

MOH/P/PAK/238.12 (BP)



NATIONAL POINT OF CARE TESTING **Policy and Guidelines**



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Policy and Guidelines

Publishing Information:
Departmental Policy of Pathology Services
in Ministry of Health,
July 2012

MOH/P/PAK/238.12 (BP)

Publisher Identity:

Medical Development Division
Ministry of Health Malaysia
Level 5, Block E 1, Parcel E
62590 PUTRAJAYA
MALAYSIA

ISBN 978-967-0399-16-4

ISBN 978-967-0399-16-4



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The document outlines optimal achievable standards in accordance
with best practices and guidelines



Foreword By The Director General of Health Malaysia

International trends see the rise in development and the use of Point of Care devices for bedside or near patient testing. Medical practitioners and healthcare workers in Malaysia are also among those who frequently utilize this technology for rapid and reliable diagnostic testing for on-the-spot decisions in therapy and patient management. Where the main laboratory is not easily accessible, especially in remote areas, or test results are needed almost immediately, Point of Care testing is an affordable, convenient and indispensable diagnostic tool for clinicians and medical practitioners.

However, there is a necessity for a well-structured national policy and guidelines for the use of this technology due to the high variability in equipment performance, vastly different methods employed for a single test, and doubts that rise in the reliability of the results obtained by non-laboratory staff. This is to ensure that patient therapy and management is not compromised in the pursuit of fast and convenient testing. If results are unreliable and inaccurate, the consequence could be devastating to the patient involved and the clinician or healthcare worker who utilized the Point of Care testing device.

Therefore, this National Point of Care Testing Policy and Guidelines aim to achieve a high standard of practice in the use of Point of Care testing devices and comprehensive governance in all aspects surrounding Point of Care testing throughout the Ministry of Health Malaysia. The intention will ultimately serve the purpose of every client charter in the Ministry of Health which underlines the need for better, efficient and reliable patient care.

I hereby extend my congratulations and thanks to the Point of Care Steering Committee and the Point of Care Advisory Council in the development and publication of this policy and guidelines with tireless and determined dedication to the standardize the quality in Point of Care services in Ministry of Health.

Dato' Sri Dr Hasan Bin Abdul Rahman
Director General of Health Malaysia



Foreword by the Head of National Pathology Services

I would like to congratulate the committee that had produced this National Point of Care Testing (POCT) Policy and Guidelines after several thorough discussions. This POCT Policy and Guidelines is produced to guide towards the implementation of national standardization, harmonization and consistency in POCT applicable to all Pathology Services, Primary Health Care Facilities and POCT sites in Ministry of Health (MOH).

POCT had gone through evolution from test done by non-laboratory staff outside the diagnostic laboratory to bedside testing. POCT is actually a branch activity of Chemical Pathology and we are driven to produce the policy and guidelines to outline all the required steps in setting up a well-managed POCT site which may benefit the patients as well as healthcare facilities in MOH. It also provides guidance to all POCT users and there is a need for laboratory-based professionals to be involved in all aspects of POCT provision.

I believe that POCT is moving rapidly ahead and will be a major challenge in clinical settings. I strongly agree that the clinicians and the laboratorians are responsible in delivering effective management in POCT services in MOH, Malaysia and areas of concern are: cost effective patient care, competency, quality assurance, POCT equipment standardization, procurement and IT connectivity.

With the launching of National POCT Policy and Guidelines, I hope the implementation and management of POCT can be carried out in accordance to the regulatory and national accreditation standards like MS ISO 22870:2008 and MSQH.

Finally, I would like to thank all the POCT National Steering Committee Members for their commitment and hard work in coming up with this National POCT Policy and Guidelines.

Dr Shahnaz bt Murad

Acknowledgement

The Point of Care Testing Steering Committee (PSC) wishes to acknowledge individuals from the Ministry of Health Malaysia, various departments, institutes and representatives from related professional bodies their invaluable contributions and commitment towards the successful completion of this book.

A word of thanks is also extended to the Medical Development Division, Medical Practice Division, Family Health Development Division, Head of Specialized Diagnostic Centre IMR and Head of Activity for their kind support and co-operation.

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POINT OF CARE TESTING (POCT) POLICY



POINT OF CARE TESTING (POCT) POLICY

1.0 OBJECTIVES OF THE POLICY:

This policy is provided for the guidance of procurement, use and support for all Point of Care Testing equipment used throughout the MOH. The objectives of this policy are to:

- Outline the management and governance of POCT.
- Ensure a standardized POCT practice is maintained throughout the MOH.
- Outline the various roles of clinicians, pathologists and support staff.
- Ensure POCT users take responsibility for the quality of patient results.
- Ensure the highest quality of correct test results are produced for correct action.

1.1 INTRODUCTION

Point of Care Testing (POCT), or near patient testing (NPT), is a term used to describe laboratory testing performed usually by non laboratory staff - mainly medical and nursing staff - outside the main laboratory. POCT is widely used in the Ministry of Health (MOH) and is likely to increase because of advancing technology and changing clinical practices.

A formal policy specifying the leading role of Pathology, and where appropriate, representation from clinical services (eg. Emergency & Trauma, Anaesthetics, Critical Care, Medical, Obstetrics & Gynecology, Paediatrics, Surgery, Outpatient, Public Health Facilities), is essential. This will ensure that the whole process is conducted in accordance with the principles of clinical governance and national accreditation standards.

Professional partnership between Pathology and clinicians ensures that POCT equipment is suitable for its intended use, is adequately supported, safety and quality standards are met, results of investigations performed are recorded and that it is operated only by staff trained in its use. The established POCT committee, with overlapping responsibilities for all these areas, will achieve this for the MOH. Joint planning through the POCT committee will incorporate advice about equipment purchase, agreement on support, consumable costs, user training and accreditation.

This will enable the MOH to provide:

- High quality and cost-effective patient care.
- Effective risk management, including control of infection.
- Coherent and informed service planning and equipment standardization.
- Optimum financial arrangements, including discount agreements with suppliers for equipment and consumables.
- Fully trained users of POCT, resulting in efficient use of ward, clinic and laboratory staff time.

- Networked IT support of POCT, for activity monitoring, faster trouble-shooting and patient data capture.
- Record-keeping and audit
- Ability to continue and extend, as necessary, high quality support of expanding service needs.

1.2 BACKGROUND

In line with the current trend world practices to have Pathology monitor the quality in POCT, it is recommended that Pathology plays a lead role in managing POCT. The Pathology POCT Steering Committee on POCT, quality assurance published guidelines, on which Pathology professional organizations are represented, for the implementation of POCT, covering procurement, quality control and assessment (QC or QA), health & safety, risk management, user training, equipment maintenance and clinical liaison. These were written in 2011.

Standards Malaysia, the national quality standards body for Medical Laboratory requirements, requires that POCT support is managed by Pathology as an accredited service and recommends a nationwide committee to manage this service.

The Pathology POCT Steering Committee on POCT has specified the essential elements of:

- Clinical governance, risk management and quality, audit, staff management and training, clinical effectiveness and outcomes.
- The Standards Malaysia has issued MS ISO 22870:2008 & MS ISO 15189:2007 for consultation.
- Fulfillment of MSQH requirements.
- POCT equipment.
- This Policy is designed to ensure that POCT at the MOH complies with all such advice and guidance. It applies to all Pathology Services, Public Health Facilities and POCT sites. Equipment actively supported in the MOH currently includes glucose meters, cardiac monitoring analysers, haemoglobin A1c analysers, blood gas analysers (which may measure electrolytes and metabolites in addition to pH and gases), coagulometers, bilirubinometer, haemoglobinometers, FBC, CRP, blood grouping, microbiology (e.g. malaria, tuberculosis) rapid test kits and urine testing equipment.

2.0 POCT COMMITTEES AND THEIR ROLES

2.1 National Committee of Pathology Services

Comprises of:

- Pathologist – Head of Services
- Head of Activity - National Sub-committee of Haematology
- Head of Activity - National Sub-committee of Chemical Pathology
- Head of Activity – National Sub-committee of Medical Microbiology
- Head of Activity - National Sub-committee of Anatomical Pathology
- Head of Activity National Sub-committee of QAP, Accreditation, Human Resource, Budget, Environment & Facilities, IT, Training, Transport

2.2 National Committee of Chemical Pathology

Comprises of:

- Head of Chemical Pathology Activity
- Chemical Pathologists
- Senior Scientific Officers (Biochemistry)

2.3 POCT Steering Committee (PSC).

The PSC is set up by the POCT Sub-committee of the National Committee of Chemical Pathology and shall meet at least once a year except when there are urgent matters, an extraordinary meeting may be called.

The PSC comprises of:

- Head of Chemical Pathology Services – as an advisor
- PSC Supervisor (Chemical Pathologist)
- Individuals consisting of Pathologists (Chemical Pathologist & Medical Microbiology), Medical Officers from Pathology Department, Scientific Officers (Biochemistry & Microbiology) and Medical Laboratory Technologists.
- Representatives of the Public Health are from MKA/K, Family Health Development Division (FHDD); consisting of Public Health physician/s, scientific officer/s and MLT/s, and Disease Control Division (DCD).

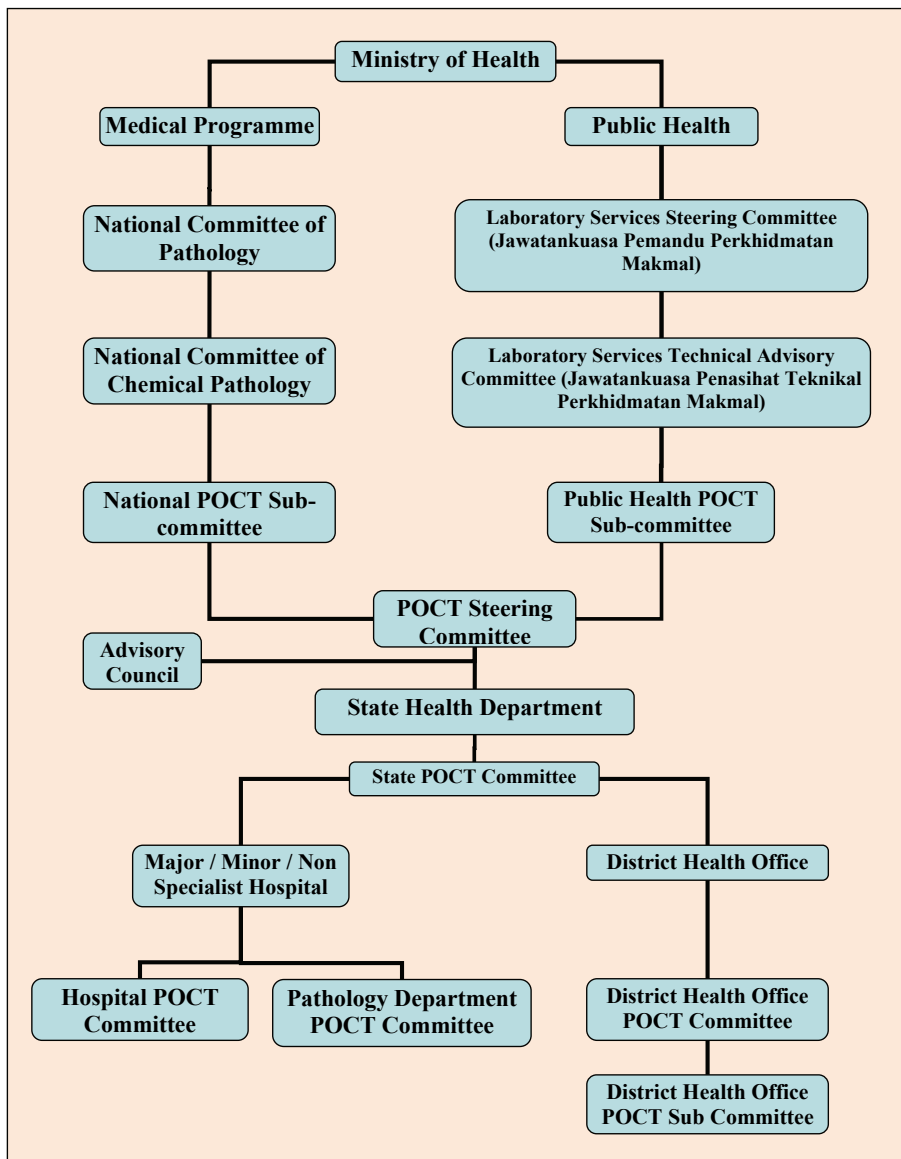


Figure 1: National Level POCT Committee Organization Chart

2.3.1 Roles of the POCT Steering Committee:

- a) To establish national POCT policy and guidelines.
- b) To ensure the policy is fully implemented at all government health facilities.
- c) To improve the quality of patients' results obtained from POCT devices.
- d) To approve use of POCT equipment regardless of whether it is purchased, reagent rental, placement or leased to the site for MOH.
- e) To improve management of equipment in terms of proper procurement and commissioning done in appropriate manner and accordingly to policy guidelines.
- f) To standardize practices e.g. specification, evaluation, IQC used.
- g) To ensure POCT equipment is only handled by competent and trained users. A list of competent users shall be maintained by POCT Committee.
- h) To define criteria for taking action against unsatisfactory performance, inappropriate use, poor quality practices including withdrawal of POCT equipment when appropriate, elimination of POCT tests that do not meet quality standards and removal of incompetent users from the list of competent users.
- i) To introduce new technologies and consolidation of technologies at all POCT sites.
- j) To work towards MS ISO 22870:2008 accreditation.
- k) To establish common quality control and quality assurance programme to ensure regulatory compliance and to maintain quality testing.
- l) To standardize all reporting and to collect and compile all reports periodically from all the states and evaluate the reports. The analyzed reports are to be sent to the National Committee of Chemical Pathology.
- m) To review overall POCT performance through audit reports and customized or adapted quality assurance.
- n) To provide advice to, and assist in the achievement of accreditation for POCT.
- o) The PSC shall assist and provide consultation for training for POCT sites.
- p) To review trends identified through the analysis of audit data, and provide advice and direction. Where appropriate to do so, recommend the appropriate credentialing qualifications and requirements.

2.4 Advisory Council

The Advisory Council is chaired by the Head of Chemical Pathology Activity and the Advisory Council shall be the advisor for the PSC. It is composed of chemical pathologist, scientific officers (Biochemistry and Microbiology), PSC members, Medical Development Division and Family Health Development Division of MOH and a group of clinicians who are directly involved with and/or have a keen interest in the utilization of POCT as a means to improve patient care.

The clinicians are from:

- Emergency & Trauma
- Surgery
- Obstetrics & Gynecology
- Anaesthesia
- Pediatrics
- Medical
- Family Medicine

2.4.1 Roles of the Advisory Council:

- a) Responsible for reviewing and monitoring the National POCT Policy.
- b) To act as a resource to the PSC on particular issues brought forward to the Advisory Council as a whole, or to individual members of the committee.
- c) To offer advice on proposed policy and guidelines.
- d) To review policy and guidelines every 3 years.
- e) To ensure the effectiveness of implementation of the POCT policy in their respective areas.
- f) To ensure the implementation is seamless.

2.5 State POCT Committee

Comprises of representatives from both the hospital and public health:

- State Health Director (Advisor) – 1
- State Pathologist (Chairperson) – 1
- Clinical and *Public Health Specialists – 6 from Medical programme, 1 from FHDD and 1 from MKA/K
- Pathologists – 3
- Scientific Officers - 3 from hospital and 1 from MKA/K
- State Assistant Medical Officers - 1
- State Medical Laboratory Technologists – 1 from Public Health
- Matron – 1 from Medical programme and 1 from Public Health

*Consisting of Family Medicine Specialist (FHDD) and Public Health Specialist (Quality Unit).

In total, 21 individuals from diverse positions shall be appointed in the State POCT Committee.

2.5.1 Roles of State POCT Committee:

- a) To report to the PSC in matters relating to national level POCT services.
- b) To review proposals to introduce new POCT devices (in selective cases) and to provide consultation on POCT devices e.g. specifications and evaluations for all hospitals, clinics and POCT sites (outside medical facilities).
- c) To provide consultation on EQA services for users of the POCT devices.
- d) To monitor, collect and analyse POCT reports from all hospitals, clinics and POCT sites (outside medical facilities) in order to monitor compliance in line with set QA standards.
- e) To review audit on POCT users from the hospitals, clinics and POCT sites (outside medical facilities) in order to detect possible non-compliance with POCT SOPs, policies or guidelines with regards to technical competency of POCT users, data collection, IQC errors and EQA non-conformity.
- f) To suggest steps in corrective measures for the non-compliant hospitals, clinics and POCT sites (outside medical facilities) in line with QA standards.
- g) To ensure that the appropriate training is provided.
- h) To ensure POCT devices comply with MS ISO 22870:2008.
- i) All analyzed reports collected shall be forwarded to National POCT Sub-committee yearly.
- j) To ensure all new point-of-care procedures and POCT devices are appropriate and clinically justified. The POCT Coordinator of hospitals and public health facilities (MKA/K) shall ensure that an appropriate device for the task is chosen, satisfactorily commissioned and that all training, record keeping etc are properly documented and kept.

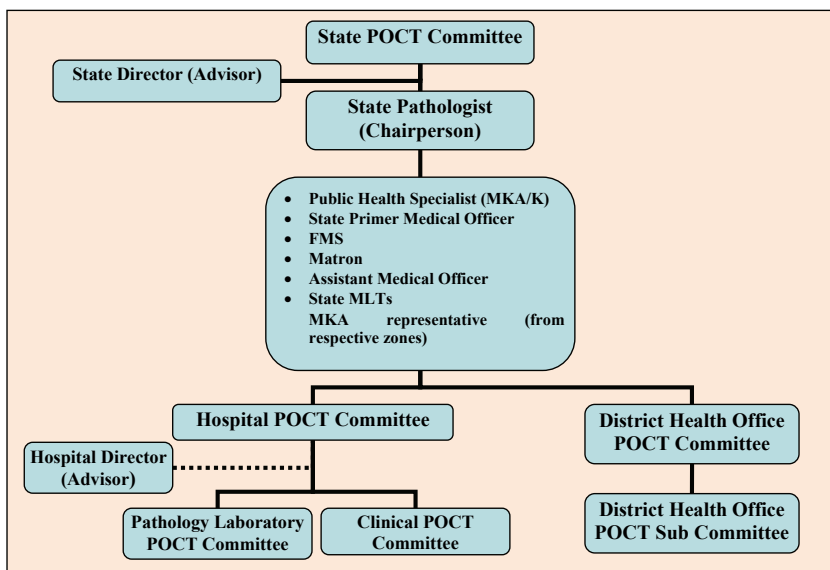


Figure 2: State POCT Committee Organization Chart

2.6 District Health Office POCT Committee

Comprises of:

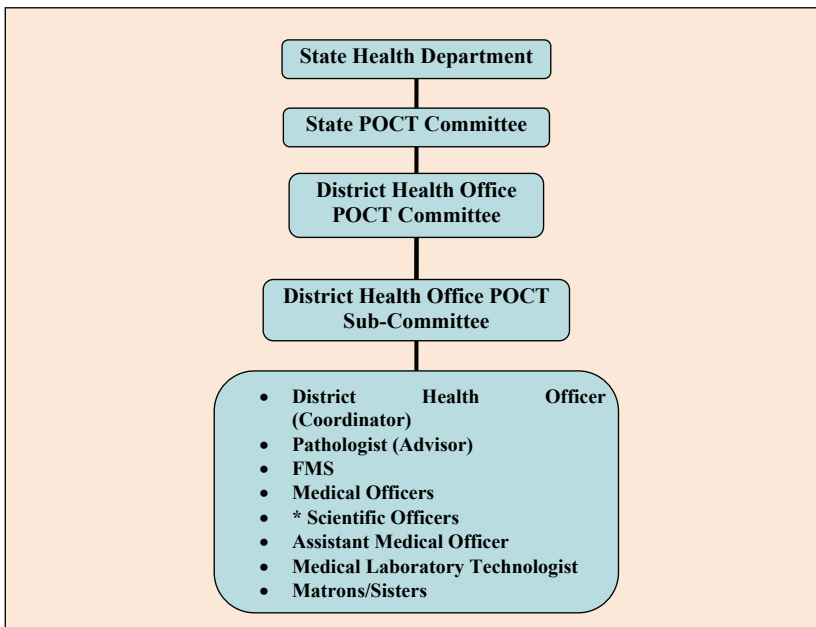
- District Health Officer (Coordinator)
- Pathologist (Advisor)
- FMS
- Medical Officers
- * Scientific Officers
- Assistant Medical Officer
- Medical Laboratory Technologist
- Matrons/Sisters

*If available

2.6.1 Roles of District Health Office POCT Committee:

- a) To report to the PSC in matters relating to national level POCT services.
- b) To review proposals to introduce new POCT devices and to provide consultation on POCT devices e.g. specifications and evaluations for public health facilities.

- c) To review SOPs and practices for maintenance and safe use of POCT devices. To ensure adherence and implementation of those practices.
- d) To monitor IQC for POCT devices that is used in the clinics or departments.
- e) To provide consultation on EQA services for users of the POCT devices.
- f) To monitor, collect and analyze POCT reports from public health facilities in order to monitor compliance in line with set QA standards.
- g) To review audit on POCT users from public health facilities in order to detect possible non-compliance with POCT SOPs, policies or guidelines with regards to technical competency of POCT users, data collection, IQC errors and EQA non-conformity.
- h) To suggest steps in corrective measures for the non-compliant clinics in line with QA standards.
- i) To provide training whenever requested.
- j) To ensure that the budget meets the requirement for quality and services.
- k) To forward reports to State POCT Committee quarterly.



***if available**

Figure 3: District Health Office POCT Committee Organization Chart

2.7 Hospital POCT Committee

2.7.1 Major and Minor Specialist Hospital POCT Committee:

Hospitals with specialists in all the major disciplines including Medical, Paediatric, Surgical, Obstetrics and Gynecology, Anesthesiology, Emergency and Trauma and Orthopedic disciplines.

Major Specialist Hospital POCT Committee consists of:

- Hospital Director (Advisor)
- Head of Department of Pathology (POCT Coordinator)
- Clinical Specialists from major disciplines
- Pathologist
- Medical Officers from Pathology Department
- Scientific Officers
- Medical Laboratory Technologists
- Matrons or Sisters
- Assistant Medical Officer
- *Visiting Pathologist (POCT Committee Coordinator)

*where applicable

2.7.2 Non Specialist Hospital POCT Committee:

Hospitals without specialists.

Non Specialist Hospital POCT Committee consists of (where available):

- Hospital Director
- Visiting Pathologist of Pathology Department (POCT Committee Coordinator)
- Medical Officers
- Scientific Officer
- Senior MLTs
- Matron / Sisters / Nurses
- Assistant Medical Officer

2.7.3 Roles of Hospital POCT Committee:

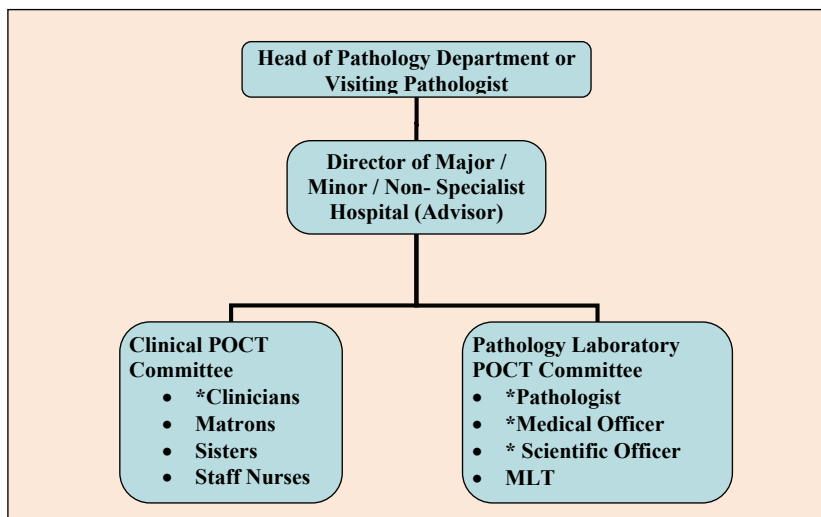
- a) To keep data base of testing personnel, coordinate training on new personnel, evaluate testing method, and monitor quality control and proficiency testing programme.

- b) The Matron / Sister / Nurses / AMO / MLT in Hospital POCT Committee are to enforce policies, schedule new employee training, take corrective actions, schedule annual point of care competency evaluation of staff, audit, and provide annual reports on all POCT activities.
- c) To organize and delegate duties to the POCT Committee members at hospital and department level.
- d) To organize new staff training, aid in privileging of testing personnel, download (where LIS is available) or review quality control data, verify equipment function and maintenance.
- e) To provide training for all staff and POCT users so that they are competent in the use of POCT devices and to ensure that proficiency or competency testing is carried out periodically.
- f) To analyze and send reports to the State POCT Committee.
- g) To provide consultation on POCT devices e.g. specifications and evaluations when required.
- h) To monitor QA (e.g. IQC, EQA, customized or adapted QA, acceptance sampling on arrival, QC results, evolving QAP and analyzers) and troubleshooting.
- i) Focus on errors involving clinical impact which includes specimen collection, sample preparation, results or readouts or raw results, preliminary review, and equipments or reagents, which are integrated into patient records.
- j) To carry-out regular audit on the reliability and effectiveness of the test being carry out by checking of record or maintenance logs, SOP, and QAP performance.
- k) In institutions where there are no pathologists available, a visiting pathologist will take the responsibility of the Hospital POCT coordinator.
- l) To conduct a periodical audit on POCT users in hospitals, in order to detect possible non-compliance with POCT SOPs, policies or guidelines with regards to technical competency of POCT users, data collection, IQC errors and EQA non-conformity.
- m) To determine if POCT should be implemented or if there are other potential alternatives sites that may be introduced which includes analysing pre-analytical, analytical and post analytical phase (TAT) data collected by respective requesting site before establishing POCT for a particular patient care area.

2.7.4 Roles of Pathology Laboratory POCT Committee in Hospitals:

- a) To develop point-of-care-programme at hospital level.
- b) Referral for the POCT users.
- c) To audit periodically in order corrective actions are taken and comply with MS ISO 22870:2008.
- d) To ensure traceability of patient results obtained at POCT site.
- e) To evaluate proposal for POCT device system during the cost or benefit analysis of a potential new POCT service and the procurement of equipment, assessment of the clinical need, available options, suitability and specification of equipment, required accuracy and precision, evaluation of equipment, correlation with laboratory results, interpretation of results and maintenance requirement.

- f) To advise that Standard Operating Procedures for all aspects of the testing process are documented in accordance with the requirements of accreditation body.
- g) To ensure scheduled review of SOP is carried out.
- h) To ensure a quality assurance programme, both internal and external are implemented and monitored.
- i) To distribute material for external quality assurance testing and provide feedback reports to link personnel in circumstances where the laboratory acts as an external QA body.
- j) To assist and resolve poor performance with the appropriate corrective action and implementation, where necessary.
- k) To audit the routine operation, records and training requirements.
- l) To advise on regular competency training.
- m) To call for quarterly meeting or when necessary.
- n) To validate and compare the POCT method with the current laboratory method and provide comparative data for review.



***if available**

Figure 4: Major / Minor / Non Specialist Hospital POCT Committee Organization Chart.

3.0 POCT Implementation at POCT sites

This chapter covers the key issues to be considered in ensuring the accomplishment and standardization of POCT.

3.1 Cost Benefit

- 3.1.1 There shall be a clear statement of needs and formalized request to undertake POCT as a service requirement by the facility or individual departments or units.
- 3.1.2 The POCT user shall be involved in the production and evaluation of the cost benefit based on whole life cost of the device.
- 3.1.3 The department concerned shall produce detailing all the financial consequences of the purchase. These will include the direct costs of running, maintenance, consumables quality control and service contract. The cost benefit shall include the full indirect costs for the POCT Committee's involvement, including support, training and IQC / EQA monitoring, as well as the inevitable cost of back-up.
- 3.1.4 The cost benefit shall recognize the need for any device to be compatible with existing equipment, both in the laboratory and in other areas of the hospital. The POCT Committee shall be consulted about the compatibility of all devices.
- 3.1.5 Any POCT device being considered shall be compliant with the POCT Committee's laboratory requirements.
- 3.1.6 Any POCT device being considered shall be evaluated by the POCT Committee.
- 3.1.7 Any device being considered in public health facilities shall be evaluated by any hospital appointed by State POCT Committee or other facilities appointed by MOH.

3.2 Risk management

- 3.2.1 Any POCT device carries will have its merit and/or limitations. The POCT user shall recognize this, and maintain accountability for any undesirable consequences or outcomes of its use.
- 3.2.2 It is essential that the risks associated with the use and interpretations of results obtained are properly managed by training and support from the respective POCT Committee appointed by the State Pathologist or District Health Office concerned.

3.3 Health and Safety

- 3.3.1 In hospitals and clinics, managers of the Clinical service involved together with the Pathology service shall jointly develop and enforce policies consistent with current legislation and Guidance. For example: the Health and Safety at Work Act 1974, Consumer Protection Act 1987, the Control of Substances Hazardous to Health Regulations 1988, Safe Working and the Prevention of Infection in Clinical Laboratories – Model Role for Staff and Visitors, HSC 1981, Protection against Blood-borne infections in the workplace: HIV and Hepatitis (ACDP) 1995.
- 3.3.2 There shall be close liaison between the Safety Officers of the testing site and the respective POCT Committees.
- 3.3.3 POCT devices shall be commissioned by the POCT Committee to the standard e.g. FDA & CE requirements.

3.4 Training

- 3.4.1 Only staff whose training and competence has been established and documented in a list of ‘authorized personnel for equipment’ shall use any device, including simple dip-stick tests and portable hand-held POCT devices.
- 3.4.2 Staffs that have not undergone training for the specific POCT device shall not be permitted to use or handle the device for performing tests.
- 3.4.3 Relevant staff shall be trained in the safe and proper use of the device. The training and certification of POCT users shall be overseen and monitored by the POCT Committee.
- 3.4.4 The training course shall be specified and supervised by a qualified person provided by the supplier of the POCT device or trained and certified staff who has been appointed to oversee the training by the POCT Committee.
- 3.4.5 The appropriate trainer shall have the capability and experience and shall be certified by the respective POCT Committee appointed by the Hospital POCT Committee or District Health Office committee/subcommittee concerned.
- 3.4.6 Training shall include other issues such as patient preparation, pre-analytical aspects of the analysis and interpretation of results.
- 3.4.7 For some devices update training is necessary to maintain a high standard of performance. Records of training, retraining and competency shall be retained.

3.5 Standard Operating Procedure

- 3.5.1 Tests on the device in the designated area of use may only be carried out by those on the "authorized personnel for equipment" list.
- 3.5.2 A SOP shall be produced, written to the standard required by auditors from Standards Malaysia, or equivalent accreditation agencies. This shall be available to and followed by all users of the device.
- 3.5.3 The document will include instructions on safe working practice, the interpretation of error messages, the recording of data and the relevant quality control procedures.
- 3.5.4 The POCT Committee shall provide the standard format for SOPs and the POCT users shall customize accordingly. The SOP copies shall be made available to the POCT Committee.
- 3.5.5 The users shall ensure that the SOPs are available for accreditation agency auditors.
- 3.5.6 POCT sites are to be preferably covered by accreditation.

3.6 Recording and Reporting of Results

- 3.6.1 All patient results and IQC or EQA result shall be recorded. The record shall include unequivocal patient identity, time of test, the result, relevant QC result and the identity of the user.
- 3.6.2 The mechanism for the transfer of result from the device to the patient record shall be unambiguous and stated in the SOP and monitored by the authorized person.
- 3.6.3 All POCT staff shall be responsible for formatting results. The format of the results form (i.e. electronic or paper) and the manner should be determined in discussion with the POCT Committee.
- 3.6.4 POCT committee members shall have free access to IQC/EQA result.
- 3.6.5 Result shall be legible without mistakes in transcription and results reported to persons authorized to receive and use medical information.
- 3.6.6 The result shall indicate if the qualities of the primary sample receive was unsuitable for examination or could have compromised the result.

- 3.6.7 The POCT user shall have written policies and procedures regarding the recording and reporting of results.
- 3.6.8 Record of actions taken in response to results in the critical intervals shall be maintained. These shall include date, time, responsible POCT staff member, person notified and examination result. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.
- 3.6.9 The POCT user shall have written policies and procedures regarding the alteration of results. When altered, the record shall show the time, date and name of the person responsible for the change. Original entries shall remain legible when alterations are made. Original electronic records shall retain any alterations added to the record through appropriate editing procedures so that reports clearly indicate the alteration.
- 3.6.10 Result that have been available for clinical decision making and revised shall be retained in subsequent cumulative reports and be clearly identified as having been revised.
- 3.6.11 All patient results shall be treated as confidential and kept in a secure place. If patient results are stored in a computer system, local rules on access to the system, whether stand alone or networked, should be maintained. Users should have access to the system by password which shall be regularly updated. The storage of results should be in line with the storage maintained by the POCT user and compatible with ISO requirements.

3.7 Log Book

- 3.7.1 The POCT sites shall maintain a whole life service history of all medical devices in accordance MS ISO 22870:2008 and 15189: 2007, for management of medical equipment, and its successors.
- 3.7.2 POCT users shall document all original evaluation records to POCT committee to evaluate in the timely manner.
- 3.7.3 POCT user shall ensure that all equipment is maintained either in house or by service contract, in agreement with the budget holder, to a service schedule to ensure the safe, accurate and reliable operation of all equipment documented in the log book.
- 3.7.4 All POCT users shall have a log book training for operation training and the competency shall be up to date.
- 3.7.5 The performance of suppliers shall be monitored and documented.

- 3.7.6 Each device shall have a device maintenance log-book in either paper or electronic form in which details are recorded of the daily maintenance, IQC results, faults, corrective actions and repairs by named individuals. POCT Committee members shall have free access to these log books.

3.8 Technical Support and Withdrawal of Services

- 3.8.1 There shall be a service level agreement between the users and concession companies or suppliers defining the responsibilities for maintenance, troubleshooting and repairs.
- 3.8.2 Designated POCT user shall 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.
- 3.8.3 The POCT Committee shall recommend that any POCT device or system be withdrawn from the service if a device fails to perform to analytical specification, critical requirements are not met, safety becomes an issue or if devices are not used or cared for appropriately. The device shall be withdrawn immediately from service until full remedial action has been completed. The concession companies or suppliers shall have the responsibility of removing the device from service.
- 3.8.4 Users shall be informed immediately of any quality shortfalls by POCT Committee.
- 3.8.5 An inventory shall be maintained of all POCT equipment including serial number and unique identification, manufacturer or supplier identification, date of purchase, service history, and dates which the device was out-of-service.
- 3.8.6 There shall be alternative sites for analysis in the event of device failure. It should have been agreed, documented, and made known to the users.

3.9 Quality Assurance

- 3.9.1 Point of Care Testing – Requirements for Quality and Competence, MS ISO 22870:2008 requires that departments participate in recognized External Quality Assessment schemes (EQA) relevant to their test repertoire.
- 3.9.2 Quality assurance programme (QAP) shall be the integral component of any POCT service and includes all the measures taken to ensure the reliability and accuracy of the patient result.
- 3.9.3 The Management (Hospital Director) / District Health Officer shall ensure that there is a demonstrable link between the users of the device and the appointed

POCT Committee to ensure the "Quality" aspects and reliability of the results produced.

- 3.9.4 The Management (Hospital Director) / District Health Officer shall also ensure that adequate budget is provided for EQA schemes.
- 3.9.5 The Management (Hospital Director) / District Health Office-Coordinator shall be informed of the legal implications involved if there is no supervision of devices through QA schemes.
- 3.9.6 The appointed POCT Committee shall be involved in clinical governance issues and shall carry out regular audits of the reliability and effectiveness of the tests being carried out.
- 3.9.7 The appointed POCT Committee shall be responsible for ensuring that the performance of the device is checked by appropriate internal QC and external QA assessments such as would satisfy.
- 3.9.8 The Hospital / District Health Office POCT Committee shall be responsible for the design of QAP that conforms to the quality standard of the POCT sites.
- 3.9.9 The Hospital POCT / District Health Office-Coordinator shall be responsible in the implementation and management of the analytical quality assurance for POCT site and provide feedback to the State POCT Committee.
- 3.9.10 Internal quality control (IQC) shall be performed by the POCT users as a means of determining that the POCT device is technically performing correctly at that specific time.
- 3.9.11 The POCT user shall be responsible in purchasing of IQC and EQA scheme with the advice of POCT Coordinator.
- 3.9.12 The IQC material shall be stored and handled according to the manufacturer's recommendation.
- 3.9.13 Calibration of the POCT analyzers shall be performed according to the manufacturer's recommendation.
- 3.9.14 The IQC of the POCT analyzers shall be performed according to the Hospital / District Health Office POCT Committee's recommendation.
- 3.9.15 The IQC performed shall be recorded and presented in Levey-Jennings (LJ) chart.
- 3.9.16 The POCT users are responsible in documenting and keeping the IQC data for monitoring and review by the State POCT Coordinator.

- 3.9.17 Where applicable, External Quality Assurance (EQA) scheme from a professional body or carried out by the State POCT committee or Hospital POCT committee shall be participated by the POCT user.
- 3.9.18 The POCT user shall be responsible for the enrolment with the EQA scheme in terms of planning, monitoring and financial support on the advisory of appointed POCT Committee.
- 3.9.19 POCT Coordinator shall review the performance of EQA and discuss with the users the appropriate action to be taken should there be any shortfalls in the quality standards.
- 3.9.20 The Pathology / District Health Office POCT Committee coordinates training for the POCT user to be competent to carry out the IQC and tests.
- 3.9.21 Hospital Quality Management Review (Hospital Director / District Health Officer -Management) shall discuss quality performance of POCT.

3.10 Budgetary planning and monitoring

- 3.10.1 Prior to the procurement, there shall be a budget proposal and an agreement incorporated in the *Perjanjian Program* of the User between the Management (Hospital Director/District Health Officer) and its users for the budgetary consequences of the purchase.
- 3.10.2 The Hospital / District Health Office POCT Committee shall be responsible to monitor the cost implication and report to the Management (Hospital Director / District Health Officer) respectively.
- 3.10.3 POCT user and the respective department shall be responsible for the ordering and monitoring of reagents, consumables, inventory, maintenance, servicing, training, support, quality control and quality assessment in POCT sites.
- 3.10.4 POCT users shall budget and bear the direct costs of running, maintenance, consumables, quality control and service contract inclusive of indirect costs for POCT Committee's involvement, including support, training and QC/QA monitoring, as well as the inevitable cost of back-up.

3.11 Complaints

- 3.11.1 All complaints shall be written and directed to the Hospital / District Health Office POCT Committee to be discussed.
- 3.11.2 The relevant issues shall be addressed by the Management (Hospital Director / District Health Officer) respectively, if required and corrective action taken.



POINT OF CARE TESTING (POCT) GUIDELINES



POINT OF CARE TESTING (POCT) GUIDELINES

1.0 INTRODUCTION

A POCT service may be defined as a quality assured pathology service using analytical devices (including test kits and analyzers), provided near to the patient rather than in the traditional, core or central laboratory, typically by clinical personnel whose primary training is not in the clinical laboratory sciences.

The purpose of POCT is to improve the quality of patient care by providing rapid laboratory test results to clinicians or other healthcare workers to contribute to immediate patient management decisions. Technological advances have made Point of Care Testing (POCT) devices perform diagnostic tests with increasingly simple methods, shorter processing time and better analytical performance.

2.0 SCOPE / USE

The scope of the present guideline relates to the management philosophy of POCT, the venues where POCT may be undertaken (throughout the MOH), the range of results, the qualifications of the personnel involved in testing and interpretation of results and the timeliness of the service. Other aspects discussed in this guideline are initiation of the service, training, device, results, monitoring of quality, accreditation, safety and budget management.

The main purpose of this guideline is to provide healthcare professionals with a clear guidance on the management of a POCT service. It is intended to assist those responsible for the delivery of POCT, and to ensure that risks to patient health and safety are minimized. It is recommended that every MOH facility in Malaysia utilizes this POCT guideline which is consistent with the POCT policy.

3.0 LISTS OF POINT OF CARE TESTS

POCT is now an established part of clinical practice. However it is important that it is viewed as part of an integrated activity in which the objective is caring for the patient in the best clinical and most cost-effective way.

Examples of POCTs include (but are not limited to) blood glucose monitoring, blood gas/co-oximetry analysis, electrolyte analysis, blood coagulation measurement, blood HbA1c analysis, urine analysis, infectious disease rapid tests, pregnancy testing and urine drug of abuse.

4.0 STEP-BY-STEP OUTLINE IN THE DEVELOPMENT OF POINT OF CARE SERVICES

4.1 Obtain Authority To Coordinate POCT Services

POCT Committees shall be formed at State, District and Hospital levels. Management (State Director/ Hospital Director / District Health Officer) acts as an advisor and should be involved in Point of Care programme in this type of setting and is usually needed since several departments and budgets are impacted.

4.2 Selecting Members of State / Hospital / District Health Office (DHO) POCT Committee.

POCT Committee shall be established in every state, hospital or DHO to take responsibility for all POCT services and to ensure effective monitoring for quality assurance in POCTs.

The state, hospital or DHO POCT Committee shall aim for the institution to obtain POCT accreditation from accreditation bodies. Documents published by various accreditations and regulatory agencies propose that an interdisciplinary committee be constituted at any site performing POCT (MS ISO 22870:2008; Malaysian Association of Clinical Biochemist).

The committee shall be multidisciplinary including laboratory staff, clinicians, nursing staff and other non-laboratory staff from hospitals and public health representatives. In hospitals or DHOs with POCT services the State Pathologist shall be appointed as State POCT coordinator (refer to POCT policy) and shall be responsible for the POCT clinical governance. The POCT User shall prepare quality manuals and requirements complying with POCT MS ISO 22870:2008. Standard operating procedures (SOP) shall be written and regularly reviewed and include details of procedures relating to POCT performance.

4.2.1 Terms of Reference

4.2.1.1 Terms of reference for POCT User.

- a) Ensures all requests for services, devices and quality measures are submitted to the respective POCT Committees.
- b) Ensures that approvals for services, devices and quality measures are obtained from the respective POCT Committees and shall be followed-up and implemented.

- c) Ensures that all quality recommendations by the POCT Committee shall be followed up and implemented.
- d) Plays a major role in quality management e.g. daily Internal Quality Control, scheduled External Quality Assurance, schedule maintenance, inventory records, result reporting and all documentation records.
- e) Ensures their respective HODs / DHOs are involved in all the Quality Assurance activities suggested to improve on-site analysis for better patient management.
- f) Ensures that their respective HODs / DHOs are involved in planning and monitoring of purchasing, storage of reagents and consumables.
- g) Ensures that their respective HODs / DHOs are responsible for all devices and purchases (including reagents, consumables and devices) at the POCT site.
- h) Maintains records and related documents e.g. KEW PA 312, maintenance logs, QC records, periodical preventive maintenance, corrective actions, patient records.
- i) Ensures that all new POCT devices are acquired at the POCT sites are evaluated by the State, hospital or DHO POCT Committee.

4.2.1.2 Terms of reference for Scientific Officer / MLT.

- a) Ensures QC for proficiency testing is performed at POCT site.
- b) Records all troubleshooting, visit and results in record book or file at POCT sites as well as in the laboratory to help in reporting and ensures that the relevant documents are available.
- c) Receives results of QC, analyze and does troubleshooting when required.
- d) Gives suggestions for improvements after identifying the problems faced in the POCT sites. Gives advice and implements corrective actions whenever required.
- e) Ensures quality is maintained at POCT sites.
- f) Responsible for the interpretation of proficiency testing and to provide recommendations for corrective action.
- g) Provides training with regards to QC, maintenance and troubleshooting (provided staffs are also trained for the particular analyzer).
- h) Prepares the POCT report to be submitted to State POCT Committee.

- i) Responsible for specification, evaluation and requirements at POCT site.

4.2.1.3 Terms of reference for HOD / District Health Officer

- a) Responsible for appointing a *FMS / Medical Officer for POCT management. (*if unavailable, appoint the next senior officer.)
- b) Responsible for ensuring the monitoring of daily performance of IQC on every POCT device before use.
- c) Responsible for the upkeep of documentation of daily IQC, EQA and maintenance logs and to ensure that all subordinates comply with the SOPs and requirements from manufacturers' inserts.
- d) Reports to the State POCT Committee on the performance of the POCT devices.
- e) Takes the necessary corrective and remedial actions if the POCT devices used are not up to standard with the daily IQC and periodic EQA and ensuring that all subordinates apply the corrective actions.
- f) Responsible for the ordering and monitoring of reagents, consumables, inventory, maintenance, servicing, training, support, quality control and quality assessment.
- g) Responsible to ensure adequate budget is allocated from the respective departments for the running of POCT services.

4.2.1.4 Terms of reference for POCT Coordinator.

- a) If no resident pathologist is available in the hospital facilities, a visiting pathologist shall act as the POCT Coordinator.
- b) Initiates the formation of POCT Committee and initiates POCT services.
- c) Ensures POCT site complies with the policy and guidelines of the POCT Steering Committee (PSC).
- d) Ensures that every department is represented, and that they play active roles as POCT users.
- e) Delegates duties to all committee members to enforce the rules and requirements as stated in the National POCT Policy.

- f) Liaises with the Hospital Director or MKA/K for aspects involving budgeting and interdepartmental cooperation to ensure the success and continuity of the POCT services.
- g) Liaises with the State Director for occupational safety and health aspects.
- h) Ensures that the National POCT Policy and Guidelines are made available to every department in the hospital / PHF and to ensure compliance especially in the training of qualified personnel to use POCT devices.
- i) Has scheduled meetings with the POCT Committee to review performance of POCT devices and training records in order to enforce compliance with requirements.
- j) Reports to the State POCT Committee.

4.2.1.5 Terms of reference for suppliers/concession companies of POCT devices and materials.

Adheres to the National POCT policy and guidelines in aspects of:

- a) Procurement of POCT devices.
- b) Training of POCT users of the devices that are provided by the supplier.
- c) After sales services and performance of scheduled preventive maintenance and troubleshooting of the device when there are technical problems. Concession companies shall be fully responsible for the preventive and corrective maintenance, where applicable.
- d) Provision or supply of EQA materials where possible to POCT sites that have no EQA programme of their own.

4.3 POCT Committee Reviews POCT Devices In All Sites

The POCT tests are performed in multiple areas of medical care in hospitals and also outside hospitals including primary healthcare clinics. Sites for hospital POCT includes intensive care units, emergency and trauma departments, operating theaters and postoperative care units, renal dialysis units, neonatal units, outpatient departments and research laboratories (undertaking clinical tests).

POCT devices shall be defined as testing equipment, strips, cartridges and cuvettes. POCT systems shall be defined as the package of device, IT components, printers and IQC programmes.

POCT in patient care areas may be unknown to the POCT Committee members. Various methods throughout the institution may not give comparable values or the method may not be appropriate for how the results are used. All patient care areas should be reviewed for POCT such as blood gases, glucose, urine dipstick, infectious disease rapid kits etc. Therefore, POCT Committee members need to do a complete survey of the all POCTs performed in their respective institutions in order to have effective monitoring of POC tests to ensure quality results for the intended purposes.

4.4 Evaluation of Proposed POCT

4.4.1 The Selection Criteria of POCT for Implementation of New or Replacement POCT Devices.

There is a wide variety of POCT devices available for measuring tests or analytes from most of the pathology majoring. However the sheer number and diversity of instruments can lead to confusion, incorrect decisions, and inappropriate applications. This can result in wasted money and a lost opportunity to improve patient care.

The following section offers some rules and advice in selection of POCT device / system:

Criteria	Concerns
Justification to introduce POCT services	<ol style="list-style-type: none"> 1. TAT 2. Improve patient care 3. Number of tests available 4. Methodology 5. Sample stability
Sufficient space availability	The amount of space available for instruments, consumables, storage and paperwork should be considered, including fridge/freezer space required.
Ease of use	<ol style="list-style-type: none"> 1. Is it user friendly for operators? 2. Power/network requirements. 3. Maintenance requirements.
Sample type	Whole blood is preferable for POCT
Sample volume	Are you testing pediatric patients?

Expiry date of consumables	<ol style="list-style-type: none"> 1. Will you be performing sufficient tests to ensure that consumables shall be used before expiry? 2. Testing throughput – will it be adequate to ensure ongoing operator competency?
Standardization of device / Results / Correlation	Results comparability with local laboratory – this is particularly important if a combination of laboratory and POCT results is used to assess the same patient.
Connectivity	<ol style="list-style-type: none"> 1. Can results be transferred electronically to patient records? 2. Barcode capability for patients, operators and consumables.
Quality	<ol style="list-style-type: none"> 1. Precision and accuracy should be appropriate for the clinical needs. 2. Portability – Do you need to move the POCT device? And if you do, is it portable enough to meet your testing needs? 3. Are appropriate internal quality control materials available? 4. Are appropriate external quality assurance programmes available?
Service contract	<ol style="list-style-type: none"> 1. Do you have access to ongoing service and support and what are the terms of the contract? 2. Are training and training materials provided by the supplier? 3. What is the length and terms of the warranty offered for the device?
Supplier evaluation	<ol style="list-style-type: none"> 1. Reliability of supplier? 2. Is there a supplier helpline? 3. Training available post-procurement e.g. refresher course?

Budget	<ol style="list-style-type: none"> 1. Capital Expenditure 2. Is it affordable? 3. Are the running costs (including maintenance contract, consumables, quality control, quality assurance materials and connectivity costs) affordable / sufficient?
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Table 1: Criteria for selection of POCT device / system.

4.4.2 Other Important Evaluation Factors To Consider

Evaluation of the proposed testing needs to be carried out by POCT User and final review by POCT Committee, and it shall include the following:

4.4.2.1 Purpose: Why is POCT performed instead of routine laboratory testing? i.e.: turn-around time, reduction of length of stay, patient convenience, improved patient care management.

4.4.2.2 Volume: The test may be beneficial, but a low volume / request may result in concerns about the proficiency of the testing personnel and cause reagents and controls to expire before reasonable usage thus escalating costs.

4.4.2.3 Methodology: What methodology is used for each analyte? Further evaluation by Pathology Department shall be carried out for the purpose, for example

- a) Method
- b) Precision
- c) Sensitivity
- d) Specificity
- e) Interference
- f) Linearity
- g) Batch vs. discrete technology
- h) Reagent and control stability
- i) Reagent and control storage requirements
- j) Quality control requirements
- k) Correlation

4.4.2.4 Certification of device: Device must be from a certified body e.g. CE, FDA etc.

4.4.2.5 Cost of the test method: Cost of a point of care service shall look into the whole process of patient care, rather than the cost of an individual point of care test method vs. the cost in the laboratory test method.

An appropriate point-of-care test in an emergency room however may prevent the admission of a patient into the hospital. Items that should be assessed include:

- a) Cost of training the testing personnel and maintenance of competency.
- b) Labor associated with processing and analyzing the specimen.
- c) Labor associated with maintaining the device.
- d) Annual reagent, control, maintenance and depreciation costs.
- e) Costs of proficiency programmes for testing performed.
- f) Cost reduction because of early treatment thus reducing the length of patient stay.
- g) Decrease in admission rates.

4.5 Implementation of Guidelines

4.5.1 Staff Training and Competency

4.5.1.1 All staff involved in POCT shall be trained and competent in the use of POCT devices.

4.5.1.2 The training and certification of POCT users should be regularly assessed by the POCT Committee.

4.5.1.3 POCT training should be organized by a POCT Coordinator. The POCT Coordinator shall be responsible for overall supervision and management of the POCT activity, and ensuring compliance with the policies and quality standards that are required by the programme - particularly in selection and evaluation of instruments, staff training and competency assessment, surveillance of the entire testing process, quality control and quality assurance procedures, and troubleshooting.

4.5.1.4 Training should be delivered by the POCT Coordinator or his / her appointed representatives, who may include for example regional trainers, additional support staff from the pathology laboratory or specialist POCT provider and/or the supplier of the POCT device.

4.5.1.5 Training should cover both theory and practice of:

- a) Inclusion in the register of certified trained users and notification of the programme for retraining and monitoring.
- b) Action on improper and unsafe use of a POCT device.
- c) Procedure for recording of adverse incidents with POCT devices.
- d) Compliance with accreditation requirements (if appropriate).
- e) To understand the differences and the similarity result between POCT devices and laboratory result as a reference center.
- f) Understanding of method, standard reference range and correlation study.
- g) Patient preparation and sample collection requirements according to health and safety regulations and the manufacturer's stated requirements (including correct preservative or anticoagulant).
- h) Reagent preparation and storage.
- i) Clinical decision limits or reference intervals.
- j) How to perform the test on the device (including calibration).
- k) How to interpret report and act on POCT results (including those outside the measuring range of the device and outside the predefined clinical decision limits for the test).
- l) Quality Assurance procedures.
- m) Instructions on safe working practices prior using POCT device.
- n) Review of the manufacturer's instructions for use, limitations of the POCT devices and interpretation of results.
- o) Review and understanding of error messages, interpretation and appropriate responses (maintenance check list and troubleshooting).
- p) Calibration and quality control requirements, to include performance, appropriate record keeping and required actions for failed calibration and QC rules.
- q) Appropriate responses to and recording of patients' results.
- r) Assignment of operator identification numbers to certified POCT users.

4.5.1.6 The practical side of training should include a complete demonstration by the POCT Coordinator or primary trainer of how to use the device and perform a test, how to run IQC and EQA samples and how to perform basic maintenance procedures, followed by a hands-on practical session for each person.

4.5.1.7 Training Manual:

- a) A training manual, either in hard copy and/or electronic form, should be provided to all POCT staffs attending training.
- b) The content of the training manual shall be determined by the nature of the POCT service being implemented and the needs of the organization undertaking POCT.
- c) POCT Coordinator shall use training manuals with simple instructions rather than scientific and analytical concepts that can be readily understood by non-laboratory staffs.
- d) Laminated posters with simple step-by-step instructions to consolidate detailed information on how to perform a POCT test on a patient and how to conduct quality management (QC and EQA) testing procedures into a practical, workable format can also be used effectively as part of a training package.

4.5.1.8 POCT Competency:

- a) Successful trainees shall receive a competency certificate at the completion of initial training.
- b) Only staff whose training and competence has been established and recorded shall be permitted to perform POCT device.
- c) Post training surveillance of competency shall be undertaken by regular review of quality control and quality assurance testing results.
- d) Trainee competency shall be determined by written and/or practical assessment in a log book.
- e) Trainee competency shall be assessed in a practical sense by both the successful conduct of a routine POCT test (ideally the entire testing procedure not just analytical) in the presence of the POCT user and by a written assessment through a series of short questions to ensure key theoretical concepts have been grasped. Competency shall be formally and regularly reviewed through retraining and participation in education updates.
- f) Echo training shall be conducted by certified POCT User to enable each trainee to experience using the POCT technology in a practical 'hands-on' sense and gain confidence prior to commencing patient testing.

4.5.1.9 Attendance at retraining sessions should be viewed as mandatory. These sessions may be conducted on-site, at regional workshops or at annual workshops.

4.5.1.10 If a POCT operator fails a competency review (for example because their QC / EQA performance has been poor, their level of testing activity has fallen below minimum requirements, or they exhibit a high rate of analytical errors with their testing), then they should be retrained before being recertified. Registry of trained staff and renewed competency certificates should be prepared and maintained by the POCT Committee.

4.5.2 Monitoring QAP and Troubleshooting

4.5.2.1 External Quality Assurance (EQA)

- a) External Quality Assurance (EQA), sometimes referred to as Proficiency Testing, is an essential part of assuring the quality of the testing process.
- b) It is a system designed to objectively assess the quality of results obtained by comparing the performance of different methods and different testing sites. This comparison between different testing sites is often referred to as peer comparison.
- c) All participating POCT sites are required to analyze an identical unknown specimen on their POCT device and send the results to the EQA provider.
- d) The EQA provider sends a report to the POCT users detailing their performance.
- e) EQA complements Internal Quality Control (IQC) to help assure the POCT operator and the patient that the test results are valid.

4.5.2.2 Internal Quality Control (IQC)

In general, instead of testing a patient sample, the test is done on QC material provided either by the manufacturer of the POCT device (internal QC) or by a registered external provider of quality assurance programmes (third party QC).

For most types of quality control testing, the QC material is transferred to a testing receptacle (e.g. strip, cartridge, cassette, tube or similar) containing the reagents required for measuring the test, which is then inserted into the POCT device, and the result is displayed on the device once the test is completed.

The POCT Coordinator can help to assess whether the performance of the device meets acceptable analytical standards, as there are a set of internationally accepted analytical

goals for most laboratory tests, including some common POC tests.

For Quantitative POCTs:

- a) QC material may have an assigned or 'target' value for each POC test being measured and 'set' limits for acceptable performance around that target.
- b) Where QC materials are not available direct patient comparison with a central Pathology laboratory method may be substituted. Set limits for acceptable performance should still be in place.
- c) Record the date on which the QC testing is performed and the operator's name (or initials).
- d) The results of QC testing shall be compared to assigned values and limits for acceptable performance that are set for each QC. As stated, each QC may have an 'assigned value' that is set by the manufacturer and what is called 'limits for acceptable performance' which can be set by the POCT Coordinator or the manufacturer. The QC results shall be recorded electronically or manually for traceability. The POCT Coordinator can assist in the designing of an appropriate QC result sheet.
- e) For QC test result that is outside the limits of acceptability, corrective action shall be taken and recorded following the protocol developed by the POCT Coordinator. POCT user shall ensure that QC results for the device is in control before the device can be used.
- f) The POCT user shall be able to compare the QC results with the assigned value and the set QC limits. Hence, shall be able to obtain an immediate internal assessment of the POCT device's performance and the testing system's suitability to continue.
- g) Calculate the mean and standard deviation (see below) and plot a Levey Jenning Chart where appropriate (some devices may have auto plot for Levey Jenning Chart).
- h) The key performance indicator for QC testing is imprecision. As the number of QCs tested builds up, calculate the imprecision (or degree of reproducibility) of your QC results on the POCT device.
- i) Imprecision, expressed as a coefficient of variation [CV%], is calculated using the formula:

$$1. \text{ CV\%} = (\text{standard deviation [SD]}/\text{mean}) \times 100\%$$

$$2. \text{ Mean, } x = \frac{\sum x_i}{n}$$

$$3. \text{ Standard Deviation} = \frac{\sum (x_i - \bar{x})^2}{n - 1}$$

Some devices may produce CV% results automatically as well.

- j) As a general rule, the lower the imprecision, the better the performance of the device.

For Qualitative POCTs:

- a) In general, qualitative POCTs (HIV, Hepatitis, Dengue, Malaria, Urine Pregnancy Tests, Urine Chemistry etc.) do not yield any numerical values and only shows either 'positive' or 'negative' results. These tests are in immunochromatographic strips and have an internal control which is built into each test strip to ensure that specimen volume is adequate and solution flow through the device as intended.
- b) When the built in internal control line develops, this indicates that the patient's specimen has been correctly loaded and traveled through the test strip and therefore the test is valid. If the internal control does not develop, the test result for the patient is not valid. The result cannot be reported. Do troubleshooting and repeat the test. If a second invalid result occurs, external controls or known controls should be used to evaluate as described below before repeating the test a third time.
- c) Known reactive and non-reactive specimens (positive and negative controls) are available from the manufacturer/supplier to sites purchasing the qualitative POCT kits. They are used to evaluate the accuracy of the test and to check if the person conducting the test performs it correctly. Whenever possible, a weakly reactive positive control should be included that has been validated to yield weakly reactive results on all test kits used.
- d) To verify that the POCT device is accurate, external positive and negative controls must be tested on a scheduled basis (refer to Table 1) and when these conditions occur:
 - There is a change of lot numbers.
 - A new operator (a trained staff member who has not been doing testing for a while or a newly trained operator) is performing test.
 - If rapid test kits are exposed to environmental conditions that fall outside the range needed for stability as defined by the manufacturer.
- e) Each QC test must be read and validated by two trained POCT users/operators and must be recorded into an IQC/EQA report log.
- f) When IQC and external controls provide incorrect results, none of the tests that were run since the last time control results were correct, can be considered valid. This means that everyone who was tested since the last time controls ran correctly will

need to be called back and retested (unless a confirmatory test by another method was ordered).

- g) Take appropriate corrective action when performance goals are not met and record all actions taken and the subsequent results/findings after retesting in IQC/EQA records log. If the POCT user at the site is unable to perform the corrective action, the POCT Coordinator or the POCT Committee must be informed. It is then the responsibility of the POCT Coordinator/Committee to assist in troubleshooting of the problems. Troubleshooting assistance from the supplier of the POCT kit should also be used when necessary.

4.5.2.3 Frequency of QC Testing

Every batch of reagents shall have QC check. Frequency of use of quality control material is dependent on several factors. The condition of the kits must be evaluated over time. In areas where environmental conditions are sometimes extreme, difficult to control, and where transportation can be challenging, it will be important to check kits fairly often.

Recommended minimum frequency of IQC testing is stated as in Table 1.

Device	Instrument type	Frequency	Remarks
ABG	Bench Top	Once per day	} At least 2 levels. IQC shall be carry out for all analytes measured by ABG.
ABG	Cartridge	Once per day	
FBC	Bench Top	Once per day	
Glucometer	Strips	Once per day	
Blood Ketone meter	Strips	Once per day	Storage, stability, expiry shall meet the requirements
Haemoglobinometer	Cuvette	Once per day	
Bilirubinometer	Cuvette	For every run	
Troponin	Cartridge	Once per day	
BNP	Cartridge	Once per day	
Myoglobin	Cartridge	Once per day	Whenever electronic QC is available, IQC shall be done daily.
D-Dimer	Cartridge	Once per day	
Infectious Rapid Test	Strips	~ 3% / box	
Serology Test	Strips	~ 3% / box	Where appropriate / recommended, each analyte shall be tested within pathological range.
Urine Pregnancy Test	Strips/Cartridge	~ 3% / box	
Urine Chemistry	Strips	Once per day or every bottle, whichever comes first.	
Cholesterol meters	Strips	Once per day	
Occult blood	Strips	~ 3% / box	
Coagulometer	Strips	Once per day	

Table 2: POCT Devices and the Frequency of IQC testing.

Electronic QC may be available that can be used to assess the electronic measurement circuitry of a POCT device. It uses a surrogate material (such as a reference cassette, colored filter, colored solution or bar code) to generate an electric signal that would normally be produced by a sensor responding to an analyte in a patient sample. Thus, electronic QC only tests the 'reader' steps in the total testing process. It does not test the analytical process.

Whenever electronic QC is available, IQC shall be done daily. Where appropriate or recommended, each analyte shall be tested within pathological and normal range.

4.5.3 Procurement

4.5.3.1 All POCT devices are subject to the criteria described in this document (see 4.4) irrespective of whether the device has been purchased (including from endowment funds), hired, loaned, reagent rental, placement or received as a donation.

4.5.3.2 Analysis, which shall be presented to the POCT Committee for evaluation and approval before submission to MOH for financial support.

4.5.3.3 The Quality & Benefit Analysis for patient care shall detail all the quality consequences to Pathology and the proposed POCT site. These shall include capital costs associated with the device itself and all staffing resources required by both the laboratory and the clinical area to provide the service.

It can be further broken down as follows:

- a) Initial purchase of device and accessories.
- b) Provision of a safe environment e.g. health and safety improvements.
- c) Site renovations or alterations (e.g. electrical points) to accommodate POCT.
- d) Interfacing with information management systems.
- e) Staff time (clinical and laboratory) required for patient analysis, support, training, quality assurance and audit.
- f) Routine and preventative maintenance e.g. external service contracts with manufacturer's internal quality control material and participation in external quality assessment scheme.
- g) Accreditation scheme compliance.

- h) Consumables.
- i) Records keeping e.g. data handling system.
- j) Cleaning and waste disposal.

4.5.3.4 When funding has been identified, an operational specification shall be drawn up jointly by Pathology and the clinical users, and then suppliers shall be invited to submit their tender.

4.5.3.5 Short-listed suppliers shall be invited to submit their device for demonstration and / or trial.

4.5.3.6 The Pathology laboratory shall evaluate the technical quality of the device and any interfacing requirements.

4.5.3.7 The final selection shall be ratified or vetted by the POCT Committee.

4.6 Documentation and Records

4.6.1 Standard Operational Procedures (SOPs) and additional supporting documents

4.6.1.1 The standard operating procedure (SOP) incorporates the details included in the standard training procedure; which it complements. It shall conform to ISO standards with a mechanism for regular revision, and a copy shall be retained near the device for convenient access.

It should provide clear precise instructions on

- a) Methodology.
- b) Operating and Technical Manual.
- c) Health and safety.
- d) Specimens required, request / sample identification criteria (2 unique identifiers) and specimen handling.
- e) Preparation of reagents (storage & stability) and other materials.
- f) Calibration.
- g) Quality control procedures.
- h) Sample analysis procedures.
- i) Reporting of results, including abnormal results.
- j) Documentation/transmission of results.
- k) Limitations of the procedure.
- l) Reference values.
- m) Specimen storage and stability.
- n) Disposal of reagents and materials.

4.6.1.2 All SOPs shall be written to the standard required by MS ISO 22870:2008. A master copy of the SOP shall be held by Pathology and be available to Assessors from ISO, or equivalent accreditation agencies.

4.6.1.3 Other documents that shall be stored together with the SOP include POCT device maintenance log, National Institute for Occupational Safety and Health and Risk Assessments, Manufacturers Operator Manuals, relevant MDA notices and Named Certified Operator Lists.

4.6.1.4 This POCT device's maintenance log should contain the instrument serial number and detailed history of instrument maintenance, downtime, breakdowns and corrective action taken, including dates and signatures.

4.6.2 Recording and Reporting Of Results

4.6.2.1 All patient and Quality Control/Quality Assessment (QC/QA) results shall be recorded.

4.6.2.2 This record shall include unequivocal patient identity (name of patient with registration number or IC number – 2 unique identifier), date and time of analysis, the results obtained, relevant QC results and the identity of the user. Management of these records is the responsibility of the POCT User and the POCT Coordinator/Committee shall have free access to all data.

4.6.2.3 A more permanent record of documentation in the patient's notes shall replace reports issued by POCT devices. This should take the form of a paper report (book) or electronic in the case of devices with connectivity. All patients' results shall be treated as confidential and kept in a secure place. If patients' results are stored in a computer system, local rules on access to the system, whether stand-alone or networked, should be maintained.

4.6.2.4 There shall be an established procedure for recall of results.

4.6.2.5 The POCT results shall have a clear delineation / be distinguished from the patient laboratory results.

4.6.3 Retention Of Records

Records of POCT device maintenance log, training records, POCT user competency and assessment records, Quality Control/Quality Assessment (QC/QA) should all be retained

for the length of time specified in the Guidelines on Retention of Pathology Records and Materials, (Version 1/2005) Malaysian J. Pathology 2005, 27 (1): 51 – 56.

5.0 EVALUATION OF POCT ACTIVITIES

Point of Care Testing Activities shall be monitored and evaluated minimally, at least once a year; in order to assure that the activity is meeting the needs of its customers, i.e. POCT Committee, testing personnel and patients. The POCT Committee may accomplish this by monitoring and reviewing the quality assurance, staff training, competency assessments, and customer surveys.

6.0 TRAINING

- 6.1 All staff involved in POCT shall be trained and competent in the use of the POCT system. The training and certification of POCT users shall be overseen and monitored by the POCT Committee. Only trained and competent staff shall be permitted to handle POCT devices. The topics listed below shall be included in the staff-training programme for POCT.
- 6.2 There shall be a Competency Officer in the POCT Committee to ensure training, registry of staff trained, competency assessment, monitoring of training and retraining.
- 6.3 Training topics list includes:
 - a) To understand the differences and the similarity between methods, standard reference range and correlation study result between POCT devices and laboratory result as a reference center.
 - b) Components of a POCT staff training programme (Pre-analytical, analytical and post analytical).
 - c) Instructions on safe working practices and principles of operation of the POCT devices.
 - d) Review of the manufacturer's instructions for use, limitations of the POCT devices and interpretation of results.
 - e) Review and understanding of error messages, interpretation and appropriate responses (maintenance check list and troubleshoot).
 - f) Calibration and quality control requirements, to include performance, appropriate record keeping and required actions for failed calibration and QC.

- g) Patient preparation, sample collection and handling according to health and safety regulations and the manufacturer's stated requirements.
 - h) Appropriate responses to and recording of patient results.
 - i) Facilitating the assignment of operator identification numbers to trained certified POCT users.
 - j) Inclusion in the register of certified trained users and notification of the programme for retraining and monitoring
 - k) Action on improper and unsafe use of a POCT device.
 - l) Procedure for recording of adverse incidents with POCT device.
- 6.4 Suppliers should modify and deliver their established training programme to suit local needs.

7.0 CONCLUSION:

POCT is now an established part of clinical practice. However it is important that it is viewed as part of an integrated activity in which the objective is caring for the patient in the best clinical and most cost-effective way to provide a rapid test result in timely manner to the patient. This may lead to improve turnaround time which allow rapid clinical intervention and informed counseling for clinical management.

Therefore, it is important that each hospital or health clinic has a clearly defined and well-structured approach to POCT, to ensure that it is carried out in accordance with POCT policy.

It is recommended that these guidelines be adopted by those responsible for POCT in hospitals and public health facilities in MOH. An appropriate, patient safe, quality and sustainable POCT service shall be a common desired goal for all providers. This is in keeping with initiatives and aspirations of the ministry towards developing an optimally managed and well governed health or medical facility.

All POCT sites shall try to achieve the MS ISO 22870:2008 accreditation standard.

8.0 REFERENCES

- a) NACB Laboratory Medicine Practice Guidelines. Evidence-Based Practice for Point of Care Testing Management. 2006 (www.nacb.org)
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- c) Clinical Governance of Point-of-Care Testing: The Role of the Point-of-Care Testing Committee. Irish Medicines Board Newsletter. Vol. 1 Number 15, 2006.
- d) MS ISO 22780:2008, Point-of-Care Testing Policy – Requirements for Quality and Competence. (ISO 22780:2006, IDT)
- e) Departmental Policy of Pathology Services, Medical Development Division, Ministry of Health, September 2010, MOH/P/PAK/211.10 (BP).
- f) Guidelines on Retention of Pathology Records and Materials, Part 1 (Version 1/2005), Malaysian J. Pathology 2005, 27 (1): 51 – 56.
- g) Quality Assurance Guidelines for Testing using the OraQuick® Rapid HIV-1 Antibody Testing. U.S Department of Health and Human Services, Centers for Disease Control and Prevention.
- h) Guideline for Assuring the Accuracy and Reliability of HIV Rapid Testing: Applying a Quality System Approach, U.S Department of Health and Human Services, Centers for Disease Control and Prevention and WHO.
- i) Point of Care Testing in Microbiology; The Advantages and Disadvantages of Immunochromatographic Test Strips, Enno Sturenburg and Ralf Junker, Dtsch Arztebl Int 2009; 106(4):48-54.

9.0 ABBREVIATIONS:

AMO – Assistant Medical Officer

CE - *Conformité Européenne*, meaning "European Conformity"

DCD – Disease Control Division

DHO – District Health Office/Officers

EQA – External Quality Assurance

FBC – Full Blood Count

FDA – US Food and Drug Administration

FHDD - Family Health Development Division

FMS – Family Medicine Specialist

IQC – Internal Quality Control

LIS – Laboratory Integrated System

MKA/K – Makmal Kesihatan Awam / Kebangsaan (National Public Health Laboratory)

MLT – Medical Laboratory Technologist

MOH – Ministry of Health

MSQH – Malaysian Society for Quality in Hospitals

POCT – Point of Care Testing

PSC – POCT Steering Committee

QAP – Quality Assurance Programme

SHD – State Health Department

SOP – Standard Operating Procedures

TAT – Turn Around Time