

The CDHB POCT Policy

1. Point of Care Testing (POCT) Management

1.1 Policy

Clinical staff in partnership with Canterbury Health Laboratories staff (via the Point of Care Co-ordinator) manage POCT throughout the CDHB.

All POCT must comply with the quality system requirements of Canterbury Health Laboratories.

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 should not be used to replace routine non-urgent tests.

POCT is introduced with agreement from the relevant clinical services and laboratory staff via the POCT Co-ordinator. Only those staff members authorised to order laboratory tests can initiate POCT.

1.2 Purpose

To ensure that when POCT is introduced:

- Equipment is managed and maintained in a safe condition to minimise the risk to patients, staff and CDHB.
- POCT is performed in accordance with the quality standard requirements of the International Standards Organisation Standard, ISO 15189 and associated Annex D, (ISO/WD 15189) and Quality Health New Zealand (QHNZ) Accreditation Standards.
- POCT equipment is standardised throughout the CDHB.
- Test results are accurate and reliable.

1.3 Scope

All CDHB staff who are involved in the use of POCT equipment.

1.4 Associated Documents

Division Wide Documentation

Volume A: Introduction of New and Approved Products Policy – Christchurch Hospital (in preparation)

Volume E: Nursing Procedures

- Blood Glucose Monitoring Procedure
- Urinalysis

Location Specific Documentation

Canterbury Health Laboratories' Location Manual

- Equipment Evaluation Guidelines

- Laboratory Method Documentation Protocols

1.5 Definitions

POCT – “Diagnostic testing that is performed near to or at the site of the patient care with the result leading to possible change in the care of the patient”. (Source- ISO/WD 22870).

Point of Care Tests include but are not limited to glucometers, urine dipstick, pregnancy tests, coagulation, blood gases, electrolytes, haemoglobin measurements.

- whole blood tests – blood gases, glycated haemoglobins, cardiac markers, tests of haemostasis, haemoglobin
- urine test strips with or without reflectance meter technology, pregnancy tests
- faecal occult blood tests

POCT Co-ordinator – A position provided by Canterbury Health Laboratories, whose role it is to liaise with clinical staff and to provide support in the use of POCT.

Quality Control (QC) – A set of procedures designed to monitor the test method and results to assure 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 operator.

“Clinical staff” – A generic term defining all persons other than laboratory workers employed by the CDHB. In this document it is used specifically to differentiate CDHB workers who perform laboratory testing in a POCT environment from laboratory staff who perform tests in a laboratory environment.

1.6 Evaluation & Selection of POCT Equipment.

POCT Co-ordinator must be involved in the initial assessment, installation and set-up of new POCT equipment.

POCT Co-ordinator must be included in discussions with suppliers regarding POCT equipment.

There must be a clear definition of the problem that the POCT would solve so that a full investigation of all possible solutions can be made.

Specialist clinical staff e.g. diabetes physicians and nurses would be consulted on proposed changes or the introduction of new

POCT equipment.

The evaluation and selection of POCT equipment is coordinated by the POCT Co-ordinator and follows the Canterbury Health Laboratories, Equipment Evaluation Guidelines. This includes:

- needs assessment
- accuracy, precision and correlation studies
- space and service requirements
- methodology assessment
- environmental assessment
- computer requirements
- efficiency assessment

An evaluation report is completed by the POCT Co-ordinator and includes recommendations on the suitability and performance of the equipment. The Evaluation Report is sent to the relevant clinical and laboratory staff for approval or otherwise to purchase the equipment.

The final decision to proceed is a considered consensual agreement by the participants of the process.

Purchase of
POCT Equipment
Installation of
New POCT
Equipment

Follow the procedures in the CDHB Policy & Procedure Manual Vol, 4 Authorities and Purchasing.

The POCT Co-ordinator organises in conjunction with relevant clinical staff the installation of POCT equipment.

The POCT Co-ordinator completes the Canterbury Health Laboratories Procurement of New Test Equipment Checklist.

The POCT Co-ordinator and the relevant clinical staff hold a copy of the checklist.

1.7 Documentation

All POCT procedures must be documented in consultation with the POCT Co-ordinator.

A permanent record of all POCT testing must be maintained within the appropriate clinical record of the patient.

1.8 Training/Competency

Training Program

All staff using POCT equipment receive training in the use of the equipment. The POCT Co-ordinator will ensure a training program is in place and there is a system for documenting when training has been given. The training program should include:

- collection, transportation and disposal of specimens
- quality control requirements

- step by step procedures
- recording results
- interpretation of results
- troubleshooting
- maintenance of equipment

Staff may not train each other unless approved by the POCT Co-ordinator or designated representative.

Competency
Records

All staff using POCT equipment must have up to date competency/audit records, a copy which the POCT Co-ordinator can access.

Templates for recording competency review are available from the POCT Co-ordinator or the POCT web site on the CDHB Intranet.

Competency
Review

Competency is reviewed at least annually for all POCT excluding glucose meters and urine test strips testing. This may take the form of a peer-group, laboratory or senior clinical staff review or audit.

For glucose and urine test strips, a randomly selected group of staff members in each ward or clinic would be reviewed every six months. In the event of an upgrade of instrumentation allowing electronic competency, this process of random review would be revisited.

1.9 Quality Control Program

POCT must have the same level of quality assurance as is provided for testing performed within Canterbury Health Laboratories.

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 Canterbury Health Laboratories.

Internal QC

Internal QC is performed daily or at a suitable interval determined by laboratory staff.

Clinical staff using POCT are responsible for performing, recording, reviewing and actioning QC results.

External QC

External QC programs are performed by selected clinical staff at appropriate intervals determined by the laboratory.

1.10 Performing POCT

Only clinical staff who have been trained in POCT can perform POCT.

Procedures for POCT must be clearly documented using the Laboratory Method Documentation Protocol. POCT procedures must be authorised by the relevant laboratory staff.

All patient and quality control results must be recorded. This can be electronically or on paper. The record must include:

- At least 2 unique patient identifiers e.g. hospital number & name, name & DOB
- Date and time of test
- The result.
- Relevant QC results
- The identity of the operator

The transfer of results into the patient's clinical record must be traceable and stated in the POCT procedure.

Unexpected and extreme results must be checked by sending a sample to the laboratory.

1.11 Troubleshooting/Maintenance/Cleaning of POCT Equipment

POCT equipment must have a documented preventative maintenance schedule. Appropriate back up must be available in case of breakdown.

When a fault is found with POCT equipment it is labelled 'OUT OF ORDER' and must not be used. The POCT Co-ordinator and other relevant staff must be notified immediately.

Trouble shooting procedures must be documented and include contact details for assistance.

The POCT procedure must state who has the responsibility and authority to withdraw the equipment from service.

Only approved and appropriately qualified and competent CDHB or external service staff must service POCT equipment.

A service history must be maintained which includes maintenance, faults, corrective actions and repairs by named individuals.

Procedures for cleaning and decontamination of POCT equipment must be documented and carried out before any servicing is performed.

1.12 Role of the POCT Co-ordinator

Canterbury Health Laboratories provides management services for POCT equipment via the POCT Co-ordinator whose role it is to liaise with clinical staff and support the use of POCT equipment.

The POCT Co-ordinator can provide assistance with:

- identifying suitable POCT equipment for evaluation
- performing an evaluation
- installing POCT equipment
- writing procedures
- training staff
- preparing worksheets, log books etc
- maintenance schedules
- QC programs
- trouble shooting
- monitoring and review of procedures
- competency reviews

The POCT Co-ordinator can be contacted via Canterbury Health Laboratories on extension 81850 or 025 973 645 during normal working hours. Outside normal hours phone extension 80376.

1.13 Responsibilities of the POCT Co-ordinator

- Is responsible for ensuring that all POCT is performed to the same standard as would be expected from regular laboratory testing.
- Identifies the types and locations of all POCT equipment within the CDHB. An electronic record of all equipment is maintained.
- Is responsible for ensuring that all of the CDHB staff performing POCT have current competency training and documentation. Included is an awareness of health and safety issues pertaining to samples and equipment.
- Is responsible for ensuring regular Quality Assurance is maintained and Quality Control (QC) samples are analysed on POCT devices, with up-to-date documentation and history.
- Is responsible for ensuring that adequate supplies of consumables and QC materials are maintained, to ensure continuity of service.
- Is responsible for troubleshooting of POCT devices, with up-to-date documentation and history.

1.14 Responsibilities of the Clinical Staff

- All staff must use the equipment in a safe and responsible manner.

- All staff must have a unique identifier (password) where applicable.
- No password must be shared with another staff member.
- An accurate and up to date maintenance log must be maintained, signed and dated each day.
- All staff members must satisfy the quality control (QC) requirements pertaining to the specific instrument.
- All patient and QC results must be documented. Included with the results should be the operator's initials and the date and time of the test.
- All staff members operating POCT equipment will have up to date competency records.

1.15 References

International Standards Organisation ISO 15189 in association with ISO/WD 22870.

IAMLT policies for near patient testing www.iamlt.org/poct-pp.htm

Joint Working Group on Quality Assurance. Near patient testing or point of care testing guidelines.

Auckland District Health Board. Point of care testing equipment management.

Near Patient Testing Working Party. Guidelines for near patient testing: haematology. Clin Lab Haem 1995; 17: 301-310.

NCCLS, AST2-A. Point of care in vitro testing, approved guideline.