## Introduction

* Bury CCG (“Authority”) wish to establish a preferred list of providers (“Contractors”) with established pharmacies to deliver the provision of an asymptomatic COVID19 Community Testing Service to members of public in Bury.
* A greater number of sites will give choice to members of the public of where to access regular Lateral Flow Device tests and allow greater access in underrepresented areas across Bury for people who may previously have faced barriers to testing.

**Background**

Bury has endeavoured to prioritise its testing strategy to protect vulnerable residents, and target where transmission is likely to be highest. The asymptomatic testing programme of work has been agreed by Greater Manchester under the term of Targeted Testing at Scale (TTaS) and linked to the Community Testing Programme (CTP).

Targeted community testing aims to test people who can leave home for work including essential workers, carers and voluntary and community sector staff and volunteers.

This Community Pharmacy programme is a targeted and purposeful programme, which aims to compliment the national testing strategy.

It should be noted that as more is understood about COVID-19 (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 programme in future if applicable

 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 C&C Policy.

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

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 measures, crowd management and appropriate and safe use of consultation rooms.

Community testing uses rapid lateral flow devices to help identify people who are infected and potentially infectious but asymptomatic and therefore unaware that they might be spreading the disease. The testing of asymptomatic people identifies positive cases, so that we can help to prevent transmission to others and support businesses to continue to remain open. Identifying infectious individuals early and isolating them can significantly reduce transmission of the virus and break transmission chains.

 **The tests**

There are several testing technologies available to detect COVID-19. This contract will focus on the Lateral Flow Tests (LFTs), of which several devices are available and considered to be reliable, quick and inexpensive. LFTs are designed to detect the presence or absence of coronavirus by running the swab’s absorbent pad across the back of the throat and to the nasal cavity in the same way that PCR tests are carried out. The device will show a visual positive or negative result dependant on the presence of the virus in under 30 minutes and do not require transporting to or processing in a laboratory. This means that they are well-suited for testing a higher proportion of asymptomatic people, on a regular basis to find, identify and isolate infectious individuals. The tests can be used at home or in a testing location, but do not require highly trained staff to administer.

 **Payments**

The payment to the providers would the on a unit per activity basis. The price per completed test for the end-to-end process will be a £10 payment with additional £250 set up fee. Please refer to the service specifications provided later in this document for further details.

**Greater Manchester Approach**

The Greater Manchester approach is informed by National Government guidance and direction. However, as GM’s context is unique to the national picture, a GM-specific approach is most effective to control transmission. This has been informed by:

● GM and Local Priorities (via Strategic Coordination Group - SCG)

● Mass Testing Expert Group’s expert advice (MTEG)

● Lessons learned in GM from the first 12 months of the pandemic

In particular, the GM approach differs from the national approach in:

* Prioritised Targeted Testing at Scale: focusing the testing resources across GM on key priority cohorts (high risk, high consequence) as opposed to mass testing whole communities.

**Aims, and Intended Outcomes of the Service**

This Service aims to identify asymptomatic residents thorough a purposeful and targeted

approach to community testing, which will require those that are spreading the virus

unknowingly, to isolate.

In addition to delivery of a programme of testing, this programme aims to increase awareness

of key COVID-19 related messages that keep individuals and communities safe 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.

**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 programme, to inform any further local, regional or national roll out of testing programmes e.g., regular testing for ‘test to release’ from self-isolation.

**Nationally defined outcomes**

Identify positive cases of COVID-19 within the population and ensure they self-isolate to reduce transmission to other people.

**Lateral Flow Antigen Test (LFT)**

Lateral Flow Testing involves the processing of human nasal swabs, throat swabs, or sputum samples with a Lateral Flow device. The device detects a protein (antigen) produced by the virus at its most infectious stage. If present in the person’s sample, a coloured line appears on the device after 10-20 minutes. This uses a well-established technique called immunochromatography, which draws the sample along the device in a similar way to a home pregnancy test kit.

**Locally defined outcomes**

The service would be expected to meet the following objectives to contribute to the borough’s COVID-19 management plan:

* + Provide rapid access to testing twice a week, for those who do not have symptoms,
	+ To respond to local intelligence that has identified a need for increased testing provision, and in some cases targeted testing provision.
	+ To ensure that an end-to-end process of testing, analysing and uploading of results to a national portal is operational.
	+ Support a competent workforce that can deliver testing.
	+ Help to ensure residents understand arrangements for testing

**Service model**

Service description and model

The following elements make up the targeted testing model for which the provider will be responsible for delivering:

Testing:

* + A predominantly self-swab model delivered twice weekly at pharmacy settings across Bury.
	+ A provision of swabbing individuals with additional needs.
	+ Registration of individuals’ details and test reference number, testing, analysis and uploading of results to the national portal.
	+ Clinical assurances and insurance for safe practice (including the disposal of waste).
	+ Robust and correct procedures for handling personal and sensitive data, which is treated in accordance with GDPR.
	+ Alignment to the DHSC testing standard operating procedure (found at appendix 3.15), including (but not limited to) a high standard of infection, prevention and control measures.

Testing outputs:

There is no formal limit on the number of individuals tested through an asymptomatic test site, but this should be limited to ensure that sites do not become overcrowded, and individuals must be allowed to conduct the swabbing process at their own pace and must not be hurried.

**Service deliverables:**

• Service to be delivered over the pharmacies normal operating hours

* The remit to deliver a full end to end process for LFT swabbing and analysis including (but not limited to):
	+ - Site registration
		- Reordering and requesting delivery of test kits through Bury CCG via buccg.covid19testing@nhs.net
		- Managing the queueing and flow of people and the wearing of face coverings
		- Ensuring a clean, safe and COVID-19 compliant environment
		- Supporting test registration
		- Supporting a self-swabbing process (and for those with additional needs conducting the swabbing for the individual)
		- Analysis and interpretation of results
		- Uploading results to the national web portal
	+ The Contractor will deliver the end-to-end process (see above), but with the additions of support of what to do in the event of a positive case, and the disposal of waste in line with the DHSC standard operating procedure.
	+ Recording and providing advice on results to individuals – this could also include directing to other appropriate services.
	+ Recruiting and training staff and maintaining adequate staff levels throughout the contract.
	+ Daily clean down of relevant parts of sites used for outreach testing, including restocking of PPE in advance of the next day.
	+ Provide advice to everyone tested on infection control, maintenance to prevent the spread of COVID-19, regardless of test result, and communicate the importance of self-isolation if positive or if a person develops symptoms.

**Workforce and structures**

The contractor will be responsible for having appropriate clinical supervision of staff undertaking assisted testing to be able to deliver the requirements of this specification.

Staff on site are required to wear the appropriate PPE for their role in line with the DHSC Standard Operating Procedure.

Mandatory DHSC training can be accessed via:
**Link**: <https://go.tessello.co.uk/TestDeviceTraining/Login.aspx>  (select register to enter the token)

**Access token**: 3wkcVi4UTX

Pharmacies will also be provided with additional training and support from Bury CCG.

All staff will have undertaken training relating to:

• Infection, prevention and control.

• GDPR.

• The national online training provision for community testing

**Population covered**

The Provider shall provide the service to the local population in Bury.

The service will be provided on a walk-in basis.

The Provider will ensure all activity is recorded to demonstrate the numbers of tests undertaken and submitted electronically on a weekly basis to the commissioner through pharma outcomes.

The pharmacies will provide the LFD test to anyone who works or lives in Bury aged 16 or over who must leave home to work and does not have access to a symptom-free test through other routes.

Childminders working from their own homes are exempt from the criteria of leaving home for work and are eligible if they meet the other eligibility criteria.

Subjects must also not have any COVID-19 symptoms (fever, new persistent cough or loss of sense of taste or smell), and they must not have been instructed to isolate by NHS Test & Trace at the time of the test.

This eligibility criteria are subject to change by Bury CCG, and pharmacies will be updated of any changes to this eligibility criteria in this service specification.

Young people aged 16-17 can consent to their own medical treatment without parent or guardian present and therefore can self-swab. If in the future, children and young people under the age of 16 are identified as eligible, tests must only be administered where appropriate consent is obtained and the approach for will be as follows:

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

 · Children 11 or under, 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 have been prepared and made available for swabbing young children.

**Acceptance, exclusion criteria and thresholds**

Only 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 LFT under this service.

Patients are permitted to receive regular testing, e.g., twice per week testing for the duration of the service.

Where Community Pharmacies identify a patient who they feel is a higher risk, they can use their discretion to suggest regular testing e.g., once or twice per week.

**Supply and equipment**

The provider will take responsibility for all LFT kits received including but not limited to.

• Secure and safe storage of test kits, at an ambient room temperature (5°C to 22°C)

• The kits will remain in the provider’s custody and ensure that they are not tampered with.

**Out of Scope of the Contract**

• Symptomatic people

It is imperative that those with symptoms are asked to book a test using local booking processes and attend one of the dedicated PCR test sites. This is to ensure that those likely to be most infectious are not near others.

**Marketing and promotion of the Service.**

The provider is expected to display the service offer through posters on site premises and actively engage with local settings and with residents that would be eligible for testing to maximise uptake. Participating pharmacies will be signposted on Bury Councils testing page.

**Governance and Operation**

The Contractor is required to have processes and procedures in place for reporting incidents including serious untoward incidents (SUIs).

The Contractor will follow the latest Department for Health and Social Care clinical standard operating procedure for the rollout of lateral flow devices for asymptomatic testing for SARS- CoV-2.

**Clinical Governance**

Each participating pharmacy responsible for ensuring:

• Premises meet all relevant legislative, certification and validation inspections and requirements including health & safety.

o Premises must be accessible, clean, secure, suitable for purpose, properly used, social distancing measures in place, properly maintained and appropriately located for the purposes for which they are being used

o Risk assessments are undertaken if the premises used mean that hygiene standards are more difficult to maintain (e.g., carpeted flooring)

• Enough suitably trained, competent, skilled and experienced persons must be deployed in order to meet the requirements of the service and persons employed by the service must:

o Receive such appropriate support, training, professional development including updated training, supervision and appraisal as is necessary to enable them to carry out the duties they are employed to perform,

o Be enabled and where appropriate, to obtain further qualifications appropriate to the work they perform

o Where such persons are health care professionals or other professionals, they will be registered with a health care or social care regulator

• Clear escalation and decision mechanisms in place to support the clinical supervisor and ensure staff understand their responsibilities to raise concerns, to record safety incidents, concerns and near misses, and to report them internally and externally where appropriate.

• Process in place to ensure lessons are learned and systemic problems and themes are identified so that an action is taken as a result of investigations when things go wrong.

• Creating clear clinical governance processes prior to the start of the testing, which should include the following:

a. Training (online mandatory DHSC training as well as on-site training and support from Bury CCG via request)

i. Knowledge assessment at the end of online training- this is done as part of online training

ii. The supervising clinician will be responsible for ensuring all staff carrying out the process of assisted testing have been suitably trained.

b. Monitoring

i. Void rates and invalid tests rates by day and by operator

ii. Recording errors

iii. Serious incident rates and escalation

**Clinical Incidents and reporting**

1. Contractors should record, report, and respond to incidents in a manner that complies with the requirements as in Department of Health and Social Care (DHSC) COVID-19

Response, National Testing Programme Standard Operating Procedure including but not limited to:

1. Maintaining a patient safety incident log. This should be available for commissioners on request

b) The Contractor is required, as part of this contract, to inform the Commissioner of all incidents relating to the provision of Covid-19 Testing.

**Infection Control & Risk Assessment**

The Contractor will maintain their premises to a high standard of cleanliness in order to minimise the risk of healthcare acquired infection for staff and customers. The provider will follow the required processes as set out in the latest Department of Health and Social Care (DHSC) COVID-19 Response, National Testing Programme.

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.

**Disposal of Waste**

The Contractor will maintain their premises to a high standard of cleanliness in order to minimise the risk of healthcare acquired infection for staff and customers. The provider will follow the required processes as set out in the latest Department of Health and Social Care (DHSC) COVID-19 Response, National Testing Programme.

All responsibility and accountability for the above actions are with the provider.

**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 pharmacist while carrying out their duties under this agreement, except as may be required by law or as directed by the commissioner. The pharmacist must protect personal data in accordance with the provisions and principles of the 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 information Governance requirements

**General requirements**

a. The Contractor is required to have an appropriate range of policies, procedures and processes, to secure and protect the personal information of clients in line with the requirements of the law.

b. The Contractor must ensure that all members of staff are aware of their responsibilities in relation to the protection of personal information.

**Confidentiality**

a. The Contractor is required to have a confidentially code of conduct (or similar).

b. The Contractor is required to ensure that testing occurs in a designated room or area. The room or area should allow for the conversation to remain confidential.

c. The Contractor is required to ensure that all members of staff know and understand their responsibilities in relation to maintaining confidentiality and can explain the code of conduct (or similar) to clients.

**Information Sharing**

The Contractor should ensure that information is shared appropriately in line with legislation:

1. Test results being inputted into the national system
2. Weekly test numbers being shared with Bury CCG by 1700 each Tuesday via buccg.covid19testing@nhs.net
3. Test numbers being inputted into PharmOutcomes

The Contractor should also:

• Provide appropriate tools to employees to enable them to best support individuals ensuring physical resources, including technology, is appropriately protected, secure and fit for purpose.

• Ensure all employees are adequately trained and kept informed in Information Governance related matters consummate to their role and function.

• Ensure all services comply with all relevant information law and the required Information Governance standards, including successful completion of the Information Governance toolkit on an annual basis.

• Take Information Governance seriously and evidentially embed Information Governance principles and processes throughout the service and the organisation.

**Recording**

The Contractor will develop/use existing data systems that will ensure that activity, performance and finance information (as outlined in this specification) are readily available to commissioners.

Pharmacies will be provided with a test site ‘code’ which identifies the pharmacy as a test site. This will be required for the logging of results. As such, an internet connection for logging results and/or a phone running Android 10 or IOS 11 to enable QR code reading.

The following expected reporting fields are to be submitted for the month completed to enable processing of invoices:

* + Total number of tests completed

 **Applicable National Standards**

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).

**Applicable local standards**

The pharmacist 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. · 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 pharmacists and 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 Public Health.

**Safeguarding**

**General Requirements:**

a. The Contractor is required to develop, adopt and implement policies and procedures for safeguarding children and vulnerable adults. These should be developed with reference to the policies and procedures of the Bury Council Safeguarding Board.

b. The Contractor is required to ensure that all members of staff are aware of their safeguarding duties and responsibilities. Staff should receive initial and refresher training

c. The Contractor is required to ensure that all members of staff know how to record concerns and refer to local safeguarding teams.

**Child Sexual Exploitation:**

a. The sexual exploitation of children and young people under 18 involves exploitative situations, contexts and relationships where young people (or a third person or persons) receive ‘something’ (e.g., food, accommodation, drugs, alcohol, cigarettes, affection, gifts, money) as a result of performing, and/or others performing on them, sexual activities

b in all cases those exploiting the child/young person have power over them by virtue of their age, gender, intellect, physical strength and/or economic or other resources

c in order to improve the effectiveness of safeguarding and protecting children and young people from this form of abuse the Contractor is expected to follow the Greater Manchester Sexual Health (SH) CSE checklist. It is vital that all staff (including non-clinical and reception staff) have access to and complete CSE training to ensure they are fully able to recognise the signs of CSE and act according to the relevant pathways and procedures.

**Premises**

a. The Contractor is required to ensure the building is COVID-compliant and able to maintain a 2m social distance between customers/ staff.

b. 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 interventions in line with existing IPC standards and guidance e.g., Community Pharmacy Patient Safety Group guidance. It must:

• Ensure that there is sufficient space, ensuring social distancing is possible between patients and testing staff.

• Be kept clean and in good repair.

• Be laid out and organised for the purpose of providing a healthcare service, i.e., testing.

• Be laid out and organised so that, once swabbing and testing has commenced and is in progress, other members of staff (or customers) cannot interrupt the consultation or enter the room / area without permission.

• Not be used for storage of stock (other than stock that could be used or supplied during a swabbing/testing).

**Partnership Working and Relationships**

Relationship with other services

The Contractor is required to develop and maintain links with other relevant services including (but not limited to):

• The specialist testing provider / community swabbing provider.

• The training and outreach testing provider.

• Bury Council.

• Bury CCG.

**Business Continuity, Resilience and Flexibility**

The approach to asymptomatic testing as proposed in this service specification is being planned against an increasing changeable landscape and national announcements that requires an approach that is both flexible and with the ability to respond at short notice. As such the service may be required to scale up or down operation as instructed by the Commissioner.

Elements of service provision, performance indicators and monitoring criteria as outlined in the specification, may be subject to continuing negotiation during the contract/ service delivery.

The Contractor will be required to work with partners to enable system flex to support unexpected variance or issues, and commissioners would encourage partners to consider having a business continuity and resilience plan to support this.

Pharmacies must have a robust business continuity plan in place. · Pharmacies must ensure they always have an adequate supply of LFTs and related materials to be able to deliver the service.

These will be provided by Bury CCG, but advance notice of additional need should be provided. · The lead pharmacist must inform locum pharmacists of the service and its standard operating procedures in advance of them providing cover.

 Locum pharmacists must also be aware of local protocols in relation to emergency situations, serious incidents and safeguarding.

**Insurance**

There is an expectation that the Contractor shares an up-to-date insurance certificate with a minimum value of two million pounds sterling [£2,000,000.00] for professional indemnity / clinical negligence to include cover for clinical negligence.

**Equality and diversity**

The Contractor is required to commit to promoting equality and diversity, this means that all organisations will have due regard to the need to eliminate unlawful discrimination, harassment and victimisation prohibited by the Equality Act (2010).

The Contractor needs to ensure that the service is flexible in being accessible by all with a focus on those with protected characteristics or from disproportionately impacted/under-represented groups

The Contractor must assure the commissioner that all staff have completed training in equality, diversity and human rights within the 12 months post service commencement. As a minimum, the Contractor must evidence how they meet the minimum requirements of the Equality Act 2010 including the Public Sector Equality Duty (PSED) – subject to the outcome of the review being undertaken.

**Commissioner Responsibilities**

To facilitate delivery of this service, Bury CCG will: · Provide all testing materials e.g., LFT’s and swabs.

 · Provide appropriate PPE, in line with the Clinical SOP.

· Setting up of a test site log-in for each Community Pharmacy, to submit test results.

Provision of training to support delivery of the service, via the National team.

 · Support and advice on IT requirements to meet the requirements of the registration and sharing of results with the portal.

· 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.

 · Arrange contractor meetings as necessary to promote service development and update the knowledge of pharmacy staff.

**Funding arrangements**

Although weekly e-submissions of tests completed are an essential requirement, a web-based invoice solution with a proven track record of connecting to Local Authority systems is required for the cumulative figure of tests completed within the past calendar month. – Pharmaoutcomes

**Appendix A**

