, pharmacy contractors should continue to enter data into the MYS portal as described above. The quantities and LOT numbers of any unused stock remaining after the notice period expires must be reported to [pharmacy.collect.queries@dhsc.gov.uk](mailto:pharmacy.collect.queries@dhsc.gov.uk), who will issue further guidance on handling that stock.

## 7. Clinical governance

- 7.1 The pharmacy governance lead (a nominated individual in the pharmacy) must provide feedback about any incidents relating to patient safety, the referral process or operational issues with respect to the Service by emailing the NHS England and NHS Improvement Central Community Pharmacy mailbox ([england.communitypharmacy@nhs.net](mailto:england.communitypharmacy@nhs.net)).
- 7.2 To comply with MHRA governance requirements, in the event of any incidents with respect to the test kits, the pharmacy contractor must provide feedback to NHS Test and Trace via email ([integrator@dhsc.gov.uk](mailto:integrator@dhsc.gov.uk)). Feedback must be submitted by 11am on Monday mornings for incidents that occurred in the preceding week.
- 7.3 The pharmacy contractor is required to report any patient safety incidents in line with the Clinical Governance Approved Particulars for pharmacies. The pharmacy contractor should also make Yellow Card reports to MHRA, as necessary (see guidance at [coronavirus-yellowcard.mhra.gov.uk/](https://coronavirus-yellowcard.mhra.gov.uk/) and <https://www.gov.uk/government/publications/a-guide-to-defective-medicinal->

[products](#)). Any incident reporting information supplied to NHS Test and Trace or NHS England and NHS Improvement must be anonymised and not contain any patient identifiable information.

## Service evaluation

- 7.4 Pharmacy contractors may be required to provide reports for service evaluation and monitoring purposes. The data and evaluation periods will be agreed with the Pharmaceutical Services Negotiating Committee and communicated to pharmacy contractors when any submission is required.
- 7.5 NHS Test and Trace will monitor compliance with the Service requirements through management information and wider intelligence available to them. Should any concerns arise with how the Service is being provided, further information will be sought from the pharmacy contractor by NHS Test and Trace. NHS England and NHS Improvement, as the commissioner of the Service, may also investigate and take appropriate action.
- 7.6 Pharmacy contractors must respond to any requests for information from NHS Test and Trace in a timely manner, meeting reasonable deadlines set in the request. Failure to comply could result in further deliveries of stock being withheld until the information is received and any issue is resolved.

## 8. Payment

- 8.1 Payments for this Service will be calculated from the MYS submissions detailed in paragraph 3.17 above, made by the end of the fifth day of the following month in line with the Drug Tariff requirements. Pharmacy contractors do not have to make a separate claim for payments for this Service.
- 8.2 The NHSBSA will make appropriate payments to the pharmacy contractor on the same payment date as other payments for NHS Pharmaceutical Services for that month. The payments will be based on the reported submission data received for each day in the particular period and will be separately itemised on the FP34 Schedule of Payments.
- 8.3 In order to ensure that the correct payments are made, comparisons will be made between the amount of stock delivered via the wholesaler and the

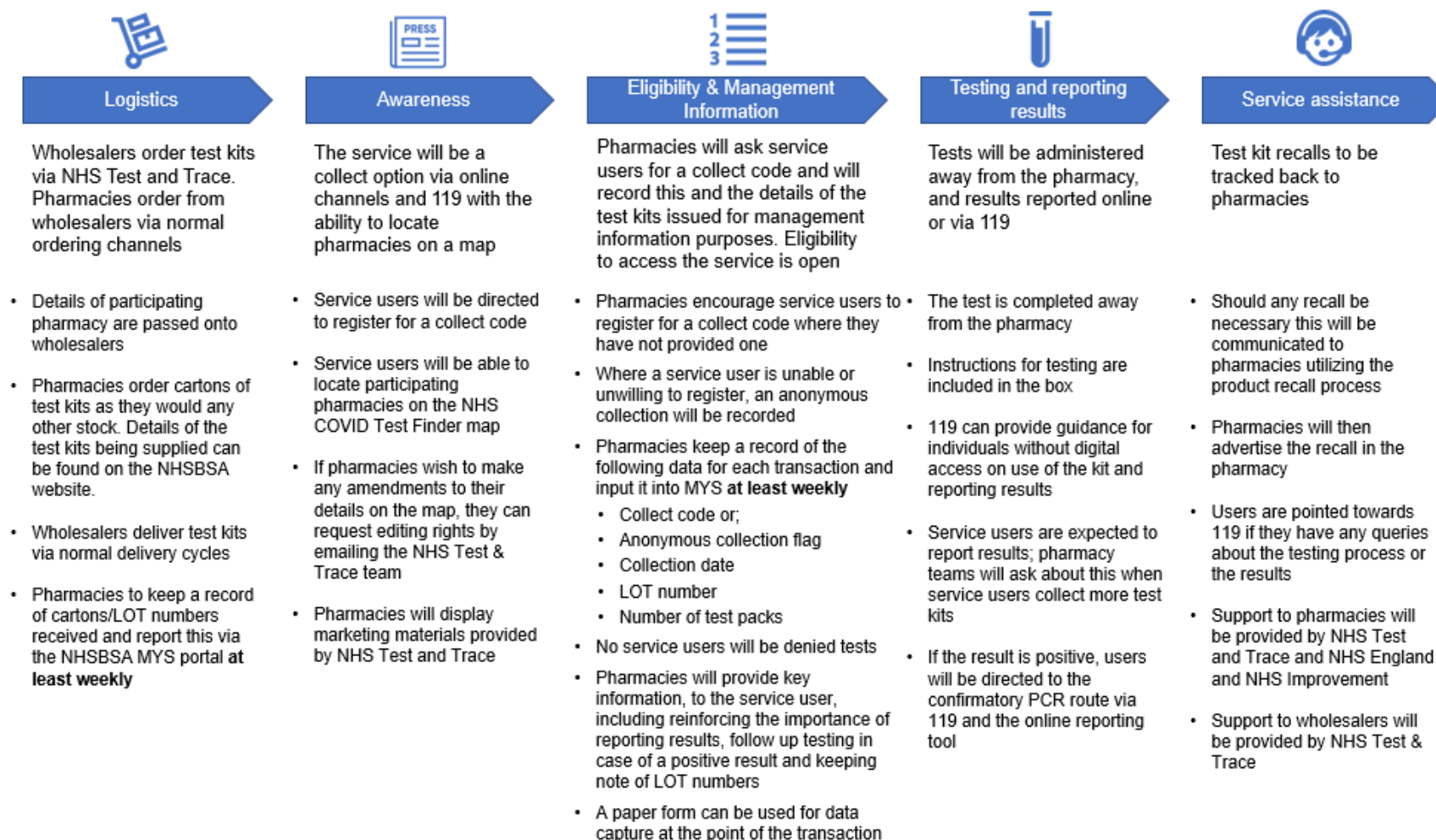
number of transactions reported. Pharmacy contractors will be contacted if there are any anomalies.

- 8.4 Payment for provision of the Service will be made up of the following elements:
- i. A one-off set-up fee of £250 + an allowance for VAT, which covers set-up costs including creating a SOP for the Service and training staff who will be involved in providing the Service. This payment will be triggered by completion of the registration declaration on the MYS portal.
  - ii. A Service fee of £1.70 + an allowance for VAT per **transaction** using a collect code, and a Service fee of £1.20 + an allowance for VAT per **transaction** using the anonymous collection route.

## 9. Compliance

- 9.1 In addition to any actions, described above, which may be taken in relation to any suspected non-compliance with the requirements of this Service specification, should there be other suspicions of non-compliance in relation to other matters, further information may be requested from the pharmacy contractor. Should the information provided by the pharmacy contractor be deemed as unsatisfactory further action may be taken, including withholding further deliveries of test kits until the issue is resolved.

## Annex A: End-to-end service model



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