☐ADMINISTRATE POLICY & PROCEDURE (APP)	☐ INSTITUTIONAL POLICY & PROCEDURE (IPP) ☐ INTERDEPARTMENTAL ☐ INTERNAL

TITLE		POLICY NUMBER/V#
Point of Care Testing (POCT)		MMC – LAB – 10 (01)
INITIATED DATE	**EFFECTIVE DATE**	**REVISED DATE**
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APPLIES TO	RESPONSIBILITY
LAB STAFF , NURSE DEPARTMENT	All lab staff.

1. Policy

1.1. The introduction of new Point of Care Testing technology within the Medical Complex is appropriate and consistent.
1.2. All POCT must comply with the quality system requirements of Department of Laboratory. 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.
1.3. To ensure that all POCT processes used within the Medical Complex are managed and produce good quality, accurate results which are used to aid the patient care.
1.4. To ensure ongoing evaluation by the laboratory director or designee of point of care testing and A point of care testing has a written QC/QM program.
1.5. A list of all point of care testing equipment in the Medical Complex is available in the laboratory.
1.6. A Standard Operating Procedure (SOP) manual for POCT available in the lab and in the areas where POCT is performed
1.7. To ensure that all in operation to detect and correct significant clerical and analytical errors and unusual or unexpected test results:
1.8. The lab has an appropriate person available at morning shift to assist with trouble shooting or other unusual POCT situations
1.9. There is a documented orientation, training, and competency for POCT users.

2. Purpose

2.1 This policy aims to ensure reliable performance and manage the risks associated with testing outside the main laboratory by:

Ensuring consistent procedures are in place throughout the Medical Complex
Ensuring that a high quality and cost effective service is provided;
Defining the organization, management and responsibilities so that the relevant issues are addressed systematically;
Establishing a standardized approach to the introduction and implementation of any POCT device.

2.2 It aims to ensure that the whole process is conducted in accordance with the principles of Clinical Governance and the guidelines issued by the Joint Working Group on Quality Assurance, which forms part of the Department of Laboratory

3. Definition

3.1 **Clinical Unit:** the clinical department or area in which a POCT device is located

3.2 **Link Nurse:** a nurse or other staff member who has particular responsibility for coordinating the use of POCT in their area

3.3 **POCT:** the performance of analytical tests on patient specimens outside the laboratory by non-laboratory staff.

3.4 **POCT device**: any analyzer, dipstick or other instrument used to obtain results on patient specimens outside the laboratory

3.5 **User:** any individual using a POCT device

4. Affected department

4.1 Nursing Department
4.2 LAB STAFF

5. Procedures

5.1 The (POCT) device and location:

POCT device	Location (ward)
Blood glucose meters	**ER, OPD , CLINICS**

5.2 Safety and infection control:

5.2.1 All POCT devices must comply with safety legislation and guidance and with infection control.

5.2.2 All users of POCT equipment must comply with all the Safety Policies.

5.2.3 A Control of Substances Hazard to Health assessment must be carried out, and safety data sheets for all relevant substances kept in the equipment information file.

5.2.4 Samples, spillages and waste from instruments must be treated in accordance with the Infection Control Policies.

5.2.5 Standard universal precautions such as hand decontamination, wearing of appropriate clothing, disposal of sharps and waste should be employed by staff using devices.

5.3 TRAINING and orientation:

5.3.1 Correctness of results is dependent on operator technique, competence and optimum storage conditions for the various reagents and consumables utilised.

5.3.2 Following procurement and installation, staff must be trained in the safe and proper use of the device. The training must be approved by the Department of Laboratory in conjunction with the Clinical Unit and provided by the staff trained to an appropriate level of competency as defined by the Department of Laboratory.

5.3.3 Training should also include issues such as patient preparation, interpretation of results.

5.3.4 For some devices, update training at regular intervals may be necessary to maintain a high standard of performance. This is particularly important for staff that use a device infrequently, or have had a break in service. This should be included in the Standard Operating Procedure.

5.3.5 Head of Clinical Units are responsible for maintaining a full record of training, which must be made available for inspection by the Department of Laboratory upon request. Individuals should also be responsible for maintaining a record of any relevant training that they have completed.

5.3.6 The Clinical Units is responsible for all training arrangements.

5.4 Training Program:

5.4.1 All staff using POCT equipment receive training in the use of the equipment. The POCT Co-coordinator 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:

5.4.2 collection, transportation and disposal of specimens

5.4.3 quality control requirements

5.4.4 step by step procedures

5.4.5 recording results

5.4.6 interpretation of results

5.4.7 troubleshooting

5.4.8 maintenance of equipment

5.4.9 Staff may not train each other unless approved by the POCT Coordinator or designated representative.

5.4.10 Whenever there is a new acquired point of care testing device the staff will undergo training and orientation first before use

5.5 Competency Records:

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

5.5.2 Templates for recording competency review are available from the POCT Coordinator.

5.6 Competency Review:

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

5.6.2 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 competency, this process of random review would be revisited.

5.7 Operation:

5.7.1 Only staff whose training and competence has been established and documented should use any device, including simple dipstick tests.

5.7.2 Where appropriate the daily operation must be coordinated by a responsible local person, e.g. Link nurse, who ensures that training, testing, quality control and recording of results occur according to agreed principles, that devices are in good safe working order and that reagent stocks are maintained.

5.7.3 The responsible local person will liaise closely with the Department of Laboratory and notify laboratory staff immediately if the performance of a meter is suspect or any other issue causes concern.

5.8 STANDARD OPERATING PROCEDURES:

5.8.1 A Standard Operating Procedure (SOP) must be produced prior to the POCT equipment being used.

5.8.2 It must be available to and followed by all users of the device

5.8.3 The document will include: instructions for the use of the device, including simple troubleshooting and safe working practice; the interpretation of error messages;

normal ranges and action to be taken when a result is obtained (normal or abnormal); the recording of data; the relevant quality control procedures IQC; decontamination procedures; who has responsibility and authority to withdraw device from service and action to be taken if the device fails.

5.8.4 To comply with laboratory accreditation standards a copy of the active SOP must be held.

5.8.5 The Clinical Unit using the POCT equipment will be responsible for regular review and update of the SOP, with support from the laboratory if required.

5.9 RECORDING OF RESULTS:

5.9.1 All patient results should be recorded. This record should include unequivocal patient identity, date of the test (and time of test where appropriate), test results and the identity of the operator (e.g. initials of the operator as a minimum).

5.9.2 All QC/QA results should be recorded as described in the SOP for the device (e.g. in the analyzer logbook, QC file or electronically).

5.9.3 The storage of QC and patient results should be in line with the storage maintained by the laboratory.

5.9.4 The Department of Laboratory and other staff responsible for overall quality assurance must have free access to QC/QA results.

5.10 LOG BOOK

5.11 Each analyzer must have a 'log book' in either paper or electronic form in which details are recorded of maintenance, faults, corrective actions and repairs by named individuals, and other problems.

5.12 These records must be kept for the lifetime of the analyzer in line with the guidelines from The Department of Laboratory.

5.13 The Department of Laboratory must have free access to the log books.

5.14 SUPPORT:

5.14.1 Designated nurses on wards must 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.

5.14.2 A device that fails to perform to specification must be withdrawn immediately from service until full remedial action has been completed. It may be necessary for a back-up arrangement to be established with the laboratory.

5.14.3 The Department of Laboratory must be informed immediately of any failure of any device.

5.14.4 In the event of device failure, alternative sites for the analyses should have been agreed, documented, and made known to users.

5.14.5 If devices are not used or cared for appropriately, despite reasonable efforts to improve the situation, The Department of Laboratory with the appropriate nurse will have the responsibility for removing the device from service.

5.15 QUALITY CONTROL & QUALITY ASSESSMENT

5.15.1 The nurse will supervise the Internal Quality Control (IQC) testing by designated ward or departmental staff as specified in the SOP.

5.15.2 IQC frequency must be stated in the SOP, but this will usually be at least once per day and whenever a problem is suspected.

5.15.3 The IQC material will be provided by The Department of Laboratory or the manufacturer, as arranged during the procurement process. These should have established acceptable ranges.

5.15.4 If IQC results fall outside these given limits, remedial action should be taken (as defined in the SOP). Patient samples must not be tested using the device until full remedial action has been completed.

5.15.5 Unexpected patient results should be checked by sending a sample to Department of Laboratory and Blood Bank, even if IQC gives acceptable results.

5.15.6 The Department of Laboratory must be responsible for ensuring that the performance of the device is checked by appropriate internal quality control.

5.16 ROLES AND RESPONSIBILITIES:

5.16.1 ROLE OF USERS

5.16.1.1 The Health and Safety at Work Act legislates that all staff are responsible for ensuring that their acts and omissions do not put themselves or others at risk. Healthcare Professionals are also bound by their Ethics and Scope of Professional

Practice which emphasis the individual's responsibility when using equipment or undertaking actions that they are not trained or competent to perform.

5.16.1.2 To use Point of Care Testing equipment only after adequate training and documentation as a legitimate user and if personally confident in their competence to do so.

5.16.1.3 To follow the procedures as set out in the documented Standard Operating Procedure, including sample taking and handling, instrument checks and/or Quality Control, recording of results and disposal of consumables.

5.16.1.4 To report suspect Quality Control results or possible instrument malfunction immediately to the Link nurse or person in charge at the time and to stop using the equipment until the matter has been resolved.

5.16.1.5 To report abnormal or suspect patient results to the responsible person without delay.

5.16.1.6 To report adverse incidents related to POCT devices to the Link nurse.

5.16.2 ROLES OF POINT OF CARE TESTING LINK NURSE

5.16.2.1 The responsible local person, e.g. Link nurse acts in his/her area as an overseer of the daily operation of POCT, to ensure that functioning equipment and reagents are available and that trained staff perform patient tests and quality control procedures as stipulated. If there is more than one POCT system in one location a local decision may be made to appoint a local person or link nurse for each.

5.16.2.2 Link nurses will be drawn from ward and departmental staff and will have sufficient clinical experience and standing to have authority with colleagues and heads. Liaison with the Department of Laboratory will be a pivotal aspect of this role.

5.16.3 Responsibilities:

5.16.3.1 To liaise between their clinical area and the Department of Laboratory

5.16.3.2 To be directly accountable to the head nurse for the performance of Point of Care testing in their area.

5.16.3.3 To participate in the writing, reviewing and updating of POCT Standard Operating Procedures that cover all aspects of the testing process.

5.16.3.4 To ensure that Standard Operating Procedures are available at the point of testing and that all staff in their area are aware of the POCT policies and work accordingly.

5.16.3.5 To ensure that relevant documentation is kept such as equipment log books, quality control results and the recording of patient results in the patient record

5.16.3.6 To ensure that the correct action is taken when abnormal patient results are obtained.
5.16.3.7 To identify members of staff who will undertake POCT.
5.16.3.8 To ensure that all staff undertaking POCT are adequately trained and to keep a record of such training.
5.16.3.9 To be trained to a high level of competence and be able to participate in training programs and/or provide cascade training if that is deemed appropriate.
5.16.3.10 To ensure that POCT equipment is stored and maintained as appropriate and is in working order and that adequate reagent stocks are kept.
5.16.3.11 To report suspected instrument malfunction without delay and take measures to prevent further testing until the instrument has been replaced or declared fit for use by a competent person (laboratory or manufacturer).
5.16.3.12 To report adverse incidents related to the POCT device to the Laboratory Director

5.16.3.13 To be knowledgeable regarding the infection control hazards associated with the POCT performed in their area.
5.16.3.14 To work with the Pathology department to set up and maintain a system of regular internal quality control checks (including accurate documentation) and the return of external quality control test results, as well as cooperating with troubleshooting and corrective measures if performance seems unsatisfactory.
5.16.3.15 POCT is under responsibility of laboratory staff

5.17 ROLES OF THE DEPARTMENT OF LABORATORY

5.17.1.1 To contribute to and advise during the cost/benefit analysis of a potential new POCT service and the procurement of equipment, including an assessment of the clinical need, available options, suitability of equipment, required accuracy and precision, correlation with laboratory results, interpretation of results, maintenance requirements and backup service
5.17.1.2 To advise on the Health and Safety aspects of POCT.
5.17.1.3 To advise that Standard Operating Procedures for all aspects of the testing process are documented in accordance with the requirements of the Clinical Pathology Accreditation body.
5.17.1.4 To advise on the internal quality control regimen and provide the materials unless otherwise specified.
5.17.1.5 To audit the routine operation, record-keeping and training requirements.
5.17.1.6 To liaise closely with Link nurses regarding the operation of the scheme and to detect problems early.
5.17.1.7 To check unexpected patient results.
5.17.1.8 To lend support as far as laboratory responsibilities will allow when instrument malfunction is suspected.

5.17.1.9 To provide a backup analytical service in case of failure of POCT equipment when a problem cannot be resolved immediately.

5.18 ROLE OF CLINICAL UNITS

5.18.1.1 To identify areas of clinical need where the introduction of POCT could be appropriate and provide the information necessary for the cost-benefit analysis.

5.18.1.2 To approach POCT in the spirit of the policy and not to attempt to introduce new testing without referring to the POCT policy.

5.18.1.3 To undertake POCT themselves only after adequate training and certification.

5.18.1.4 To be familiar with the information provided by and shortcomings of the POCT results that they use for their patient management.

5.18.1.5 To ensure that results of POCT are recorded accurately, unequivocally and safely and that information about tests upon

5.19 Guidelines for Point of Care Testing:

5.19.1 Governance Organisations:

Providing POCT are accountable for the quality of their service and maintaining a high standard of care.

Organisations performing POCT must have in place a governance framework that actively manages safety and quality risks in the delivery of POCT.

The wellbeing of individuals and their rights must be the primary consideration.

The purpose of POCT is to provide accurate and timely test results that effectively contribute to immediate management decisions.

There must be a designated and Competent POCT Supervisor, who is accountable for the conduct, quality and implementation of the POCT being performed.

There must be a documented policy/protocol for the selection, use and application of POCT tests and for the interpretation of the test results. This must include reference intervals and Decision limits.

The POCT Supervisor must ensure that staff using POCT are trained and Competent. -The analytical and non-analytical characteristics of POCT and the responsibilities for the delivery of POCT must be defined in the Quality system.

The designated POCT Supervisor under whose direction and control the POCT operates must be clearly identifiable and accessible, show leadership to promote safe and ethical practice and must have the authority and competence to ensure and take responsibility for:

5.19.1.1 Policy setting and implementation

5.19.1.2 Operational practices and staffing (including training)

5.19.1.3 Determining the range of tests provided, their methods and procedures

5.19.1.4 Regular review of the Quality system and all aspects of performance

5.19.1.5 Provision of medical or scientific consultation

5.19.1.6 procedures used and the tests performed being within the scope of the education, training, continuing professional development and experience of individual staff members (g) provision of a clearly defined process for contacting a POCT Supervisor (h) Verification of POCT procedures.

Selected tasks may be delegated but must comply with the governance system

The specific requirements for governance and supervision will differ according to the complexity of testing.

The privacy and confidentiality of individuals must be maintained at all times

Consent should be obtained, where possible, from the individual to allow the collection or procedure to be carried out.

Consent should also include informed financial consent, where relevant.

Preparation, Specimen Integrity and Individual Test Records The quality of results generated through POCT relies on the performance of a number of operations; patient or client preparation, testing and record management (also called the pre-analytical, analytical and post-analytical phases of testing)

Test results may be compromised if any of these operations are not considered when implementing POCT.

Failure to recognise and eliminate errors through the entire testing process can jeopardise test results and patient and client safety.

Risk management of these operations is essential. Factors such as patient and client preparation (e.g. fasting), specimen collection, specimen preservative used (if appropriate) and sample application can all affect the quality of the results obtained.

5.19.2 Criteria for patient and client safety and quality testing include:

- 5.19.2.1 Correct test ordered
- 5.19.2.2 Correct patient or client
- 5.19.2.3 Correct patient and client preparation
- 5.19.2.4 Correct collection technique
- 5.19.2.5 Correct specimen and processing
- 5.19.2.6 Accurate test result
- 5.19.2.7 Correct recording in the patient or client record
- 5.19.2.8 Correct clinical interpretation
- 5.19.2.9 Correct and timely clinician response.

5.19.3 Collection of specimens must be performed in accordance with the manufacturer's instructions.

Collection of specimens must be performed with accurate identification of the patient or client and ensuring traceability of the specimen to the report.

The following are examples of records that should be retained to allow traceability:

5.19.3.1 Patient or client demographic data (such as surname, sex, date of birth, unique medical record number), unless de-identification or anonymity is prescribed

5.19.3.2 Date and time of collection

5.19.3.3 The date and time of performance of the test (d) validated result data, including the result or printout from the POCT instrument and any quality control results associated with testing

5.19.3.4 Identity of the location and person issuing the report

5.19.3.5 The identification of the analyser or device.

5.20 Guidelines for Point of Care Testing

Testing Considerations

In some settings, POCT may be able to provide a more convenient and accessible service for patients and clients as well as more rapid and accessible test results than can be achieved from Laboratory settings. Before POCT is implemented, the analytical performance requirements for the intended purpose must be defined. Participation in Quality Control and External Quality Assurance programs (where available) will ensure appropriate performance. As both Laboratory and POCT results may be used for patient and client care, it is highly desirable to know how the two
methods compare.

Reference intervals and clinical Decision limits also need to be clearly defined based on current best practice and the particular characteristics of the POCT device.

To ensure that the results of testing are correct and that they continue to meet required quality performance criteria, analytical equipment must be checked and verified before use to ensure that its ongoing operation remains within required performance parameters.

Records of all quality performance checks must be retained to provide assurance that correct procedures are being maintained.

The RCPA Quality Assurance Programs Pty Ltd has developed a list of allowable limits of performance for a range of therapeutic pathology tests which can be used to guide the process of determining whether a POCT device is able to meet analytical requirements1 to

Prior to implementing POCT, the analytical performance requirements of the test must be defined.

The following must be considered when defining analytical performance requirements:

5.20.1 Quantitative analysis such as selectivity, sensitivity, accuracy, precision, trueness, limit of detection and limit of reporting

5.20.2 Qualitative analysis such as sensitivity and specificity.

Testing must be verified by the use of internal quality control material.

Quality control procedures must be utilised to ensure that all testing is performed using instruments, Reagents and consumables which are working correctly and according to specifications.

There must be documented criteria for the acceptance of quality control results. Any results and any action to be taken when these are unacceptable must be documented.

An acceptable standard of performance in external proficiency testing programs, where such programs are available, must be achieved.

Where External Quality Assessment programs do not exist for a test method, the validity of the test results must be demonstrated by methods such as inter-Laboratory patient or client sample comparisons

TABLE 1:

Quality Requirements of Point of Care Analyzers
1. Speed (test/s) should be completed within minutes of sample introduction.
2. Accuracy and precision approaching that of the central laboratory analyzer.
3. Ability to analyze an “unprepared specimen" (e.g. whole blood).
4. Low sample size.
5. Flexible test menu.
6. Broad dynamic range to minimize repeats, dilution, and confirmatory tests.
7. Ease of use by non-laboratory personnel.
8. Lock-out ability.
9. To prevent testing by unauthorized users.
10. When patient identification is not entered.
11. Cost per test approaching that provided by the main laboratory.
12. Low capital equipment outlay.
13. Quantities readout (no subjectivity on the part of the observer).
14. Automatic calibration.
15. Automated quality control interpretation.
16. Seamless interfaces with laboratory or Medical Complex information system (communication by wireless system: infrared or radio frequency).
17. Low maintenance.
18. Minimal troubleshooting requirements.
19. High reliability with minimum downtime.
20. Back up capability.
21. Bar code reading capabilities.
22. Use of either no reagent or ready-for use reagents.
23. Minimal waste production.
24. Minimal and recyclable disposables.

5.21 Preventive Maintenance

5.21.1 Glucometers: Daily check has to be done by the Lab Med Technologist on charge of the POCT on regular base

5.22 Troubleshooting Maintenance

5.22.1 Glucometers: If any of the glucometers is out of control, the glucometer has to be collected & sent immediately to the biomed maintenance department for the proper repair

5.23 Quality Control:

5.23.1 Glucometers

5.23.1.1 Internal QC usually processed on weekly base by the MT on charge of POCT & recorded in the file of the glucometer in each department

5.23.1.2 If any of the glucometers is out of control, the glucometer has to be collected & sent immediately to the biomed maintenance department for the proper repair

6. Responsibilities

6.1 All lab staff.

7. Reference

7.1 Freedman DB. Clinical governance – the implications for point of care testing in Medical Complex's: a UK perspective. In: Price CP, St John A, Hicks JM (editors). Point of care testing (second edition). American Association of Clinical Chemistry Press, 2004; pp. 171 – 177.

7.2 Pathology Modernizing Pathology services. Department if Health, 2004. www.dh.gov.UK

7.3 CBAHI Standard Number: LB.28

8. Attachments

8.1 None

APROVALS :			
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