



The Association for
**Clinical Biochemistry &
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POINT OF CARE TESTING

National Strategic Guidance for
at Point of Need Testing

Executive summary

Healthcare is changing as technology develops, more virtual and remote (from the traditional healthcare setting) models of care are emerging. These models are changing the demands of traditional services, and a clear demand is for more diagnostics to be delivered at the point of need.

This paper sets out the strategic requirements to deliver point of care services to benefit patients within a safe, high quality and accreditable framework. For patient safety, good governance and for the effective use of the right equipment, this strategy is to be used by health systems to inform the principles of adoption for point of care testing in all settings. Laboratory experts should be used as a source of trusted advice to support the design, assessment, implementation, and delivery of diagnostic services outside of the traditional laboratory setting.

There is a patient safety imperative that quality standards and good governance are maintained in this complex area of diagnostics, especially as it moves into new and novel domains, with more complex oversight models needing to be developed.

Lessons learned from the pandemic highlight the need for a clear use case for the type of test and technology, the performance of the technology and the applicability of the test type in the clinical setting being proposed.

Full and properly costed financial resources need to be identified to support high quality, fit for purpose and safe Point of Care Testing (POCT) services. Funding for diagnostic tests does not have absolute clarity within many healthcare systems, switching models of care can lead to perverse incentives financially. Clarity on the costs of POCT requires engagement from multiple parties to ensure both implementation costs and ongoing revenue is accounted for in the setup of a new POCT service without detriment to other service provision routes.

Engagement across healthcare organisations is critical to understand the flow of diagnostic information, from wherever it is undertaken, to the patient record, with visibility for all clinical staff who have reason to access this information.

New technology brings new opportunities for the better use of the existing workforce, creating a more agile workforce. Those operating, monitoring, training and educating users and selecting and deploying the equipment may well be different from current models and present an opportunity to develop new ways of working, and new roles across the healthcare system.

Recommendations:

When considering and introducing a point of care service there is a requirement to:

- Identify the **unmet need from testing** and whether there is a test to meet this need.
- Involve laboratory professionals to guide best practice in the **selection of equipment** that ensures adequate safety and quality to optimise cost and minimise risk.
- Have **operational management system** applicable to any setting, including community or multi-agency services, that ensures POCT technology is efficiently maintained and competently used by trained operators, risks are effectively addressed, device performance is monitored and optimised, and a high standard of service is delivered.
- Establish a model of good **clinical governance** that satisfies independent regulators and meets applicable quality standards.
- **Define 'POCT'** and have a policy directed to support the application within the care setting. Set out clear principles to govern the use and application of POCT. Policy sets out the method to define the use case and from there the requirements and expectations of the technology.
- Ensure **quality standards** described are met and the road map to introduction of ISO15189:2022, where applicable, proposed.
- Understand the needs and demands of the **workforce** ensuring that it is in place and resourced appropriately with correct training and support to undertake all elements of the service.
- Ensure devices are subject to appropriate Internal Quality Control (IQC) and registered for External Quality Assurance (EQA) and **performance is monitored** by a laboratory professional. Audits of all aspects of POCT services are performed to scrutinize the whole system.
- Ensure the level of **IT connectivity** required is equal to that of the main laboratory as far as possible, and not dependent upon care setting.
- Involve laboratory teams at the earliest stage of any development. **Involve Laboratory professionals** in any research and development of patient pathways using novel or innovating technologies.

- Commit to **appropriate funding** and resources to deliver services that are high quality, and meet the ambition set out in this document.

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Introduction

Healthcare is changing as technology develops, more virtual and remote (from the traditional healthcare setting) models of care are emerging. These models are changing the demands of traditional services, and a clear demand is for more diagnostics to be delivered at the point of need. This paper sets out the strategic requirements to deliver these services to benefit patients within a safe, high quality and accreditable framework.

Point of care testing (POCT) testing can be defined as those tests performed with equipment operated outside of a laboratory environment, from patient wearables and lateral flow devices, for example pregnancy tests and covid LFD's, to ward-based multianalyte devices.

The *purpose* of a POCT service is to enable the delivery of high quality, accessible diagnostics at the point of need for clinical services, improving clinical outcomes and enhancing the patients' healthcare experience.

The aim should be to ensure that POCT services nationally utilise (and inform) advances in technology and diagnostic equipment to innovate the way in which patients can access diagnostics and clinical services.

This strategy sets out a framework to support the development of well governed, clinically effective POCT services across the NHS, using available resources to deliver our aim in a safe and effective way, placing the patient at the centre of their care.

POCT has, for a number of decades, had a role outside of the laboratory to ensure clinicians and patients can access timely, accurate and appropriate results to support clinical care. Technology advances mean that more and more, laboratory equivalent tests are available closer to the point of need than ever before and through that it is increasingly being used in a range of novel and more patient appropriate settings.

The NHS England Long Term Plan¹ and the Richard's review² highlights the importance of patients receiving care closer to home, shifting from acute hospital-based services towards more adaptive community-based settings. There are further areas where POCT is expanding to include population health screening and diagnostic testing access for hard-to-reach social groups. Similar moves are happening across all four of the devolved UK nations.

Following the SARS-Cov-2 pandemic, patient expectations and rapidly developing technology have changed perceptions on the art of the possible around diagnostics dramatically. Pathology service es need to respond to and support this evolving diagnostic capability. Integrated Care Board (ICB) and healthcare systems are being called to move to a process of 'point of need'³ testing; giving patients and systems wider options and improving access to healthcare.

It is our task to ensure that cost effective diagnostic services truly benefit the population, individual patients, clinicians and improve patient pathways, ensuring that even outside of

the laboratory, the right tests are available at the right time to the right patient to the right quality.

POCT is increasingly being used in a range of settings where laboratory medicine needs to have an input.

- **Self-testing** – Indwelling sensors, self-monitoring for long term conditions e.g., Glucose and INR.
- **Home testing** – COVID-19, pregnancy, and sexual health.
- **Clinical setting** – Community Diagnostic Centres (CDC), Ambulance and pre-hospital services, GPs, Outpatients, pharmacy and dentists.
- **Hospital setting** – Emergency Departments, ITU, Acute care, Maternity and Neonatal care.

Some of these areas fall outside the traditional remit of the laboratory, such as community diagnostic centres and virtual wards, but no less require the input from laboratory professionals. For patient safety, good governance and for the effective use of the right equipment this strategy is to be used by health systems to inform the principles of adoption of point of care testing in all settings.

Quality

Medical laboratories are governed by recognised international standards (for example: ISO 15189 and 17025), although these exist for POCT (ISO 22870) the application is variable and there are only a few examples of POCT services reaching this standard. The latest revision of ISO15189 published in 2022 brings POCT into this widely adopted standard and it is expected that laboratory services will extend their accreditation to include POCT as ISO 22870 is withdrawn.

There is a patient safety imperative that quality standards and good governance are maintained in this complex area of diagnostics, especially as it moves into new and novel domains, with more complex oversight models needing to be developed.

Inclusion of all POCT across an ICB or healthcare delivery network, using the local pathology network or pathology provider, in a single quality management system reduces duplication. This is enabled by allowing for the services to be covered by the existing laboratory quality management system, providing for regular audit, monitoring, provision of training and quality assurance by the most appropriate healthcare experts in addition to technical and procurement support.

Experience dictates that high performing POCT services, (mainly those which have attained UKAS accreditation to standard ISO22870), have a clear approved point of care policy

covering the use of such technology outside of the laboratory that is supported by the executive team. ICBs, as part of their wider pathology strategic programmes, should adopt a clear policy covering the operation, adoption, assessment, monitoring and use cases of POCT tests and devices.

All POCT devices should carry the relevant certification approval markings for their intended use (such as those given by MHRA - CE and/or UKCA). All POCT devices should be subject to internal quality control (IQC) and external quality assurance (EQA), recognising the limitations of some continuous monitoring devices where this is not possible. Additional testing via a different route may be required to confirm correct operation and ongoing performance of such devices. IQC at a minimum should follow the manufacturers recommendation but may require additional measures dependent on the particular deployment, advice should be sought to ensure appropriate control of the device. It would be expected for devices to be enrolled in an appropriate EQA scheme.

Both IQC and EQA must be monitored by an HCPC registered laboratory professional (Biomedical Scientist or Clinical Scientist). This monitoring should be provided by the local pathology service (or similar service) to ensure appropriate expertise is available to support the end user to manage discordant results and also to ensure the efficient use of quality materials, supplies and resilience.

Introduction of POCT devices across a system footprint will require a system that allows for the recording, notification and recording of changes to policy, process and operation to ensure all users are following the most up to date guidance and that competency is current.

Technology

Lessons learned from the pandemic highlight the need for a clear use case for the type of test and technology, the performance of the technology and the applicability of the test type in the clinical setting being proposed. Further work is needed to define acceptable target technical performance (TTP) characteristics for each setting that POCT is to be used to support the selection and deployment of all equipment at the point of need.

It is acceptable for the performance of testing technology to vary dependent upon the setting and the clinical question or purpose it is being used.

- **Testing to treat** - Testing to diagnose or support a clinical pathway. Diagnostic standard, with high reproducibility and precision. Laboratory standard, able to be used for diagnosis, true rule in or rule out .e.g. main laboratory tests and tests with high sensitivity and specificity to the diagnostic question.

- **Testing to care** - Testing to support a care pathway or intervention. Able to provide clear clinical guidance in terms of cut off, or low false negative performance. e.g. LFT / Rapid testing in COVID, POCT Creatinine estimation for CT contrast media administration, or antimicrobial resistance (AMR) stewardship.
- **Testing to monitor** - Testing used in the home by a patient to monitor their long-term condition e.g. glucose testing, INR
- **Testing to protect and testing to control** – Public health interventions, screening and surveillance.

For each of these settings consideration needs to be taken around the needs and purpose:

- Is the result to be used as part of the long-term monitoring of the patient, to guide and inform treatment?
- Is the result to be used once to allow access to a patient pathway, or is it to be used to monitor the progression of a disease course?
- Does the simplicity of the device allow for the device to be used in the setting required safely and robustly, with accessible training for the user of the test.
- Does the technology replace the need for a laboratory derived result, or can it be used to triage diagnostic testing?
- Could home sampling or improved phlebotomy and logistics deliver the same outcome?
- Does the technology improve the experience of the patient?
- What is the workforce demand and training burden for the technology?
- How will the result reach the permanent patient record and be recorded appropriately and digitally?
- Can the test, testing approach and the result form part of the quality management system?
- What are the contingencies in the event of equipment failure, or where the result exceeds the analytical range or performance of the device.

Funding

Full and properly costed financial resources need to be identified to support high quality, fit for purpose and safe POCT services. Funding for diagnostic tests does not have absolute clarity within many healthcare systems, switching models of care can lead to perverse incentives financially. Clarity on the costs of POCT requires engagement from multiple parties to ensure both implementation costs and ongoing revenue is accounted for in the setup of a new POCT service without detriment to other service provision routes.

Funding for an expanded POCT service should not be taken from the existing laboratory service and new sources of funding are more likely to enable successful deployment. Laboratory professionals should be engaged prior to a service being setup. Both implementation costs and ongoing costs need to be appropriately factored into the service costs. It is worth noting that savings derived from the main laboratory service due to delivery of a POCT service model are likely to be insignificant due to the absolute numbers of tests being conducted and the procurement models used in main laboratory operations. It is also worth noting that changes in care models enabled by POCT can show savings to other non-diagnostic budgets.

Implementation costs include:

- Clinical and laboratory professional staff time to assess appropriate technology to address the clinical question. Complex or novel approaches may require formation of a working group with wider engagement from groups such as IT, procurement, infection control and others.
- Evaluation and verification of the device/test which may include verification panels to be purchased from an independent supplier. For novel devices, additional post market evaluation may also be required and costed into the implementation phase.
- Consumables will be required to set up the device, run tests and assess results before being used for clinical service.
- IT connectivity, build of result entry points and associated expert staff time costs.
- Capital if devices are to be purchased.
- Storage of reagents, consumables and /or IQC. This may require secure local storage and may require a dedicated fridge or freezer.

Ongoing costs include:

- Device lease / rental. Consumables including reagent, IQC, sampling devices and stationary. Facilities and room costs.
- EQA registration, consumables and staff time to run these tests.
- Dedicated staff time to run the service.
- Laboratory healthcare scientists to oversee the quality of results, to support training needs and provide clinical governance of the service to achieve accreditation standards.
- IT connectivity licences, server space and maintenance of connection to together with dedicated IT staff time.
- Service and maintenance contracts for the devices
- Provision of business continuity.

Digital

Engagement across healthcare organisations is critical to understand the flow of diagnostic information, from wherever it is undertaken, to the patient record, with visibility for all clinical staff who have reason to access this information. This reduces test duplication and can enhance progress of a patient through a pathway and can build a better care plan.

IT connectivity should be seen as mandatory whenever the option allows, but not to prevent access to testing where this is not possible. Due to the known issues of subjective interpretation of results, devices read by the human eye should be avoided wherever possible and technology that can electronically read and/or report such results be encouraged. AI assisted reading devices are likely to increase over time, these should be assessed as part of the total assessment and verification of the device, test and test setting.

The results of all POCT tests, detailing the test result, the reference range, lot number of the reagent/test used, the name of the user and action taken must be entered into the patient care record to ensure long term monitoring of results and to ensure accurate culminative result monitoring. If at all possible, the test type and care setting (i.e. POCT / primary care) should also be recorded.

Adequate data recording allows for results to be used or reflected on in future care episodes. In the event of a manufacturing or quality issue, lot tracing can be performed and contact with the clinical team can be made if required for discussion.

The digital connections required for POCT, particularly in the community, are complex to navigate. It is critical that staff with the expertise to make these connections (primarily those with laboratory IT expertise) are used in within laboratory services and the wider health service to ensure result communication is clear, correct and safe.

Workforce

New technology brings new opportunities for the better use of the existing workforce, creating a more agile workforce. Those operating, monitoring, training and educating users and selecting and deploying the equipment may well be different from current models and present an opportunity to develop new ways of working, and new roles across the healthcare system.

The wider laboratory workforce, experts in delivering high quality diagnostic services, do not need to be the operators of diagnostic testing, but must always be involved in the selection, monitoring and audit of diagnostic services. Their experience of training and education

should also be utilised to ensure that those operating acquire all the knowledge, skills and competencies needed to ensure a safe service is provided at all times. Training and competence of the workforce is essential, as is the commitment to ensure training is supported alongside restricting access to only those with current competency and in date training.

Procurement

Standardisation of testing and testing strategies across an ICB or healthcare system can lead to benefits from central procurement, with associated economies of scale, through a single selection and assessment criteria and process, to ongoing service, monitoring and contract management. Additionally, the resultant test results will align (e.g. with regard to reference ranges and/or action limits).

Further combining community and virtual ward care settings' POCT requirements with those of secondary care can derive further benefits in cost, and also connectivity, reagent and supplies management and system resilience. It will also allow for clinicians to move between care settings and have access to the same POCT kit, therefore negating the need for further training and subsequent competency assessment.

Any POCT procurement must involve the pathology provider and/or local pathology network at each stage from use case (i.e. what test will answer the clinical question being posed) through to deployment. Ideally, it should match the footprint of the agreed quality management governance and provide a route for equity of access for all patients and served population.

What tests should be available at the point of need via POCT?

It is not the purpose of this document to be prescriptive of what tests should or should not be delivered at the point of care. Point of care testing should not be seen as a replacement for the extensive, high throughput main laboratory services. These services deliver tests on a cost base that the majority of POCT tests cannot achieve, and at an analytical performance that matches the diagnostic need. The delivery of POCT should only be considered once the premise that:

- this testing cannot be delivered in a timely way through better sample collection (e.g. phlebotomy) and transport logistics using the main laboratory.

- that the cost benefit through this proposed testing strategy delivers a clear patient pathway benefit that utilising the main laboratory service could not achieve.
- that the POCT test offers a benefit that the main laboratory cannot deliver.

The following considerations must form part of the selection process:

- Does this test provide important or additional information to support the patient and the patient pathway?
- Are the clinical settings appropriate for the management of the patient in the event of an abnormal result or critical values being exceeded?
- Should the patient have already had this test routinely as part of the ongoing monitoring via other current care settings?
- Is the result going to provide immediate benefit to the patient or the operational delivery of their immediate care?
- Are there alternative diagnostic strategies that could be considered and excluded first?
- Does this enable access and drive down health inequalities?
- Does the test have the required sensitivity and specificity to answer the clinical question adequately.

Conclusion

Diagnostic testing in a range of care settings can and does add benefit to patients and the care pathway. Effective use of the right test, in the right place, at the right time, for the right individual is vital to ensure delivery of effective, safe patient care. Selection, assessment, training, monitoring the quality and audit of point of care tests by laboratory healthcare scientists is essential for high quality and safe services for patients. Innovative and flexible testing approaches should be adopted within the framework outlined in this document to ensure that patients continue to access diagnostic tests that support them in their care pathway.

Recommendations:

When considering and introducing a point of care service there is a requirement to:

- Identify the **unmet need from testing** and whether there is a test to meet this need.
- Involve laboratory professionals to guide best practice in the **selection of equipment** that ensures adequate safety and quality to optimise cost and minimise risk.
- Have **operational management system** applicable to any setting, including community or multi-agency services, that ensures POCT technology is efficiently maintained and competently used by trained operators, risks are effectively addressed, device performance is monitored and optimised, and a high standard of service is delivered.
- Establish a model of good **clinical governance** that satisfies independent regulators and meets applicable quality standards.
- **Define 'POCT'** and have a policy directed to support the application within the care setting. Set out clear principles to govern the use and application of POCT. Policy sets out the method to define the use case and from there the requirements and expectations of the technology.
- Ensure **quality standards** described are met and the road map to introduction of ISO15189:2022, where applicable, proposed.
- Understand the needs and demands of the **workforce** ensuring that it is in place and resourced appropriately with correct training and support to undertake all elements of the service.
- Ensure devices are subject to appropriate IQC and registered for EQA and **performance is monitored** by a laboratory healthcare scientist. Audits of all aspects of POCT services are performed to scrutinize the whole system.
- Ensure the level of **IT connectivity** required is equal to that of the main laboratory as far as possible, and not dependent upon care setting.
- Involve laboratory teams at the earliest stage of any development. **Involve Laboratory professionals** in any research and development of patient pathways using novel or innovating technologies.

- Commit to **appropriate funding** and resources to deliver services that are high quality, and meet the ambition set out in this document.

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