

SERVICE SPECIFICATION

SERVICE	Lateral Flow Device Testing in Community Pharmacy
AUTHORITY LEAD	Sue Cochrane
PROVIDER LEAD	Community Pharmacy
PERIOD	26th April 2021 – 30th June 2021 with option to extend
DATE OF REVIEW	June 2021

1. POPULATION NEEDS

1.1 National/local context and evidence base

As part of Isle of Wight Council's approach to tackling the COVID-19 pandemic, Isle of Wight Council are delivering a service of Target Community Testing using Lateral Flow Device Tests (LFD) to identify asymptomatic residents.

Community testing aims to identify people without symptoms of COVID-19 with additional targeting for people who may be at heightened risk of infection – including those who need to leave home for work, carers and people who either work or live with children.

This Community Pharmacy service is complimentary to the national testing strategy and other local testing already in place.

It should be noted that as more is understood about COVID-19 and the virus which causes it (SARS-CoV-2), new technology will be developed, and national and local testing strategies will be reviewed, and so new initiatives will be added to this service in future.

Providers are reminded that Risk Assessments should be in place to reduce the risk to staff and patients. These should include the strict use of appropriate Infection Prevention Control (IPC) measures, crowd management and appropriate and safe use of consultation rooms.

This service is only for asymptomatic residents.

2. PURPOSE

2.1 Aims and intended outcome of the service.

This Service aims to identify asymptomatic residents through a targeted approach to community testing, which will require those that are spreading the virus unknowingly, to isolate.

This service also aims to increase awareness of key COVID-19 related messages that keep individuals and communities safe e.g., 'hands, face and space' and to mitigate impact of COVID-19 by making lifestyles changes e.g., stopping smoking for higher risk residents who are identified opportunistically by Community Pharmacy.

2.2 The Service Objectives are:

- To identify asymptomatic cases of COVID-19 within the population, to ensure that they self-isolate to reduce transmission to other people.
- Improve awareness of key messages around keeping safe and mitigating health harm in higher risk residents.
- To learn from the service, to inform any further local, regional or national roll out of testing programmes e.g., regular testing for 'test to release' from self-isolation by key workers.

3. SCOPE

3.1 Service description/pathway

- This service requires the Community Pharmacy to deliver a service for asymptomatic testing for COVID-19 of eligible patients, using an LFD device.
- The service will be delivered in Community Pharmacies across Isle of Wight (need per area determined by Council), operating up to 7 days per week.
- The pharmacy will deliver the service in line with this specification, the Standard Operating Procedures (SOP) (Appendix A) and any current or future guidance.
- The Community Pharmacy will provide support and advice to the patient, including referral to other services where required e.g., referral to stop smoking services.
- The Community Pharmacy must be able to demonstrate that all staff delivering this service are competent to provide the service.
- The Community Pharmacy should have Risk Assessments in place for staff (Appendix B). These should include the strict use of appropriate Infection Prevention Control measures (IPC), crowd management and appropriate and safe use of consultation rooms, including waiting for tests or test results.
- Pharmacies will offer a user friendly, non-judgmental, patient centred and confidential service.
- There must be a sufficient level of privacy and safety in which to provide the service and so Community Pharmacies will be required to have a consultation room for the patient to perform the test in.
- Isle of Wight Facilities Management would undertake storage and delivery of kits and PPE to the pharmacies once per week.

3.2 Service Outline

The Community Pharmacy will deliver a testing service for asymptomatic residents in line with the Standard Operating Procedure (SOP) and any relevant national guidance.

The Community Pharmacy will provide a comprehensive, quality service to eligible patients that covers the core components set out in the SOP, including:

- Ensuring that patients can register their personal details on the government website <https://www.gov.uk/report-covid19-result> either themselves, or if not possible then the Community Pharmacy should provide support.
- Ensure that those providing the service use appropriate PPE as set out in the SOP.
- Provide guidance and supervision of the self- swabbing in line with the SOP.
- Inform the patient that they will receive their result via text or e-mail to the account used for registration.
- Prepare the test and analyse the result (Appendix C).
- Upload test details on PharmOutcomes.
- Upload the results on the National Portal.
- Safely dispose of the LFD and related waste in line with the SOP.
- Reporting weekly regarding stock levels in order to inform the supply route.
- MECC should be included as part of the testing process.

Referrals

Patients will self-refer via the individual pharmacies own booking mechanisms. These will be made by booking an available slot at the community pharmacy for a specific date and time.

Community Pharmacy will advise Isle of Wight Council Testing Operations Cell of the times for booking slots that are available. Isle of Wight Council will email the Community Pharmacy of their list of appointments every evening for the following day.

Patients will be made aware of the Community Pharmacy testing service by Isle of Wight Council and its partners. There will be no requirement for active promotion by Community Pharmacy, however Community Pharmacy are able to use their discretion and opportunistically suggest a test and if appropriate encourage regular testing e.g., twice per week, if they deem the patient is in a higher risk group.

Business Continuity

Pharmacies must have a robust business continuity plan in place.

- Pharmacies must ensure they always have an adequate supply of LFDs, PPE and related materials to be able to deliver the service. The LFDs and PPE will be provided by Isle of Wight Council, but advance notice of additional need should be provided.
- The Community Pharmacy must inform locum pharmacists of the service and its standard operating procedure (SOP) in advance of them providing cover. Locum pharmacists must also be aware of local protocols in relation to emergency situations, serious incidents and safeguarding.

Risk Assessment

Pharmacies must have a robust Risk Assessment in place. These should include the strict use of appropriate Infection Prevention Control measures (IPC), crowd management and appropriate and safe use of consultation rooms, including waiting for tests or test results.

Underpinning Knowledge

- Pharmacists and staff delivering the service should have completed the relevant training (see section 5).
- Pharmacists and staff delivering the service should have completed training on Infection, Prevention and Control (IPC) including the donning of, wearing of and doffing of Personal Protection Equipment.

Core Competencies

Those providing the service must have a good understanding of

- COVID-19; including clinical definition, symptoms, terminology and approaches to testing e.g., LFD.
- Non-Pharmaceutical Interventions (NPIs) that reduce the transmission of coronavirus e.g., wearing of face coverings, social distancing and good hand hygiene.
- Effective and courteous communication with patients.

- Be aware of how and when to refer/signpost patients and when to ask for support.
- Healthy lifestyles and services available in Isle of Wight including stop smoking, weight management and mental health wellbeing.

3.3 Population covered (inclusion criteria)

- The pharmacies will provide the LFD test for patients over 12 years of age in Isle of Wight. This offer is available for all residents, with a focus on those who are within the following groups.
- People who can leave home for work including essential workers.
- Voluntary and Community Sector Staff and Volunteers, who provide direct care to others within Isle of Wight Council.
- Carers, both formal and informal, who have caring responsibilities in Isle of Wight.

Young people aged 16-17, can consent to their own medical treatment without a parent or guardian present and therefore can self-swab. Tests must only be administered where appropriate consent is obtained.

Children aged 12-15 may self-swab with supervision of a parent or guardian.

Children aged 11 or under are not currently included in this testing offer. If this policy changes and they are eligible in the future, the accompanying parent or guardian is required to administer the test on the child (they are not permitted to self-swab). The accompanying adult should only administer the swab if they are comfortable to do so and appropriately trained individuals are not available to undertake swabbing. Specific instructions are available for swabbing young children. Specific instructions have been prepared and made available for swabbing young children.

3.4 Any acceptance and exclusion criteria and thresholds

Patients who meet the above criteria are eligible for the service, however Community Pharmacy discretion is advised, and no formal proof of eligibility is required to access an LFD test under this service.

Patients are permitted to receive regular testing, e.g., twice per week testing for the duration of the service provision, with booking via the portal, as per normal practice.

3.5 Interdependencies with other services

Community Pharmacies delivering the service are required to be aware of other Community testing services (PCR and LFD) and other related services and programmes e.g., COVID-19 vaccinations.

3.6 Information Technology

Community Pharmacies will use their secure NHS.net e-mail address for sharing of Patient Identifiable Data (PID) from the booking site.

Community Pharmacies will be provided with a test site 'code' for the government website portal, that identifies the pharmacy as a test site and will be required for the logging of results.

Community Pharmacy must have an internet connection for logging results.

3.7 Consent

Informed consent must be obtained from all participants prior to undertaking any testing procedures. It must be made clear that participation is entirely voluntary, that there is no

requirement to provide a reason for a decision not to take part in testing and that such a decision will not incur any penalty.

The participant being tested will issue their consent verbally and this will be captured on PharmOutcomes.

3.8 Premises

The Community Pharmacy is required to have an appropriate consultation room, that is used for confidential discussions with the patient. This should be 'Covid-secure' and should be cleaned in between tests in line with existing IPC standards and guidance e.g., Community Pharmacy Patient Safety Group guidance.

3.9 The responsibility of the Commissioner

To facilitate delivery of this service Isle of Wight Council will:

- Provide all testing materials e.g., LFDs, PPE.
- Set up service on PharmOutcomes for each Community Pharmacy to submit their data.
- Provide details of relevant referral points which pharmacy staff can use to signpost service users who require further support.
- Provide health promotion material to pharmacies which is relevant to the service users.

4. QUALITY STANDARDS

4.1 Applicable national standards e.g., NICE

This list is not exhaustive, and it is expected that the provider will keep up to date with the latest documentation and guidance and incorporate into their practice.

- Community Pharmacy Contractual Framework, including Clinical Governance.
- Clinical Governance Requirements for Community Pharmacy” PSNC & NHS Employers (March 2012).
- The pharmacy is expected to operate the scheme in accordance with the code of Ethics and Professional Standards, as laid down by the Royal Pharmaceutical Society of Great Britain.

4.2 Applicable local standards

- The named pharmacist has, and shall hold, the responsibility for providing the service described within this document.
- Locum pharmacists must be made aware of this service and the procedures, in advance of them providing the cover. All records must be kept up to date and the pharmacist should be aware that they will ultimately be held accountable. It shall not be acceptable that a locum be employed in the knowledge that they do not wish to provide the service.
- Community Pharmacies must ensure and will be responsible for ensuring that the appropriate arrangements are made to cover the service, and the staff who are employed in its function.
- The pharmacy is expected to review its standard operating procedures and the referral pathways for the service on an annual basis.
- The pharmacy can demonstrate that staff involved in the provision of the service are competent to deliver this service.

- The pharmacy participates in an audit of service provision when requested by the Council.

5. EDUCATION & TRAINING FOR PARTICIPATING PHARMACISTS

Community pharmacies providing the end-to-end COVID-19 testing service, using an LFD device must complete training prior to performing any elements of the testing service with eligible patients.

Training includes:

- National LFD process training videos
<https://go.tessello.co.uk/TestDeviceTraining/Login.aspx>
 - LFD process training
 - LFD results recording training.
 - Infection prevention and control
 - Guidance on self-swabbing

Site leads e.g., the named Community Pharmacist may want to organise additional practical training or supervision for other staff members taking part in testing procedures.

6. INFORMATION GOVERNANCE, CONFIDENTIALITY INFORMATION AND DATA PROTECTION

The named pharmacist shall not, whether during or after their appointment, disclose or allow to be disclosed to any person (except on a confidential basis to their professional advisers) any information of a confidential nature acquired by the pharmacy under this agreement, except as may be required by law.

The pharmacist must protect personal data in accordance with the provisions and principles of the Data Protection Act legislation and must ensure the reliability of the staff that has access to such data.

All participating Community Pharmacies will be compliant with Data Security and Protection requirements.

7. CONTRACT MONITORING

7.1 Monitoring and Review

- The Provider shall ensure that the necessary data, as detailed in this service specification, is populated on PharmOutcomes in a timely manner to enable the service to be monitored and for the purpose of post-delivery payment verification.
- Commissioners may undertake a visit to the Pharmacy to inspect the provision of the service and to ensure that the Pharmacy is meeting the service specification terms. These may include 'mystery shopping' to check adherence to IPC and other measures in place to the risk to staff and patients.

7.2 Activity/Audit Record

The Pharmacy shall ensure that all consultations are logged on PharmOutcomes to enable the commissioner to monitor activity and verify payments for services provided.

Expected reporting activities are:

- Confirmation of each booked test completed via PharmOutcomes.

8. SERVICE SPECIFICATION REVIEW

8.1 It is recognised within this specification that the service may be subject to change due to a range of national and local policy initiatives. For example, government guidance and legislation, industry professional standards, NICE Guidance, Public Health England or local policy.

8.2 The Service Specification shall be reviewed on a regular basis, in partnership with the LPC, to reflect the changes in legislation. Adequate notice will be given to the Pharmacy of any significant changes which may impact on the service provided and will ensure sufficient transition arrangements are secured to ensure service continuity.









9. FINANCIAL INFORMATION

9.1 Payment and Reimbursement

Payments will be made at a fee of £ for each complete service. Invoiced monthly.

Pharmacies should note that across the service, there is a cap on activity.

- standard services (valued at up to a maximum of £80,000)

Useful resources	
Appendix A National SOP	 National SOP.docx
Appendix B Example Risk Assessment	 Appendix F_Example Risk Assessment.docx
Appendix C Test Kits	 Test_kits_CT3.1.pdf
Operational risk assessment template	 Operational risk assessment template
Clinical Guidebook	 Clinical_Guidebook.p df
Digital Guidebook	 Digital_guidebook_v 3.1CT (1).pdf
Quality Checklist	 QUALITY_CHECKLIST. pdf
Minimum Viable Service for ATS at Community pharmacies	 Use_of_community_ pharmacies_for_ATS