Governance Policy for the role of Point of Care and Rapid Testing of COVID-19 in Clinical Management

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Contents

1. Foreword/Introduction

2. Executive Summary

3. Definition and Scope of Policy

4. Aims and Objectives

5. Clinical Indications for Testing

6. Safe and Effective Use of POCT Equipment

7. Sensitivity and Specificity

8. Management of a positive result and contact tracing

9. Digital Links with Laboratories and other databases

10. Quality Management

11. Health and Safety (see also Annexe 1, section 1.6)

Annex 1 – Governance and Responsibilities
Documentation and Data Protection
Training and Workforce
Service and Maintenance
Infection Control and Decontamination
Health and Safety (further information)

Annex 2 – Establishing a satellite POCT service

Annex 3 – Steering Group Membership

References

1. Chair's Foreword

COVID-19 is continuing to have significant clinical effects on the human population, not only on those it directly infects, but also on the population at large as a consequence of social distancing and shielding those at greatest risk. Understanding the extent to which the SARS-CoV-2 virus is being transmitted through the population is crucial in terms of limiting spread and safeguarding vulnerable individuals, especially as we enter winter 2020 when we shall be faced with the additional seasonal challenges brought by other respiratory pathogens such as influenza and RSV. How we carry out testing for COVID-19 is therefore of paramount importance in maintaining population health as it will be necessary to continue to test stringently for COVID-19 in anyone who presents with concerning respiratory symptoms, not only for that person's individual clinical management, but also so that the ramifications of a positive test are acted on in terms of contact tracing and isolating appropriately. From this viewpoint it is likely that asymptomatic testing will assume a growing role in the weeks and months ahead.

The NHSScotland response to this pandemic has resulted in a significant number of changes in how we are presently delivering care, both strategically and operationally, including such initiatives as an enhanced reliance on virtual technologies, more multiagency collaborative working, and the establishing of COVID-19 'hubs', whose aim is to manage potential COVID-19 presentations in the community thereby reducing unnecessary secondary care attendances and admissions. There have therefore been a number of significant 'gains' in our response to COVID-19, and it is imperative that we capitalise on these and ensure any national testing strategy take cognizance of these novel approaches to healthcare and its delivery. It is also very likely we shall be managing the immediate and delayed effects of this pandemic for some years to come so all these factors play into any testing strategy.

Point of care testing (POCT) offers the opportunity to obtain a rapid result from a 'near patient' investigation in a number of different investigation modalities, and is used to great effect in primary, community and secondary care settings; we therefore have an opportunity here to apply the principles of POCT, or 'rapid testing' to our management of COVID-19 and this guidance aims to set out clear principles on how this should be done in health settings across Scotland. Given the rapid pace of change underpinning our response to this pandemic we have focused on clinical management where POCT is concerned and will pick up some further specific laboratory considerations in a more comprehensive national document around all POCT management to be published in due course. We also hope that this guidance will work as a living iterative document that will be updated to reflect the changes in our response to this pandemic.

2. Executive Summary

This guidance has a number of primary objectives for SARS-CoV-2 near-person/point of care testing (POCT) which are to:

1. **Improve the management of individuals presenting with features of COVID-19** across all clinical settings, and to protect both staff and patients from the sequelae of any infection

2. Use the test to inform a **risk assessment** around the acute management of any individual presenting with features consistent with COVID or in those who are about to undergo a more elective procedure such as endoscopy

3. Support and inform **patient management and flow** across health and social care systems, especially in the context of the redesign of urgent care national programme

4. Link with established laboratory testing as a **quality control** on testing

5. Support the implementation of the Four Nations **infection prevention & control (IPC) guidance** on remobilisation of services in healthcare settings (see https://www.hps.scot.nhs.uk/a-to-z-of-topics/covid-19/infection-prevention-and-control-ipc-guidance-in-healthcare-settings/); reduce transmission and prevent nosocomial infection wherever possible

6. Support the **Enhanced Surveillance of COVID-19 in Scotland (ESoCiS)** programme on behalf of the Scottish Government

7. **Focus on the clinical management of particular individuals** (as opposed to offering guidance on the situation of mass testing).

3. Definitions and Scope of the Policy

3.1 Definitions

POCT is defined by the MHRA as 'any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting'[1]. It is also important to give consideration to the timeframe involved and turnaround so POCT includes the following descriptors:

- rapid testing
- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated / decentralised laboratory testing.

The term COVID-19 refers to the clinical disease spectrum that is caused by the pathogen SARS-CoV-2. Throughout this document the disease will be referred to as COVID-19, and the virus by its given name.

3.2 Scope

This policy will pertain to all clinical situations where POCT for COVID may be utilised; for the purposes of this document we have categorised this into the three key settings of primary care, community care and secondary care. **The principles outlined in this document do not strictly apply to individual patient self-management** (e.g. home testing kits). However, advice and guidance on their use, and testing in general, can be found here: https://www.gov.scot/publications/coronavirus-covid-19-getting-tested/pages/arrange-a-test/.

4. Aims and Objectives

The aim of this national policy is to create a set of recommendations around the use of POCT in the diagnosis and management of COVID, across the three key settings as detailed above.

The objectives of this policy will help to ensure that:

- Regardless of the setting used, POCT schemes must be safe, efficient and governed robustly by, for example, a local Clinical Governance Committee in association with an accredited laboratory (see section 10)

- No person must come to harm as a result of POCT use; this guidance takes a strong focus on reducing potential harm from any systems failures; systems of quality control and assurance for POCT must therefore be in place and adhered to prior to any testing

- POCT must be used only by appropriately trained and authorised staff

- The approach to procurement and authorisation of POCT systems and associated materials must be approved by advisory structures that enable clinical input and compliance with this policy

- POCT devices and facilities must be managed throughout their life cycle and supported once introduced

Recommendations will fall into:

1. Clinical indications for testing
2. Appropriate setting for test environment
3. Sensitivity and specificity of tests
4. Linking POCT results with laboratory data
5. Management of a positive result and contact tracing

All key recommendations are identified by the § symbol to allow easy navigation of the document.

5. Clinical Indications for Testing

Point of care testing aims to make it possible to determine very rapidly[2] whether an individual has COVID-19 or not (but see sensitivity / specificity section).

However, this accelerated approach to obtaining a result should not be used indiscriminately as this risks unnecessary costs, intrusive testing, workforce implications and governance considerations. For more information and guidance see (NHS Inform).

Clinical Settings	Guidance
Primary and community care Clinical assessment centres Covid Hubs Scottish Ambulance Service Pharmacy	Primary care guidance is available at the following link: https://www.hps.scot.nhs.uk/web-resources-container/covid-19-guidance-for-primary-care/ (this includes guidance for optometry and optometrists, dental teams and pharmacies)
Care Homes	Care home testing guidance is available at the following link: https://www.hps.scot.nhs.uk/web-resources-container/guidance-on-covid-19-pcr-testing-in-care-homes-and-the-management-of-covid-19-pcr-test-positive-residents-and-staff/
Secondary care	Clinical and testing consideration of other respiratory pathogens (e.g. Flu and RSV) need to be in place; Secondary care guidance is available at the following link: https://www.hps.scot.nhs.uk/web-resources-container/covid-19-guidance-for-secondary-care/
Population health, test and protect	Guidance for health protection teams is available at the following link: https://www.hps.scot.nhs.uk/web-resources-container/covid-19-guidance-for-health-protection-teams-hpts/ Guidance for contact tracing can be found at the following link: https://www.hps.scot.nhs.uk/web-resources-container/covid-19-contact-tracing-health-protection-team-guidance/

Recommendations for Clinical Indications for Testing	
1	§ Indications for using POCT for suspected COVID-19 should follow current clinical algorithms. Any change to these indications as new evidence of the disease emerges should be adopted in any POCT clinical strategy
2	§ POCT for COVID-19 may also be carried out as part of the Enhanced Surveillance of COVID-19 in Scotland (ESoCiS) programme, to determine disease prevalence and behaviour nationally

Clinical Pathway Utility

As distinct from the laboratory polymerase chain reaction (PCR) test, which may take 24-48 hours for a result to become available, POCT has the obvious advantage of a rapid turnaround in delivering results so has clear benefit in the following situations (but be aware of negative predictive value in the use of any given test – see Sensitivity / Specificity section):

1. where the test will determine an **immediate change in the acute management of an individual**:

a) e.g. individuals with respiratory features who suddenly deteriorate and require aerosol-generating procedures (AGP), such as non-invasive ventilation; this has implications for infection prevention and control where staff exposure and the donning of full personal protective equipment (PPE) are concerned; this may also have implications for eligibility and inclusion in clinical trials. NIV cannot be administered in ward settings because of the infection risk from this AGP so patients have to be moved to HDU settings, at potentially significant risk to both patients and staff. Similarly, POCT would offer very good potential to keep elective surgery green pathways open (and therefore significantly better capacity to operate)
b) in prehospital settings as part of the clinical decision-making process; eg in symptomatic patients being reviewed by community nursing and ambulance clinicians

c) where the result would inform the type of transport that can be used eg critical care aeromedical transfers

2. in the management of **(semi)-elective procedures such as endoscopy and bronchoscopy** where individuals may currently have to wait for a negative laboratory (PCR) test before the procedure can be undertaken; POCT would be invaluable in allowing such procedures to go ahead without the current delay (but see Sensitivity/Specificity section)

3. **cohorting of patients** who potentially have COVID-19 in secondary care areas; e.g. in respiratory wards, intensive care units, emergency departments, maternity units, oncology wards etc; this will obviously impact on patient flow through secondary care systems

4. in the **initial assessment of those presenting with mild to moderate features** of COVID-19; this will allow better triaging and guide appropriate safe management using home monitoring etc

5. in individuals who are **immunocompromised or at increased clinical risk of sequelae** from COVID-19 to allow rapid determination of their clinical management (e.g. admit directly to HDU, rather than general ward)

6. in **remote and rural areas or district general hospitals** where laboratory facility is either not available or does not allow sufficiently rapid turn-around of test results

7. to inform a risk assessment on **healthcare or other essential workers** with mild symptoms who are currently self-isolating in order that they may be able to return to their workplaces – currently management of any potential contacts with the virus are absorbed under the test and protect national strategy.

Confirmatory tests

Validation/verification of POCT device assessments aligned with the manufacturer's recommendations should determine whether or not confirmatory tests are required and how they should be carried out. In particular, and in liaison with IPC teams and Virology leads, clinical cases that fit the clinical criteria for COVID-19 that test POCT negative should be assessed further by confirmatory approaches and be placed in amber/red pathways whilst such testing is being carried out (see Sensitivity/Specificity section for further detail).

6. Safe and Effective Use of POCT Equipment

Point of Care SARS-CoV-2 Testing Environment

SARS-CoV-2 is a hazard group 3 pathogen. Public Health England has detailed safe handling and processing of SARS-CoV-2 specimens in laboratory environments https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens).

Safe testing for SARS-CoV-2 **outwith** a laboratory environment will depend on the POCT system being used. POCT systems where the virus can be inactivated will have the benefit of being used in a greater number of environments. Where the SARS-CoV-2 virus cannot be inactivated, additional safety measures will need to be undertaken. Information for both is found within the table in **Annexe 2**.

Setting up a POC Testing Environment

To conduct safe SARS-CoV-2 testing outwith the laboratory environment will require a structured standard operating procedure, staffed with trained individuals to run tests and report findings. Testing equipment will need to be validated, quality controlled on a regular basis and, importantly, interfaced with the laboratory information management system (LIMS). All planning arrangements, including assigning of roles and responsibilities, must be agreed in advance of setting up the service. Further information on the establishing of a satellite testing space can again be found in **Annexe 2.** The table included in this Annexe provides further information on POCT environments depending on the system used.

Medical devices such as POC should be used as described by the manufacturer in their instructions. Any other use is considered off label use, without the manufacturer's approval use of the device would be at the user's own risk. Guidance can be found at the following link[5]: https://www.nss.nhs.scot/publications/guidance-on-management-of-medical-devices-and-equipment-in-scotlands-health-and-social-care-services/

Recommendations for Safe and Effective Use of POCT Equipment	
3	§ Appropriately skilled and trained healthcare professionals should collect the specimen from the patient and perform POCT, ensuring correct identification of the patient as well as recording patient and user identification details on the POC device
4	§ All POC testing should fall within agreed clinical algorithms as per section 5
5	§ Medical devices should be used as described by the manufacturer in their instructions. Any other use is considered off label use and guidance is referenced in section 6.
6	§ Attendance to appropriate PPE and hand hygiene must be adhered to throughout its administration
7	§ All specimens and tests should be disposed of safely according to infection control and manufacturers' guidelines

7. Sensitivity and Specificity

No test performed in a laboratory or elsewhere is correct 100% of the time.

The way we measure the effectiveness of a test is by using the terms sensitivity and specificity.

Sensitivity is how often a person who has the disease will test positive. Manufacturers aim for as sensitive a test as possible, which reduces the number of **false negatives** (i.e. people who actually have the disease but test negative on that particular test).

Specificity is the converse, measuring how often a person with the required symptoms but not infected with the particular pathogen tests negative for that particular agent/pathogen; for example, in a patient who appears to have symptoms of COVID-19 but actually has flu. Again manufacturers aim for 100% specificity but again there is the risk of obtaining **false positives** i.e. someone who does not have the disease registering positive.

The majority of tests are therefore designed to give an indication of whether a person exhibiting the clinical signs and symptoms of a disease is actually infected with the

causative organism. One problem with COVID-19 is that many infected individuals are clinically well (asymptomatic) but still appear to be able to pass on infection to others, particularly those who are more vulnerable.

Having the clinical presentation consistent with the disease increases the likelihood of a correct result when tested; this is termed a high pre-test probability, and is the reason, in general, we should only be testing those who have clinical features of COVID-19 (rather than, e.g. the common cold) (obviously this is not necessarily the objective where surveillance monitoring is concerned). When a positive result is generated for an asymptomatic individual it is not possible to distinguish between someone incubating the disease who will develop clinical signs in the next few days (pre-symptomatic – definitely an infection risk); someone who is infected who will never develop signs (asymptomatic – possibly an infection risk); or simply where the test got it wrong (false positive – not an infection risk). These different scenarios have significant ramifications for the individual patients and their contacts.

POC tests often have poorer sensitivity and specificity than laboratory based tests, not only because the technology has been adapted for greater ease of use but also because there may often be less rigorous control over sampling and processing[3,4]. The latter two features can significantly alter sensitivity and specificity over and above the test itself (for further information on target product profile see https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-point-of-care-sars-cov-2-detection-tests).

For example, a sensitivity of 80% will indicate that the test will only identify 8 out of 10 of all positive cases. Thus testing individuals for COVID-19 in order to clear them for mixing/working with a highly susceptible population (e.g. care homes, oncology units, immunosuppressed areas etc) in the knowledge that some positives will be missed would clearly not be appropriate.

However repeating the test may be a solution in situations that are higher risk, especially in the clinically vulnerable; e.g. individuals who test negative on day one but then positive on day two. Here we have a trade-off between sensitivity and rapid turnaround of the test, which may be more acceptable in the context of mass testing.

Furthermore, as the 2 out of 10 that are expected to be missed are most likely to be those with a low level of virus, testing individuals who have classical COVID-19 symptoms (and thus likely to have a significant viral load) may be more appropriate where quoted sensitivity is less than 100%; here again the role of pre-test probability is crucial in establishing the likelihood of an individual carrying the disease.

Similarly, a test with a specificity of 95% will wrongly report 5 cases positive for every 100 that were actually negative. In situations where the disease is not common, false positive results can easily outnumber the true negative results. Whilst this may not be suitable in many settings, where it is used as a quick screen and there is the option for a rapid confirmatory test it may save both time and money.

Finally, although they are not infallible, laboratory-based PCR tests have become the gold standard for diagnosing COVID-19 which means that, during validation, POC tests are measured against PCR. However it is important to remember that **sensitivity and specificity for the laboratory PCR test is not 100% so POCT**

sensitivity/specificity values quoted must be considered relative to an imperfect system.

Sensitivity and Specificity Considerations - Recommendations	
8	§ Care should be taken to ensure the POCT selected has the characteristics that best match the clinical situation
9	§ The pre-test probability must always be taken into consideration when interpreting the results of any test (this also applies to the 'gold standard' laboratory PCR test which is not 100% sensitive and specific)
10	§ Going on from 9, although the laboratory PCR test is currently considered to be the 'gold standard', if there is a discrepancy between the laboratory result and the POC result, interpretation should always be made with regard to the clinical context and, if there are any concerns, the individual should be managed according to current clinical advice and algorithms, including self-isolation where necessary
11	§ Where an asymptomatic individual, either staff or patient, initially tests negative on a POCT, this should be repeated at an appropriate, and agreed, interval on subsequent days if there are any risks either to the individual or to public health, especially in those situations where there is a potential impact on clinical vulnerability

8. Management of a Positive Result and Contact Tracing

Management of a positive result via a POCT should align completely with the nationally agreed current clinical algorithms; for up to date information, please see (NHS Inform), and the section above on clinical indications for testing. Although the laboratory PCR test is considered to be the gold standard, as stated above it, like all other tests, does not have 100% sensitivity and specificity so clinical features should determine the appropriate clinical management of any patient, especially those who have the cardinal features of the disease but appear to test negative – such individuals should be managed as if they have COVID-19 and a PCR confirmatory test should be sought.

Recommendations for the Management of a Positive Result		
12	§ **POCT results should be interpreted in view of the clinical context.** In the event of any discrepancy between the clinical presentation and the POCT result, the patient should be managed as per clinical assessment and further laboratory investigations should be sought	Guidance for sampling and laboratory investigations can be found https://www.hps.scot.nhs.uk/web-resources-container/covid-19-guidance-for-sampling-and-laboratory-investigations/
13	§ A positive result should be acted on to inform, not only clinical management, but also the wider public health concerns and should lead to transmission based precautions, notification and contact tracing via test and protect	Guidance for contact tracing can be found https://www.hps.scot.nhs.uk/web-resources-container/covid-19-contact-tracing-health-protection-team-guidance/

9. Digital Links with Laboratory and Other Databases

There are many areas to consider with regard to POCT and information technology, particularly the connecting of POCT device results to external data systems such as management workstations and laboratory information systems.

For public health reasons it is important that **POCT results contribute to the estimation of virus prevalence and infection patterns across Scotland as well as contact tracing information that links into the test and protect national programme**. This is a novel virus, responsible for a pandemic which is having a very significant impact on everyone's lives, as well as, importantly, the capacity of our NHS systems. It is therefore imperative that the results of any testing used to inform clinical management should also be assimilated into local/regional/national

epidemiology and public health surveillance. This can only be achieved reliably where recording of positive test results is taking place in central repositories such as laboratory information management systems (LIMS) and hospital information management systems (HIMS).

Board diagnostic laboratory services should inform Public Health Scotland with details on which POCT tests are being used; timing of adoption, and confirming the dataflow solution via completion of the PHS Respiratory Point-of-Care (POC) Questionnaire; this provides updates as required and ensures testing decisions are confirmed or changed appropriately. The results of the questionnaire will be collected by HPS Public Health Microbiology Team, and further updated as new information on serviced deployment becomes available.

Board diagnostic laboratories should provide a daily extract of the results they have for SAR-CoV-2, Influenza A, B and RSV in their LIMS (including results from Point of Care systems), so that the HPS Public Health Microbiology Team can complete a cross-check of data completeness in ECOSS/NSS data systems. The need for this will be reviewed as the season progresses.

Laboratories must liaise with HPS Public Health Microbiology Team to ensure suitable codes are used to differentiate POCT from laboratory-based testing. Such codes can also be used for internal audit purposes.

Recommendations for Digital Links with Laboratory and Other Databases	
14	§ All POCT results should be linked electronically to the patient record and consistently transmitted to relevant data repositories, including Laboratory Information Management Systems (LIMS) as well as any national databases designed for, and aligned with, test and protect
15	§ The overarching aim of any POCT strategy should be that it connects seamlessly with LIMS and HIMS. This should ensure that LIMS data feeds seamlessly onwards to ECOSS, HPZONE and CMS systems for example
16	§ Boards should ensure that results from POCT tests are made available for the central databases within a maximum of 24 hours after sample collection. Wherever possible this should be via an electronic data feed from the POCT machine to their local LIMS
17	§ Information codes for results obtained from POCT should be differentiated from those obtained from laboratory tests

10. Quality Management

All POCT services must be managed through a robust Quality Management System (QMS). The QMS must be aligned with the hosting medical laboratory QMS. Only competent Quality Management staff can design and manage the QMS, which should be accredited to international standards ISO 15189 and ISO 22870. Where a hosting medical laboratory is not accredited to international standard, evidence of links to an accredited Scottish medical laboratory will be acknowledged in the Service Level Agreements (SLA). Medical laboratories accredited to ISO 15189 should be working towards the UKAS POCT accreditation to ISO 22870.
All POCT services must be validated and verified prior to use in routine practice. The national POCT group/committee will procure equipment and devices where required. Responsibility for validation and verification will be identified and defined through competently trained staff. A project team should be established and robust documentation should be maintained prior to implementation of POCT services.

Local POCT groups/committees will be responsible for the verification of the POCT devices under the delegation from their legal entity. Where there is a lack of resource or competent staff, another Board can be utilised to perform local verifications, detailed in a signed Service Level Agreement between NHS Boards. POCT groups/committees should have processes to ensure samples of verifications are reviewed regularly for consistency and quality.

Recommendations for a Quality Management System for POCT		
18	§ POCT services should have a robust and validated governance system, that reports into a national system. The legal entity must ensure POCT is governed by a local group/committee, with the relevant supporting units, such as finance, procurement, eHealth, IPC etc	See annex section 1.1
19	§ The POCT service level agreement must confirm which users have access to POCT, and comply with locally-derived data protection policy (as per General Data Protection Regulations 2018). The QMS must be designed to inform POCT users of the policies and procedures associated with the POCT services	See annex section 1.2
20	§ Only appropriately trained and competent staff must use POCT policies/documentation	See annex section 1.3
21	§ An Equipment Asset Register must be managed to ensure a traceable result. This must be managed to an internationally accredited standard	See annex section 1.4

(Annex 1 Sections 1.1 – 1.4 are elements of the QMS and must be adhered to, providing Quality Assurance for the POCT services).

11. Health and Safety

It is the employer's legal duty to protect the health, safety and welfare of their employees and all other people who may be affected by their acts or omissions and employers must do whatever is reasonably practicable to achieve this. The term 'employer' refers both to the individual manager and the organisation responsible for the provision and use of POCT services, equipment and for the environment in which they are provided. See Annex 1 section 1.6.

Annex 1

1.1 Governance and Responsibilities

It is vital that all POCT services have designated staff and their responsibilities documented (flow diagrams can be used to complement detailed descriptions). Only competent staff should be allocated responsibilities that meet the level of competence, with objective evidence to confirm the level of competence.

Delegated duties for staff involved with the POCT services, must be documented with the inter-relationships defined. The delegated duties will originate from the signatory of the legal entity and laboratory director.

The **legal entity** for each POCT service is the individual/organisation responsible for the patient results, e.g. in the context of NHS secondary care systems that responsibility rests with the Board. Each legal entity must ensure POCT is governed by a local group/committee, with the relevant supporting units, such as finance, procurement, eHealth, IPC etc. Where a POCT group/committee is not in place locally, an SLA can be utilised to define the relationships/responsibilities with another Scottish Board. The roles/responsibilities and interrelationships must be defined and documented. Each POCT service should have a signed SLA, which will be regularly reviewed. The SLA defines the processes of the POCT service and how this will be utilised through the patient pathway to ensure a robust governed service.

Every POCT user must be aware of the governance processes to ensure the POCT service is safe and effective. Section 1.3 details the training and competence requirements for every POCT user. Where a POCT user has identified an adverse event in the POCT service, this must be reported promptly and accurately via the appropriate local adverse event reporting system, to allow the responsible managers to investigate and identify mitigating actions. Non-conformance identified through POCT services, must be managed according to the international standards [6,7]

i. Responsibilities and authorities for managing non-conformities are designated.
ii. Immediate actions are defined and accurately recorded.
iii. Extent and impact of the non-conformance is defined.
iv. Tests are halted and results withheld where necessary.
v. Clinical significance of non-conformities is considered and recorded.
Note: the requesting clinician or authorised individual responsible for using the results is informed.
vi. Results of non-conformities or potentially non-conformities already released are recalled or appropriately identified/escalated, where necessary.
vii. Responsibility for authorisation of the resumption of testing is defined.
viii. Each occurrence of non-conformance is documented and recorded, with these records being regular reviewed to detect trends and initiate corrective action.

The hosting medical laboratory should collate and manage the non-conformance data, regularly performing trends analysis. Output data from each hosting medical

laboratory should be reviewed and monitored nationally by the National POCT Committee/Group/POCT Co-ordinator.

1.2 Documentation and Data Protection

The POCT SLA's must confirm that POCT users have access to and comply with locally derived data protection policy (as per General Data Protection Regulations 2018). Each Board must have data to confirm that POCT users have successfully completed data protection training (e.g. LearnPro, Turas Learn). POCT users who are registered with a professional body will have data protection requirements within their professional registration. Each legal entity must ensure registered POCT users continue to revalidate and comply with their professional standards and ethics.

The QMS must be designed to inform POCT users of the policies and procedures associated with the POCT services. POCT QMS will structure documents to ensure they remain legible; the correct version of each policy and document is available at point of use. The QMS will enable staff to read and acknowledge policies and procedures for the POCT service to ensure traceability to every patient result. Access to the QMS at point of use is extremely important to uphold the integrity of the QMS. Where access is difficult, hard copies will be managed in such a way to avoid the use of out of date document versions, preventing variation in the practices of POCT users, however this will be limited by current licence agreements.

Every POCT user upon completion of training and password issue must sign Terms and Conditions of use for the POCT passwords. The Terms and Conditions detail good practice as well as how not to practice as a POCT user. It is essential that POCT user passwords are never shared with other colleagues. Poor practice breaks the traceability of the patient result and breaches professional registration and clinical governance, with potential financial and legal penalties.

Where results are not transferred electronically from the POCT devices, documented procedures must be followed to safeguard the confidentiality and security of patient results for clinical governance and audit purposes e.g. result printouts must be stored with the patient records for transcription into IT systems.

1.3 Training and Workforce

As documented in the role and responsibilities, all POCT staff must be aware of their responsibilities within POCT services. It is important that all given roles have deputies identified and the deputies can confirm the level of training/competence required for the role/responsibilities.

Only appropriately trained and competent staff must use POCT policies/documentation. Each legal entity and POCT service must sign a training declaration, with a specific POCT reference, to denote delegated responsibility for ensuring all staff responsible for patient results are trained and monitored for ongoing competence. Training for POCT users must include corporate training and POCT-service specific training.

Training records are essential to maintain a traceable record for every patient result. All results must be traceable to a trained competent POCT user.

The SLA and training agreement will detail the delegation route and escalation routes for good and substandard practice. There should be no confusion in identifying the responsible officer for confirming training in the POCT service, or monitoring the POCT service within the Legal Entity.

1.4 Service and Maintenance

In order to maintain robust equipment/consumables within a POCT service, robust records and certificates/evidence must be stored in the QMS. An Equipment Asset Register is essential to effectively manage property of the POCT service. To ensure a traceable result can be achieved, every part of the process from test to result must be managed to an internationally accredited standard. Responsibilities for equipment service, maintenance and repair must be defined as per section 1.1 of this policy and should follow manufactures guidance.

Each POCT service following a business risk assessment should ensure contingency processes are identified and defined. The contingency plans have to mitigate a loss of service, and additional business risk to the Legal Entity. Contingency plans must be regularly reviewed and tested to ensure business risks are minimised and a POCT service can continue in the event of contingency measures. Where a POCT service cannot continue in contingency, the business risks must be identified and escalated to the Legal Entity and to the national POCT co-ordinator/committee.

Where there is a need for traceable calibration, e.g. temperature monitoring, this will be managed appropriately, sub-contracting the relevant accredited service. The measurement uncertainty from such calibrations will be managed with the risk of the POCT service to ensure a robust quality POCT service.

All equipment must be appropriately decontaminated prior to service, maintenance or repair. Robust records must be maintained to enable traceable patient results.

Equipment or consumables found to be out with the acceptance criteria for the POCT service must be identified and escalated to the relevant governance responsibility. Equipment that is not fit for use must be appropriately labelled as to avoid inappropriate use with patients.

1.5 Infection Control and Decontamination

For further information on infection control and the safe management and disposal of equipment and body fluids please see: http://www.nipcm.hps.scot.nhs.uk/scottish-covid-19-infection-prevention-and-control-addendum-for-acute-settings/.

1.6 Health and Safety

The provision of POCT services requires the co-operation of various sections within the organisation; each individual section manager retains the legal duty to ensure compliance with relevant health and safety legislation for each element of the POCT service within their remit and control.

The employer's duty includes in particular:

- the provision and maintenance of plant and systems of work that are safe and without risks to health;
- arrangements for ensuring safety and absence of risks to health in connection with the use, handling, storage and transport of articles and substances;
- the provision of information, instruction, training and supervision as is necessary to ensure the health and safety at work;
- the maintenance of the place of work in a condition that is safe and without risks to health and the provision including safe access and egress;
- the provision and maintenance of a working environment that is safe, without risks to health, including provision of adequate facilities and arrangements for employee welfare at work.

Employers have duties under health and safety law to complete suitable and sufficient risk assessment of health and safety risks in the workplace. The identification of significant hazards and subsequent elimination or adequate control of the remaining risk must be completed for all POCT services, equipment, environments and associated activities. This assessment must not be limited to those hazards presented by the possible presence of Covid-19. Health and safety risk assessments must be undertaken by those competent to do so.

Employees must be provided with adequate information on the risks in the workplace and how they are protected in addition to being provided with instruction and training on how they are to deal with the risks.

The Health and Safety at Work etc Act 1974 and all other relevant health and safety statutory instruments must be considered and complied with in regards to the provision of POCT services. However it must be noted that, in light of the exceptional circumstances posed by COVID-19 and the potential impact on the diagnostic sector, a risk-based proportionate approach has been adopted in agreement with the Advisory Committee on Dangerous Pathogens (ACDP) and the Health and Safety Executive (HSE) where certain laboratory activities can be undertaken within a microbiology safety cabinet at containment level 2 rather than at containment level 3. Reference to current government guidance on this matter must be made when undertaking the risk assessment.

https://www.gov.uk/government/publications/wuhan-novel-coronavirus-guidance-for-clinical-diagnostic-laboratories/wuhan-novel-coronavirus-handling-and-processing-of-laboratory-specimens#section5

Annex 2

Establishing a Satellite POCT Service

1. Establishing a clinical satellite POCT service will require shared input from the following services from the outset:

- Microbiology/virology laboratory manager +/- consultant clinician
- Point of Care Testing Lead (one will need to be appointed if not currently in post; this may be a senior laboratory role or a skilled doctor or nurse with experience in all aspects of laboratory management)
- Health and safety
- Infection prevention and control
- Management
- eHealth
- Estates
- Finance
- Procurement
- Clinical engineering/medical physics

POCT service set up may also need input from:

- Human resources
- Staff Bank
- Practice development

2. Environmental considerations for POCT

Environmental Considerations		
	Active Virus	**Inactivated Virus**
Location & Space	A dedicated room for testing should be identified and agreed by the group. At a minimum, the room must: • be located near the population(s) to be tested to minimise sample transfer time • be of an appropriate size and layout to accommodate staff, testing instrument(s), storage and safety equipment • have sufficient lighting 24 hours a day • have suitable ventilation to work comfortably and operate machinery in optimal conditions • have storage for instruments, testing kit, reagents, QC and safety equipment (including spill kit) • consumables and QC must be maintained at the appropriate temperature as per manufacturer guidance • have controlled access • have surfaces and floors that can be easily decontaminated • have space for waste with regular collection • have a telephone • have internet connectivity for testing equipment to LIMS and a PC • have safety plan for staff who might be lone working • have agreed management of result reporting, incidents, staffing and training	POCT device(s) can be located in clinical environments providing the following conditions are met: • follows all environmental and safety specifications laid out by manufacturer • dedicated work surface for device and associated equipment (e.g. PC, barcode scanners) and consumables. • dedicated testing space • storage space for consumables • dedicated waste • device can be connected (physically or wirelessly) to LIMS • adequate power supply, lighting • agreed by the following teams: clinical, infection control and health and safety • clinical team retain ownership of the space and therefore responsible for safe management
Instruments/Testing Equipment	Any point of care testing instruments/equipment used must have valid CE marking and meet the Medicines and Healthcare products Regulatory Agency https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/target-product-profile-point-of-care-sars-cov-2-detection-tests	
Training	A training log must be developed, managed and maintained by the Point of Care testing co-ordinator. All staff working in the space must demonstrate competence in all aspects of testing, including using equipment as well as health and safety aspects	A training log must be developed by the Point of Care testing co-ordinator and managed/maintained by local clinical manager. All staff working in the space must demonstrate competence in all aspects of testing, including using equipment as well as health and safety aspects
Operation	Day to day operation of the space should fall under the management of the Point of Care Lead. They will write the SOP,	The clinical area hosting the device retains responsibility for the space and management of devices in their space. A POC Lead can

Environmental Considerations		
	Active Virus	**Inactivated Virus**
	manage staffing and troubleshoot any problems as they arise. They will ensure adequate stock of consumables are available. If the POCT Lead has concerns this should be directed to their service manager	help clinical teams with day-to-day operation queries and agree who will undertake responsibility for ordering test kits and consumables
LIMS and Order System connectivity	Any POCT device should ideally have means to record results directly into the local LIMS and to any other relevant hospital systems (e.g. ICNET) as appropriate. Local eHealth should offer 24/7 support for this service, with contingency plans in place; the order system should then be able to identify if a test is being ordered as a POCT rather than a laboratory test	
Quality	POC Lead will be responsible for quality aspects of POCT. All patients and quality control/assessment results must be recorded. This record should include unequivocal patient identity, time of test, the result, relevant quality control results and user identity. Procedures should be in place to ensure record is kept of batch numbers of test kits used, including date opened and use by date. The internal quality control and external quality assessment procedures (as appropriate) must be clearly documented in the device SOP and adhered to by POCT users	
Safety	Safety is paramount and the POC Lead, along with Health and Safety input, will ensure proper safety. A full risk assessment must be performed. Improperly managed virus can cause infection and therefore must be managed in the safest circumstances to reduce this risk. Within satellite testing spaces microbiological safety cabinets staffed by trained personnel should be used to handle specimens that may contain SARS-COV-2	POC Leads and Health and Safety teams will need to assess environments where POC devices will be placed. Clinical teams hosting the devices will be responsible for ensuring space remains safe at all times
Staffing	POC Lead will organise and remain responsible for staff. There must be enough staff to safely run the service for the period expected by the Board. POCT staff can be remotely supervised as per https://www.ibms.org/resources/documents/point-of-care-testing-near-patient-testing/ Staff performing POCT must receive a full induction and training and demonstrate competence in: • how to operate testing equipment and perform QC • working within a microbiology safety cabinet • how to decontaminate workspaces and manage spills, and • troubleshoot IT issues	The clinical area will retain responsibility for ensuring appropriately trained staff are available and rostered to operate the POCT. Staff performing POCT must receive a full induction and training and demonstrate competence in: • how to operate testing equipment • how to decontaminate workspaces and manage spills • troubleshoot IT issues • only users with log in details to use POCT device

Environmental Considerations		
	Active Virus	**Inactivated Virus**
Decontamination	POC Lead will ensure dedicated space has appropriate decontamination protocols in place	POC Lead and infection control will work with clinical areas to manage issues surrounding decontamination
Waste	POC Lead will ensure protocol for waste	POC Lead and infection, prevention, control team will develop protocol for waste

3. Steering Group Membership

Jacques Kerr, Senior Medical Officer, The Scottish Government (Chair of the National POCT Working Group)
Karen Stewart, Interim Chief Healthcare Science Officer (Co-Chair)
Kerry Chalmers, Medical Devices and Legislation Head of Unit, Scottish Government
Sara Davies, Consultant in Public Health Medicine, Scottish Government
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David Anderson, Consultant in Respiratory Medicine, Queen Elizabeth University Hospital and MCN Lead for Respiratory, Greater Glasgow and Clyde
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Tom Evans, Consultant in Infectious Diseases, Professor in Molecular Microbiology and Chair of the Clinical Cell, Scottish Government
Laura Imrie, Consultant Lead, ARHAI, National Services Scotland
Michael Lockhart, Consultant in Microbiology, Public Health Scotland
Dave Yirrell, Consultant in Virology, Public Health Scotland
Alison Smith-Parker, Lead Healthcare Scientist (Epidemiology),Public Health Scotland

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Dr Noha El Sakka, Consultant and Service Clinical Director, Medical Microbiology and Virology, Lead Infection Prevention and Control Doctor, NHS Grampian
Rory Gunson Consultant Clinical Scientist, Virology, NHS GG+C
Mairiead MacLennan, Quality & Training, Department of Medical Microbiology & Infection Control, NHS Fife
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Ryan Cooper, Lead Quality Manager, Blood Sciences and Microbiology, NHS Tayside
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Erica Peters, Consultant Infectious Diseases and General Medicine, Queen Elizabeth University Hospital
Conor Doherty, Paediatric Surgeon, NHS GG+C

Mary Stewart, Policy Lead, COVID Testing and Contact Tracing Policy Division, Scottish Government

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7. **ISO 22870:2016** Point of Care Testing (POCT) – Requirements for Quality and Competence https://www.iso.org/en/contents/data/standard/07/11/71119.html

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