Point of Care Testing Policy

HBDHB/CPG/101

Approved by:	Chief Nursing & Midwifery Officer	**First Issued:**	October 2012	HE KAUANUANU RESPECT ĀKINA IMPROVEMENT RARANGATETIRA PARTNERSHIP TAUWHIRO CARE
Signature:	Chris McKenna	**Review Date:**	September 2020	
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PURPOSE

This policy is designed to ensure that the use of Point of Care Testing (POCT) systems within the Hawke's Bay District Health Board (HBDHB) is managed in accordance with national and international guidelines and accreditation standards, and that all relevant risk and governance issues are addressed.

The policy describes accepted best practice in the management, use, (technical) control and care of POCT. It is impossible to be prescriptive as the range of devices or instruments included under POCT is so varied. However, any local decision to deviate, reduce or alter practice away from the guidance given below must be risk assessed, justified and documented locally and must facilitate records that allow for a full audit trail of all implementation, training, quality control and test results information. Records must be such that, in the event of an audit or investigation into an untoward incident e.g. query as to the validity of a result, they would clearly and unambiguously provide the information required.

Any doubt as to the relevance of this policy to a specific device, test system or clinical area should be referred to the POCT Committee for clarification.

PRINCIPLES

- Laboratory tests should be performed in the laboratory whenever possible, unless there is a clear advantage in patient management from POCT and the appropriate equipment and trained staff are available.
- POCT equipment will be operated and maintained according to the POCT quality management system as prescribed in ISO15189:2012 and ISO22870:2016, and in association with Quality Health New Zealand and International Accreditation New Zealand accreditation standards.
- All HBDHB staff operating POCT equipment will have appropriate training, and reach and sustain required competency levels to ensure quality outcomes.
- Standardisation of POCT equipment and consumables will be adopted to reduce variation in result(s) generated.
- Accommodation and environmental conditions for POCT equipment will be determined according to manufacturer's recommendations to ensure safe operation.
- Improved management of POCT equipment will enhance quality outcomes, minimise risk to patients, staff and organisation, and facilitate external POCT accreditation for clinical units.

SCOPE

All HBDHB staff who are involved with evaluating, purchasing, operating and maintaining POCT equipment within the organisation.

DEFINITIONS

POCT – Diagnostic testing of tissue or bodily fluids that is performed near to or at the site of the patient, with the result leading to possible change in the care of the patient.

Quality Control – A set of procedures designed to monitor the test method, user and results, to assure appropriate test system performance. QC includes testing control materials, charting the results and analysing them to identify sources of error and evaluating any remedial action taken as a result of the analysis.

Competency – A documented demonstration of an adequate level of training, understanding and responsibility on the part of the POCT User.

POCT Committee – The group of health professionals responsible for oversight of all aspects of POCT in the HBDHB, including the evaluation and introduction of any new or replacement tests or equipment.

POCT Quality Manager – A position provided by the laboratory whose role is to liaise with clinical staff and provide support with POCT oversight and quality management systems.

The User – Any person who performs tests and produces results using a POCT device. In this document this term is used to differentiate HBDHB staff performing laboratory testing in a POCT environment, from laboratory staff performing tests in a laboratory setting.

The Area Manager – In the context of this document, the person who is designated as responsible for managing the POCT device in the service area (generally but not necessarily, the Clinical Charge Nurse, or delegate).

ROLES AND RESPONSIBILITIES

The POCT committee

This group consists of but may not necessarily be confined to, the Laboratory Advisory Committee. Advice may be sought from a number of stakeholder groups including but not confined to:

Seconded Committee Member	Role
Laboratory technical advisor(s)	Provide technical advice and support
Clinical Nurse Manager and Clinical Nurse Educator(s)	Ensure POCT operated and controlled as per POCT Quality Management System
Procurement Representative	Purchase of POCT equipment
Quality and Risk Department Representative	Liaise with clinical units and laboratory on issues around POCT
Business Analyst	Purchase of POCT equipment
Information Services Representative	Provide IS advice and support

As a group of interested stakeholders, they will

- Ensure effective use and management of POCT
- Evaluate and approve any requests for the introduction of new POCT equipment
- Evaluate and oversee the selection and procurement of any new or replacement POCT devices
- Ensure that controls and procedures are in place before POCT devices are introduced
- Develop standard operating procedures and competencies for the use of POCT devices in consultation with users and the manufacturers and suppliers.

The POCT Quality Manager

The POCT Quality Manager will:

- Document, implement and maintain the POCT Quality Management System
- Be responsible for ensuring that all POCT is performed to an appropriate standard.
- Maintain a record of all POCT equipment within the HBDHB.
- Be responsible for ensuring that all POCT users have current competency training and documentation.
- Be responsible for ensuring regular quality assurance is maintained and quality control samples are analysed on POCT devices, with up to date documentation and history.
- Maintain (monitor) service records for each device.
- Be responsible for trouble shooting of POCT devices and overseeing the maintenance of up to date documentation and history.

The Users

The users of POCT devices will:

- Use the equipment in a safe and responsible manner.
- Have a unique identifier (log-in or password) where applicable.
- Not share their log-in or password with any other staff member.
- Keep an accurate and up to date maintenance log for the devices they use.
- Remove the instrument from use if it becomes non-functional and inform the Area Manager and POCT Quality Manager as soon as possible.
- Satisfy the quality control requirements for the device.
- Document all patient and quality control results according to the protocol.
- Ensure the device is left in a fit state for the next user.
- Ensure all consumables are within expiry date and have been stored correctly as per manufacturer's recommendations.
- Ensure that all used items, including but not exclusive to, strips, lancets etc are disposed of safely in accordance with the standard operating procedure.
- Be individually accountable for their practice and ensure that they acquire and maintain skills in the use of POCT devices. This will require the completion of documented competency processes as required, which will usually be on an annual basis.
- Sign that they recognise clinical responsibility for the tests that they undertake.

The Area Manager

Managers of all areas using POCT devices will:

- Be responsible for the day to day supervision or oversight of personnel performing POCT and reporting test results.
- Be responsible for the day to day care of the system and control of environment contamination, and for the maintenance of stocks of consumables and reagents within their shelf life.
- Ensure that all users of POCT devices are competent and authorised to use the devices.
- Ensure their area complies with all HBDHB POCT policy procedures.
- Ensure that training records are kept in accordance with the Procedure for the Management and Implementation of Point of Care Devices.
- Ensure that quality control procedures are documented according to the relevant POCT policy.
- Ensure that the relevant policies and procedures for the use of the device(s) in their area are in place and available to all users.
- Ensure that all requests for new POCT devices are made in accordance with the selection and procedure criteria as described in the Procedure for the Management and Implementation of Point of Care Devices, and are made in writing using the Request for New POCT form (Appendix 1).

POLICY

Risk Management

The risks associated with the use of POCT devices arise from the inherent characteristics of the devices themselves and from the interpretation of the results they provide. They can be prone to user errors arising from unfamiliarity with equipment more usually found in the laboratory. User training and competence is therefore crucial. The POCT Committee will assess the overall risks associated with individual devices and systems and will advise how these may be managed by taking into account the following:

- Patient safety
- Training requirements
- Standard operating procedures
- Health and safety
- Quality assurance
- Maintenance
- Laboratory accreditation
- Hospital certification
- Record keeping
- Adverse incident reporting
- Staff safety, infection control

Any adverse incidents involving POCT devices such as, but not exclusive to, instrument failure, health and safety issue or clinical incident must be reported according to the HBDHB Incident Reporting Policy.

PROCEDURE

Introduction of POCT procedures

- All requests to institute a POCT programme, add an additional analyte, or add new equipment must be made in writing to the POCT committee using the Request for Point of Care Testing Form (Appendix 1).
- Assessment of need and the decision to proceed with selection and evaluation of suitable equipment will be made by the POCT committee.
- The application to the Product Evaluation Committee (PEC) to proceed with the evaluation, and the recommendations to that committee to purchase new equipment or new models of existing equipment, will be made by the clinical area/s involved in consultation with the POCT Quality Manager.
- All offers of free equipment or loan equipment, on a consumables lease, or any other basis, and involving Point of Care testing, will come under the control of the POCT committee and be subject to the same evaluation criteria, and the request to institute a POCT programme procedure outlined above.

Evaluation

- Evaluation of new or replacement POCT equipment will be carried out in accordance with the process for evaluation as documented in the New Zealand Best Practice Guidelines for Point of Care Testing.
- The staff of the Clinical laboratory will provide consultation and oversight in the selection of test methodology, preparation and use of materials, training and competency checks, quality improvement and quality control procedures.

Purchase

- The purchase of new or replacement POCT equipment must first be approved by the POCT Committee, with final approval following the PEC process.
- All purchases of equipment or consumables must be governed by the HBDHB Purchase and Supply Policy - HBDHB/OPM/061.

- The unit will meet ownership and all costs involved with the running of the equipment. This may include the replacement of existing equipment due to loss or irreparable breakdown, associated licence fees, the cost of consumables, and both internal and external quality control programmes.
- Where available, all new or replacement POCT devices must be capable of issuing electronic reports to the clinical data repository.

Training and Competency

- All users of POCT equipment are required to be trained to operate the equipment, and certified as competent, before being authorised to use any equipment, including simple dip-sticks.
- An authorised trainer, approved by the POCT committee, such as laboratory staff or the manufacture's authorised representative, will train Area Managers. Area Managers will then be responsible for the training, ongoing certification and maintenance of standards of clinical staff in the unit.
- Training shall be undertaken at the introduction of new or replacement equipment and then again at defined intervals relevant to the equipment, or as otherwise deemed to be required. Typically but not exclusively, this will be every twelve months for all staff operating the equipment.
- Training will include both practical and theoretical knowledge of the device and test system. Part of this assessment may include completion of a written or an on-line theoretical test.
- Records of training shall be kept within the unit, and with the POCT Quality Manager, either electronically or on paper, and updated as required.

Infection Control

All operators must follow universal infection control precautions.

All devices used between individual patients (e.g. glucose meters) must be decontaminated/disinfected following manufacturers instructions to prevent cross contamination and nosocomial infections.

Standard Operating Procedure (SOP)

All POCT devices will have an established SOP which must be written to the standard required by ISO15189:2012 and ISO22870:2016. The SOP must be available to and followed by all users of the device.

The SOP master copy must be held by the laboratory and be available to accreditation agency inspectors.

Consumables

- Materials and reagents for POCT equipment are to be received into the appropriate department, e.g. stores.
- Each new shipment of materials shall be verified and validated prior to its issue.
- Records shall be kept of all consumables so that an audit trail is available with regard to any particular test performed.

Records of Results

- Results are to be recorded in the patient's permanent record, this may be electronically or on paper, and must include:
  - Patient name
  - Identification number (NHI or Date of Birth)
  - The result
  - Date and time of specimen collection
  - Type of specimen where relevant
  - Identity of person performing the test and reporting the results.

- The transfer of results into the patient's clinical record must be traceable and stated in the POCT procedure.
- Quality control results shall be recorded either electronically or on paper, and will be regularly reviewed by the Point of Care Quality Manager.
- Unexpected or extreme patient results must be checked by sending a sample to the laboratory. Critical levels will be defined in the individual SOP.

Quality Assurance, Calibration and Maintenance

- All POCT equipment shall be subject to maintenance, calibration and quality control to the same standard as laboratory operated equipment, including external quality control. All these activities shall be recorded.
- It is the individual unit's responsibility to ensure these activities are carried out as specified in the POCT Quality Manual. Laboratory staff, through the POCT Quality Manager, are available to offer assistance.

Quality Control Programme

- POCT must have appropriate quality assurance.
- An appropriate quality control programme is agreed and documented for all POCT and must be adhered to.
- A system must be in place to ensure that POCT results are comparable with the results produced by the HBDHB laboratories.
- Internal QC is performed daily or at intervals determined by laboratory staff.
- Users of POCT devices are responsible for performing, recording, reviewing and actioning QC results.
- External QC programmes are performed by selected users at appropriate intervals determined by the laboratory.

Trouble Shooting and Defective Equipment

- Each POCT device must have a "log-book" in either paper or electronic form, in which details are recorded on maintenance, faults, corrective actions and repairs by named individuals.
- All POCT devices must have a documented preventative maintenance schedule, where applicable. Appropriate backup must be available in case of breakdown.
- Trouble shooting procedures as defined in the SOP are to be followed and documented.
- The Laboratory POCT Quality Manager and the Unit Manager are to be informed as soon as possible of any faults in equipment. A POCT Instrument/Test Failure report must be completed and sent to the POCT Quality Manager.
- If the device is unable to be returned to normal operation it is to be removed from the clinical setting and labelled as "Out of Order".
- Service of POCT devices is only to be performed by appropriately qualified and approved staff.
- Procedures for cleaning and decontamination of POCT equipment must be documented and carried out before any servicing is performed.

Ongoing

- Continuation of POCT in an area will be contingent upon adherence to this policy. Failure to meet these requirements may result in revocation of POCT in a specific unit.
- Disregard or disinterest in the Standard Operating Procedure of POCT by an individual or a unit, will be recognised as contrary to the best interest of patient care and result in termination of the testing opportunity.

- The POCT Quality Manager and their designated representatives must have free access to all QC/QA results and to the log-books of each individual POCT device. They have the explicit authority to remove any instrument or device from service if any data indicates the instrument may be unreliable or inaccurate.

MEASUREMENT CRITERIA

All staff involved in POCT undergo training and regular competency checks in order to meet authorisation requirements.

Training records are held by POCT manager and within units where POCT occurs.

REFERENCES

International Accreditation New Zealand, Medical Laboratories – Particular requirements for quality and competence NZS/ISO 15189:2012

International Accreditation New Zealand – point of care testing (POCT) – Requirements for quality and competence ISO 22870:2016

HBDHB Point of care (POCT) quality manual: 2009

New Zealand Best Practice Guidelines for Point of Care Testing 2018

Online Resources

http://www.cdhb.govt.nz/ch_labs/

http://www.rochestergeneral.org/documents/laboratory_forms/POCTPolicy030206.pdf

http://www.nhsfife.scot.nhs.uk/about_us/corporatedocuments/policies/alpha/GPP1.pdf

http://home.caregroup.org/policies/POCT%20Policy%20Procedure.pdf

http://www.doh.wa.gov/hsqa/fsl/Documents/LQA_Docs/POCT.pdf

http://www.cmlto.com/government_policy/position_papers/pdf/point_of_care_testing.pdf

http://www.qmc.nhs.uk/about/foi/policies_and_procedures/clinical_polices/clinical_governance_and_practice/CLCGP003%20Points%20of%20Care%20Testing%20Policy%20version%202.pdf

http://www.wales.nhs.uk/sites3/Documents/115/black95.pdf

http://www.rcpath.org/resources/pdf/Point-of-CareTesting-updatedOct04.pdf

http://www.aacb.asn.au/admin/?getfile=1442

KEYWORDS

Bedside

Point of Care

POCT

Near Patient

For further information please contact POCT Quality Manager

Appendix 1

Hawke's Bay District Health Board

Point of Care Testing

Request for Testing (New, Additional or Change in Testing Methodology)

Date_____ Person/Unit requesting service_____

Contact Person_____ Phone Number_____

Test Requested_____

Is this a currently approved and available POCT?	☐ Yes	☐ No
Is this a new POCT requiring approval?	☐ Yes	☐ No
Is this a request for an additional test or equipment?	☐ Yes	☐ No

Type of specimen to be used

- ☐ Blood fingerprick/venepuncture/arterial (please specify sample type)
- ☐ Urine
- ☐ Tissue (specify)_____
- ☐ Other (specify)_____

Is this test available through the laboratory? ☐ Yes ☐ No

Why is it necessary to perform this test at the bedside?_____

Estimated number of tests that will be performed per week _____

Is this test critical for medication adjustment? ☐ Yes ☐ No

Once the results are available, how soon will they be used for clinical decision making?_____

What is the desired turnaround time if the test were to be performed in the laboratory?_____

Is a capital purchase of equipment needed to do this test? ☐ Yes ☐ No

What is the estimated cost of the equipment?_____

Is the suggested equipment IT capable?_____

Is there Australasian evaluation data available?_____

How will this equipment be funded?_____

What is the estimated cost of reagents/disposables/quality control materials?_____

Estimate the number of staff members who will be doing this test._____

What are the job categories of the potential users?_____

Is a pilot study using the proposed test system required at the location of its intended use?

Do you need assistance from the laboratory staff to organise one?_____

Who will be responsible for:

Ordering consumables_____
Arranging maintenance contracts and emergency call outs_____
Payment of external QC materials (if applicable)_____
Daily QC_____
Training the testing personnel _____
Instrument maintenance_____
Operator Competency checks_____

Has the laboratory been consulted with regard to units, reference ranges, sample types and correlation with laboratory results?_____

Do you have any further comments in support of this application?_____

Please complete this form, attach any supporting information, and return to the POCT Quality Manager at the Laboratory, for consideration by the POCT Committee.