

Policy Applies to:

All clinical staff involved in using Point of Care Testing (POCT) equipment.

Related Standards:

- Health & Disability Standard 4.2.3 – Amenities, fixtures, equipment and furniture are selected located, installed and maintained with consideration of consumer and service provider safety, needs and ability.
- EQuIP NZ Standard 1.3.1 - Health care and services are appropriate and delivered in the most appropriate setting.

Rationale

The use of POCT can result in increased clinical effectiveness and improved outcomes for patients, due to the availability of rapid results to facilitate patient management. However, this is only true if the result is accurate and reliable. POCT should be seen as complementary to, and not as a replacement for conventional laboratory testing.

Definitions

POCT: Point-of-care testing, is the analysis of clinical specimens outside of a traditional laboratory, near to or at the site of patient care. It may be performed by clinical staff whose primary training is not in medical laboratory science. The range of testing performed may be as simple as dipstick urinalysis or pregnancy tests, through to testing using more complex instrumentation such as blood gas analysis. It has the ability to provide a rapid result which is able to be acted upon immediately and which may lead to a possible change in the care of the patient (NZ Point of Care Testing, Advisory Group, 2014).

At Mercy Hospital, Point of Care Testing Equipment includes:

Dipstick Urinalysis	McAuley, DSU,
Glucometer (Blood glucose monitoring)	McAuley, DSU, PACU, ICU & Manaaki
Haemocue (Haemoglobin measurement)	PACU
I-Stat (Arterial blood gas measurement)	ICU
Spirometer (Respiratory Function measurement)	McAuley (cardiac physio)

Quality Control (QC): Procedures designed to monitor test methods and ensure reliability of system performance and results. QC includes: the use of control materials e.g. liquids or test strips to check accuracy; charting the results; analysing them to identify sources of error and evaluating any remedial action taken as a result of the analysis. QC may be *Internal* i.e. performed at specified intervals by clinical staff or *External* performed by a laboratory or other agencies external to the organisation (if required).

Clinical Staff: Nurses, Anaesthetic Technicians, Cardiac Physiotherapist or Hospital Aids employed by Mercy Hospital and Credentialed Specialists.

Calibration: Checking the accuracy of a measuring device against an established standard.

Objectives

- To deliver a safe and efficient POCT service and minimise risk to patients and staff.
- To ensure standardisation of POCT equipment throughout the hospital.
- To ensure equipment is maintained and serviced appropriately.
- To ensure POCT is performed in a way that meets accepted practice standards.

Implementation

- Policy updates notified to staff by Clinical Coordinators.
- All staff undertaking POCT are trained in the use of equipment.
- Maintenance is carried out as required in a timely manner.

Evaluation

- Quality control records, tracking charts and maintenance documentation are available in each area;
- Annual audit;
- Staff competency confirmed;
- Product evaluation meetings minutes;
- Incident forms.

Responsibilities

Service Managers (Theatre & Patient Services): liaise with the Clinical Coordinators and clinical staff to support the use of POCT, oversee audit processes and facilitate the evaluation, selection and purchase of POCT equipment with input from laboratory staff as appropriate.

Clinical Coordinators: have responsibility for overseeing POCT and quality control processes including calibration, documentation of processes, maintenance of equipment and staff training/competency in the use of equipment. Specific responsibilities related to POCT may be delegated to individual staff members in each clinical area.

Clinical Staff: Each staff member performing POCT is responsible for ensuring they are competent in the use of the equipment and in performing the procedure to the accepted standard. Results of POCT shall be documented in the clinical notes/ Electronic Patient Record (EPR); results that are outside a range deemed to be 'normal' must be communicated immediately to the appropriate Credentialed

Specialist. For clinically discrepant results see 'Performing POCT' below. Clinical staff are required to undertake internal quality control on all POCT equipment weekly or as required.

Process

Evaluation, selection and purchase of POCT equipment

- All new POCT equipment will be trialled and evaluated by departmental users and considered by the Product Evaluation Committee.
- Where equipment is required in more than one area it must be standardised across the organisation.
- Once purchased, an electrical safety check (if required) must be conducted by the hospital maintenance department before the equipment is put into circulation.
- New POCT equipment with a purchase value greater than \$500 should be notified to the Facilities Team Leader and recorded on the Asset Register. The Asset form is located on the "F" drive.

Training

- All staff using POCT shall receive training in the correct use of the equipment and in performing the procedure.
- Training shall be provided by the supplier when equipment is purchased; ongoing training may be given by the supplier or by an appropriately trained staff member.
- A user manual must be available (hard copy or on-line) and accessible for each piece of equipment and all staff shall know where this is located.

Performing POCT

- Only staff competent in the use of the equipment may perform POCT.
- Any POCT undertaken shall be clearly documented in the patient's clinical notes / EPR (see 'Documentation & Record Keeping - patient results' below)..
- Unexpected or extreme results shall be rechecked and if appropriate, a sample sent to Southern Community Laboratory (SCL) for testing.

Quality Control:

- Internal QC shall be performed by clinical staff on a weekly basis or in accordance with the manufacturer's instructions. At a minimum this should be performed prior to patient testing:
 - following each new shipment of reagents/cassettes/strips
 - following each new lot number of reagents/cassettes/strips
 - in the event of equipment problems or erroneous results;

- External QC shall if required, be performed in conjunction with the appropriate external agency.

Documentation and Record Keeping

- A documented process should be in place for all testing procedures; this may take the form of a laminated “Quick Guide”

Reagent/Cassette/Test Strip management

- A tracking chart shall be completed for the glucometer, haemocue and I-Stat whenever the control materials are renewed. This must record:
 - the batch number
 - date opened
 - use by date
 - expiry date
- QC results that are outside of acceptable limits must be recorded and reported to the Clinical Coordinator. Equipment that is faulty or likely to give inaccurate results must not be used and must be sent for recalibration or repair.
- A service history for all POCT equipment must be maintained and held on file in the clinical area where the equipment is located.
- QC records shall be retained for 4 years for patient safety and accreditation/certification purposes.
- Audits of POCT quality control will be undertaken annually and a summary of the findings must be forwarded to the Administration Secretary and placed on “F” drive.

Patient Results

These shall be recorded in the patients’ clinical notes/EPR and include:

- date and time of analysis
- device type e.g. haemocue
- test result
- operator identity

Cleaning / Maintenance / Repair.

- A user guide or manual shall be available for each piece of equipment.
- Manufacturer’s guidelines and recommendations from the Infection Prevention & Control Nurse (IPCN), if appropriate, must be followed re: use of cleaning products and frequency of cleaning.
- Where appropriate, preventative maintenance in the form of annual recalibration & servicing shall be carried out on each piece of equipment.

- Equipment for repair or calibration shall be undertaken on site by Dental & Medical Ltd. Equipment should be accompanied by a purchase order outlining the problem and stating the departmental code e.g. 250.

Adverse Event Reporting

- An adverse event may cause, or may potentially cause, an unexpected or unwanted effect. In a POCT environment an adverse event may impact on the health and safety of patients, service providers or other persons. For example, an incorrect result may lead to a delay in treatment, inappropriate treatment, a life-threatening illness or injury, a serious deterioration in the state of health, or even death.
- Any adverse event involving a POCT device must be reported to the supplier of the device.
- There is a documented process for reporting adverse events to Medsafe and information on the process of reporting may be found at the following website:
<http://www.medsafe.govt.nz/regulatory/DevicesNew/9AdverseEvent.asp>
- A Mercy Hospital Incident Form must be completed for any incident involving POCT. The incident form must include the actions taken and the outcome for the patient.

Infection Control

It is important to prevent the spread of possible infection at the POCT location and hand hygiene is one of the most important measures to achieve this. All operators must follow standard infection prevention and control precautions.

Decontamination

- All devices used between individual patients (e.g. glucometers) must be decontaminated following the manufacturer's instructions, to prevent cross contamination and nosocomial infection.
- The POCT work area / equipment tray should be cleaned weekly.
- Any blood and body fluid spills should be cleaned up immediately, following Mercy Hospital policies.

Waste Disposal

All biological waste should be considered hazardous and disposed of appropriately.

Associated Documents:

Internal

- Blood & Body Fluid Exposure and Management Policy
- Consent Policy
- Clinical Records Management Policy
- Electrical Safety Policy
- Hand Hygiene Policy
- Health & Environmental Monitoring Policy
- Patient Assessment Policy
- Product Evaluation Policy
- Risk Management Policy
- Waste Management Policy

References:

New Zealand Point-of-Care Testing Advisory Group (2014), New Zealand Best Practice Guidelines for Point-of-Care Testing, accessed from www.nzimls.org.nz