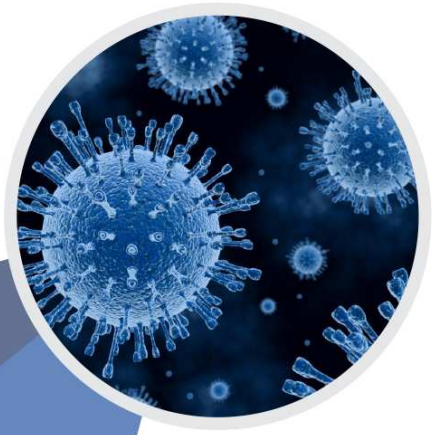
MOH/P/PAK/465.21(BP)-e

NATIONAL POLICY & GUIDELINES FOR POINT OF CARE TESTING



SECOND EDITION

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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

In the earliest days of medicine, physicians delivered healthcare services at the point of care in the patient's home. As medicine advances and new technologies develop, patient care shifted to specialised hospitals which emphasised curative medicine. Large centralised laboratories established with cost savings realised through automated systems for patient samples analysis. Point-of-care devices were only used on a limited basis in the hospital for rapid analysis in intensive care units such as the blood gasses devices or a simple home testing, such as pregnancy test kits.

Today, the emphasis of care is shifting toward preventing and early detection of the disease and managing multiple chronic conditions. The need for predictive, personalised and pre-emptive medicine could drive the development of high-quality, portable diagnostic and monitoring devices for POCT. POCT allows rapid diagnosis in the physician's office, an ambulance, home or field, enabling timely care and treatment rendering to the patient. Clinicians can deliver immediate results in non-laboratory settings to support more patient-centred approaches to strengthen healthcare delivery. Empowering clinicians to make decisions at the "point of care" can significantly impact healthcare delivery and address the challenges of health disparities.

Despite its numerous advantages, producing quality results from POCT is crucial as unreliable and inaccurate results would have devastating consequences for the patients. A well-structured policy and guidelines for the healthcare workers are pertinent to guarantee this. The arrival of this national policy and guidelines will assist clinicians in justifying POCT services when choosing appropriate POCT devices. Moreover, it will allow implementations of standardised operating procedures and comprehensive governance of POCT management, thus ensuring quality and safety improvement initiatives.

Congratulations to the National POCT Committee and the POCT Advisory Council for their effort and commitment in making this second edition of National Policy and Guideline for Point-of-Care Testing a reality. The publication of this document reaffirms the Ministry of Health's resolution to strengthening healthcare delivery, including improving access and equity healthcare to the nation.

Tan Sri Dato' Seri Dr. Noor Hisham bin Abdullah
Director-General of Health Malaysia

Foreword by the Head of Pathology Services

First and foremost, I would like to congratulate the Point-of-Care Testing (POCT) Working Group for reviewing and updating the first edition of National Policy and Guideline for POCT. In this new edition, there is one additional chapter in the policy - the use of POCT in Emergency and Disaster. With this chapter, we hope POCT Committees shall play an important role in the management of laboratory investigations during emergency and disaster.

Since the first edition was published in July 2012, majority of hospitals and health clinics have established their own POCT Committee to oversee the overall management of POCT services. This is very important in order to uphold a standardised POCT practice throughout Ministry of Health facilities. Apart from providing guidance to all POCT users and operators, the policy and guideline also outline the roles and responsibilities of various staff categories involved in POCT services. The POCT operators need to be trained and they must be competent before being allowed to perform the test.

The advantages and occasional drawbacks of POCT are widely publicised thus it is apparent to the clinical laboratory that POCT is here to stay and will continue to enhance its role in efficient patientcare. Therefore, adhering to the Standard Operating Procedure (SOP) and addressing quality assurance concerns are imperative. Record-keeping and documentation must not be overlooked and shall be part of day-to-day tasks for POCT services.

Additionally, this new edition showcases a more concise and organised content to facilitate healthcare workers in the implementation and effective management of POCT. Information on POCT data collections, records and documentations as well as generating a standardised report using a recommended format are provided in this user-friendly guideline.

Finally, I would like to thank the National POCT Committee for their hard work and dedication as well as to the POCT Advisory Council for lending their precious time to review this second edition of the National Policy and Guideline for POCT.

Dr. Tengku Norita Tengku Yazid
Chairperson of National POCT Committee
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A word of thanks is also extended to the Medical Development Division, Medical Practice Division, Family Health Development Division, Head of Specialised Diagnostic Centre IMR and Head of Activity for their kind support and cooperation.

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POLICY STATEMENT

The Ministry of Health Malaysia shall provide fast, safe, effective management and use of POCT devices that are fit for intended purpose in normal situations and during disaster, performed by competent personnel, on the correct patient with documented quality results; in order to provide high quality patient care through standardised POCT services. POCT services shall be coordinated by the POCT Committee at all levels.

The POCT Committee shall ensure this by:

- Justifying the proposed sites and devices
- Advising on test and device specifications
- Evaluating POCT devices
- Performing training and assessing competency
- Implementing quality assurance
- Documenting accurate records
- Standardising operating procedures

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 (POCT) devices used by the Ministry of Health Malaysia (MOH). The objectives of this policy are to:

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

2.0 INTRODUCTION

POCT or near-patient testing (NPT) is a term used to describe laboratory testing usually performed by non-laboratory staff mainly medical and nursing staff outside the main laboratory. POCT is widely used in the MOH and is likely to increase because of advancing technology and changes in clinical practice.

The purpose of POCT is to provide rapid laboratory test results to clinicians and other healthcare workers to facilitate immediate patient management decisions and improved quality of patient care. Technological advances have made POCT devices perform diagnostic tests with increasingly simple methods, shorter processing time and better analytical performance.

A formal policy specifying the leading role of Pathology, and where appropriate, representation from clinical services (e.g., Emergency & Trauma, Anaesthesia & Critical Care, Internal Medicine, Obstetrics & Gynaecology, Paediatrics, Surgery, Primary Care, Public Health Facilities) is essential. This ensures POCT services are conducted in accordance with the principles of clinical governance and national accreditation standards.

This policy will enable the MOH to provide:

- Competent POCT operators
- High quality and cost-effective patient care
- Optimum financial arrangements
- Effective risk management
- Record-keeping and audits
- Integrated data management
- Network information & communication technology (ICT) support for POCT
- Coherent and informed service planning and POCT device standardisation

The National Policy and Guideline for POCT was first published in July 2012 comprising of quality assurance, procurement, risk management, training and competency, POCT device selection, evaluation & maintenance for the implementation of POCT. In this second edition, a chapter on the roles of the National POCT Committee (NPC) during emergency and disaster is added.

POCT implementation activities had been progressive in the past 4 years. About 80% of State and Major Specialist Hospitals have established their own POCT committees. In some hospitals, pharmacists play an important role in the procurement of most reagents, consumables and rapid testing kits. This revision has therefore included pharmacists in Committees, where applicable.

A major problem faced by the NPC was unstandardised reports generated by the POCT Committees. In view of this, the NPC had issued standardised forms for data collection and reporting for all POCT activities. The NPC would compile a POCT device master list, review corrective actions, analyse workload and examine the success of POCT programmes. The revised policy, guideline and forms are available online on the National Pathology Service website (www.patologi.gov.my) and Ministry of Health website (www.moh.gov.my).

3.0 POCT COMMITTEES AND THEIR ROLES

3.1 National Committee of Pathology Services

Comprises of:

- Head of Pathology 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
- Chairperson - Financial, Information Technology & Logistics, Equipment, Quality Assurance & Accreditation, Training & Competency, Workload, Human Resource, Subspecialty, Research, and POCT Committee

3.2 National POCT Committee (NPC)

The NPC members are appointed by the National Head of Pathology Services and shall meet at least once a year. The NPC comprises of:

- Head of Pathology Services (Advisor)
- Pathologist (Chairperson)
- Pathologists (Chemical Pathologist, Haematopathologist, Medical Microbiologist)
- Senior Science Officers (Biochemist, Biomedical Scientist, Microbiologist)
- Public Health representatives from:
    - Centres for Disease Control (CDC)
    - Quality Unit, Public Health Laboratories
    - Clinical Support Services Sector of Family Health Development Division (FHDD)

3.2.1 Roles of the National POCT Committee (NPC):

3.2.1.1 To establish and review the National Policy and Guideline for POCT.

3.2.1.2 To ensure the policy is implemented in all government health facilities to yield better quality of patient results obtained from POCT devices.

3.2.1.3 To collaborate with evaluation committees from any MOH agencies in evaluating diagnostic POCT devices for clinical effectiveness, quality improvement, financial impact and technical performance.

3.2.1.4 To provide consultation e.g., preparing specifications and evaluations.

3.2.1.5 To review and approve proposal requests from any MOH health programmes for POCT devices (if any).

3.2.1.6 To compile all POCT technical evaluation reports and maintain them as reference for verification of new POCT devices.

3.2.1.7 To assist in proper procurement and commissioning of POCT devices according to the policy and guideline.

3.2.1.8 To standardise practices e.g., specification, evaluation, internal quality control (IQC) used.

3.2.1.9 To define criteria for intervention against unsatisfactory performance, inappropriate use, poor quality practices including withdrawal of POCT device when appropriate, elimination of POCT tests that do not meet quality standards and retraining of incompetent users.

3.2.1.11 To collaborate with quality committees in establishing common quality control and quality assurance programme to ensure regulatory compliance and to maintain quality of testing.

3.2.1.13 To establish POCT device master list, workload data and examine the overall success of POCT programme.

3.2.1.14 To provide annual POCT performance report to all responsible parties.

3.2.1.15 To advise and assist in the achievement of relevant accreditation.

3.2.1.16 To assist and provide consultation on training to POCT sites and recommend the appropriate credentialing qualifications and requirements.

3.3 Advisory Council

The Advisory Council shall be the advisor for the NPC. They are a group of clinicians and other parties directly involved with and/or have a keen interest in the utilisation of POCT as a means to improve patient care. Advisory Council shall consist of:

- Emergency & Trauma Physician
- Surgeon
- Obstetrician & Gynaecologist
- Anaesthetist
- Paediatrician
- General Physician
- Cardiologist
- Forensic Pathologist
- Family Medicine Specialist
- Pharmacist
- Representative from Medical Practices Division, Medical Development Division, Disease Control Division, Crisis, Preparedness and Response Centre (CPRC), Health Technology Assessment and Institute for Medical Research

3.3.1 Roles of the Advisory Council:

3.3.1.1 To review the National Policy and Guideline for POCT every 5 years or earlier.

3.3.1.2 To act as a resource to the NPC on particular issues brought forward to the Advisory Council as a whole, or to individual members of the committee.

3.4 State POCT Committee

Comprises of representatives from both hospital and public health:

- State Health Director (Chairperson)
- State Pathologist
- State POCT Coordinator (Pathologist/Science Officer)

- Specialists from major clinical disciplines
- Pathologists - Chemical Pathologist, Haematopathologist, Medical Microbiologist
- Hospital POCT Coordinators
- Public Health District POCT Coordinators
- State Primer Medical Officer (JKN)
- *Public Health Laboratory Team (MKA)
- Pharmacist (JKN)
- Science Officers (Hospital)
- State Assistant Medical Officer (Medical)
- State Assistant Medical Officer (Public Health)
- Matron (Medical)
- Matron (Public Health)
- Medical Laboratory Technologist (Medical)
- Medical Laboratory Technologist (Public Health)

*Public Health Laboratory Team (MKA) consists of:

- Pathologist / Medical Officer
- Science Officer
- Medical Laboratory Technologist

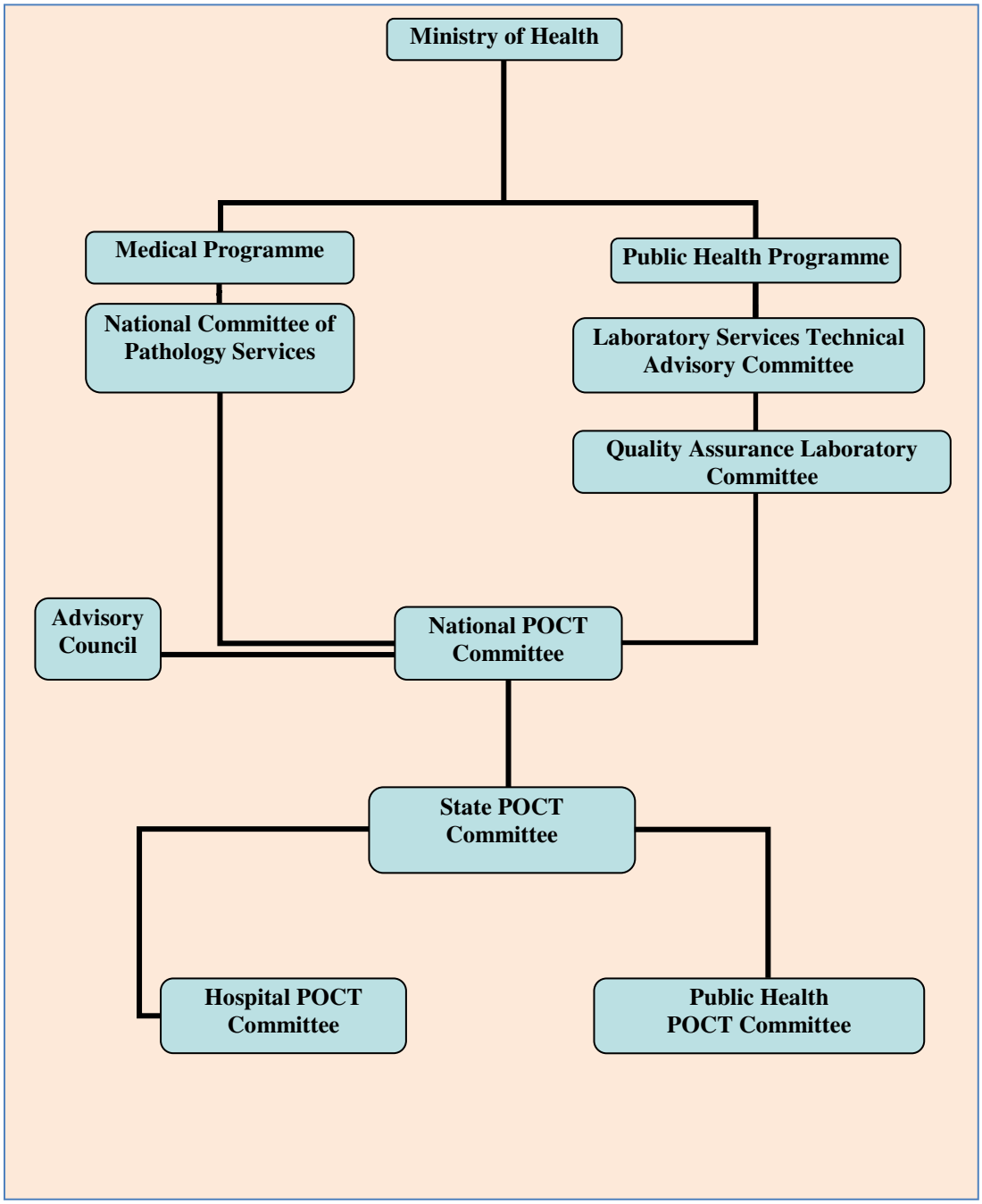

Figure 1: National POCT Committee Organisation Chart

3.4.1 Roles of the State POCT Committee:

3.4.1.1 To enforce the implementation of POCT policies and ensure that it is effective and seamless at all POCT sites.
3.4.1.2 To ensure all new POCT Standard Operating Procedures (SOP) and devices are appropriate, clinically justified and cost effective at state level.
3.4.1.3 To review and approve the proposals for any POCT devices at state level.
3.4.1.4 To assign the appropriate persons for determining specifications and performing evaluations of POCT devices at state level.
3.4.1.5 To annually collect, analyse and review POCT reports from all hospitals, clinics and POCT sites in order to monitor compliance to set quality assurance (QA) standards.
3.4.1.6 To establish POCT device database for the state, review corrective actions, workload and examine the success of POCT programme at state level.
3.4.1.7 To ensure adequate budget to meet the requirements for quality and services at state level.
3.4.1.8 To ensure that the appropriate training is provided at state level.
3.4.1.9 To provide and submit annual state report to the NPC.
3.4.1.10 To report to the NPC on matters relating to national level POCT services.

3.5 Public Health POCT Committee (PHPC)

Comprises of:

- District Health Officer (DHO)
- District Primer Medical Officer
- Coordinator (Assistant Medical Officer / Medical Laboratory Technologist)
- Family Medicine Specialist (FMS)
- Assistant Medical Officer (AMO)
- Matron
- Medical Laboratory Technologist (MLT)
- Pharmacist

*Chairperson shall be appointed from amongst committee members by the District Health Officer

3.5.1 Roles of the Public Health POCT Committee (PHPC):

3.5.1.1 To ensure adaptation, adherence and implementation of the recommended SOP and practices for maintenance and safe use of POCT devices.
3.5.1.2 To monitor Internal Quality Control (IQC) for POCT devices used in clinics and to ensure that corrective actions are undertaken and implemented.
3.5.1.3 To provide consultation on External Quality Assurance (EQA) services for users of POCT devices.
3.5.1.4 To conduct and review POCT audits using standard checklists periodically at least once a year.
3.5.1.5 To monitor, collect and analyse POCT reports from public health facilities and submit reports to the State POCT Committee annually.
3.5.1.6 To coordinate training, privileging, competency assessment and reassessment of new and current personnel periodically or when requested.
3.5.1.7 To review and determine if the requirements (e.g., budget, training, human resource) proposed by POCT operator are justified to meet quality and service requirements.

3.6 Hospital POCT Committee

3.6.1 Hospital POCT Committee with Pathologist

Comprises of:

- Hospital Director (Chairperson)
- Head of Department (HOD) of Pathology
- Hospital POCT Coordinator (Pathologist / Science Officer)
- Specialists from major disciplines
- Pathologist
- Medical Officers from Pathology Department
- Science Officers
- Medical Laboratory Technologists
- *Matrons, Sisters or Staff Nurses
- Assistant Medical Officer
- *Pharmacist
- *Concession Company

3.6.2 Hospital POCT Committee without Pathologist

Comprises of:

- Hospital Director (Chairperson)
- **Supervising Pathologist (any discipline)
- Head of Unit (HOU) of Pathology (POCT Coordinator)
- *Specialists from major disciplines
- Science Officers
- Medical Laboratory Technologists
- *Matrons, Sisters or Staff Nurses
- Assistant Medical Officer
- *Pharmacist
- *Concession Company

* *Where applicable*

** *In institutions with no Pathologists, the supervising Pathologist will assume the role of Advisor*

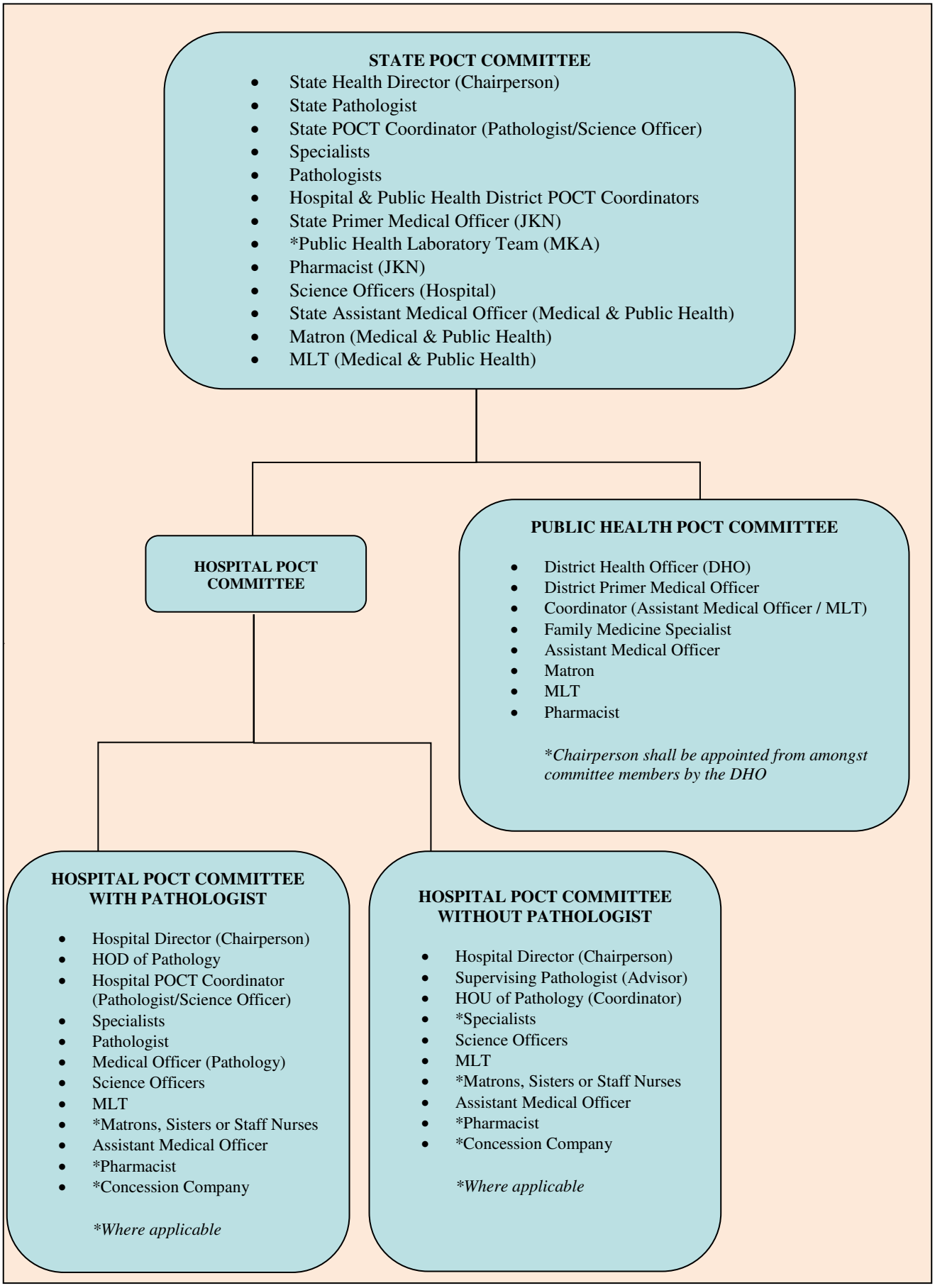

Figure 2: POCT Committee Organisation Chart at State, Hospital and Public Health Levels

3.6.3 Roles of the Hospital POCT Committee:

3.6.3.1 To develop POCT programmes at hospital level and act as a reference for POCT operators.
3.6.3.2 To review and approve proposals for POCT devices.
3.6.3.3 To ensure all new POCT SOP and devices are appropriate, clinically justified and cost effective.
3.6.3.4 To provide consultation, specifications and technical evaluations of POCT devices when required.
3.6.3.5 To coordinate training, privileging, competency assessment and reassessment of new and current personnel periodically or when requested.
3.6.3.6 To monitor quality assurances (e.g., IQC, EQA, pre-analytical requirements) and maintenance, and to provide advice on troubleshooting.
3.6.3.7 To ensure traceability of patient results obtained at POCT sites.
3.6.3.8 To keep a database of POCT devices.
3.6.3.9 To conduct and review POCT audits using standard checklists periodically at least once a year.
3.6.3.10 To ensure scheduled reviews of SOP are carried out.
3.6.3.11 To ensure adaptation, adherence and implementation of the recommended SOP and practices for maintenance and safe use of POCT devices.
3.6.3.12 To call for meeting annually or when necessary.
3.6.3.13 To analyse and submit annual Hospital POCT Committee reports to the State POCT Committee.

3.7 Summary of Roles and Responsibilities of POCT Committees

No	POCT Activity	Role & Responsibility of each POCT Committee level			
		National POCT Committee	State POCT Committee	Public Health POCT Committee	Hospital POCT Committee
	POCT Equipment & Device Procurement				
1	Review of Current Technology	/	/	/	/
2	Specifications	/	/	/	/
3	Technical Evaluation & Selection	/	/	/	/
4	Procurement Management	/	/	/	/
	POCT Device User Training & Competency				
1	Coordinate Training		/	/	/
2	Coordinate Competency Assessment			/	/
	POCT Quality Assurance Programme				
1	Review Internal Quality Control (IQC)			/	/
2	Plan and Implement External Quality Assurance (EQA)			/	/
3	Review Corrective Action			/	/
	POCT Documentations, Records & Audit				
1	Review SOP			/	/
2	Review and Report Data Collections			/	/
3	Coordinate Audit & Reports			/	/

Table 1: Summary of Roles and Responsibilities of POCT Committees

4.0 POCT Implementation at POCT Sites

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

4.1 Cost Benefit

4.1.1 Any request to provide POCT services by health programmes, facilities, units or departments, shall obtain approval through NPC / State POCT Committee / Hospital POCT Committee / Public Health POCT Committee where applicable.

4.1.2 The NPC / Hospital / Public Health POCT Committee and POCT Operator shall be involved in the evaluation of cost benefit based on cost per reportable test of the device before introducing POCT services.

4.1.3 The POCT Operator concerned shall provide financial details of the purchase. Details include direct costs of running, maintenance, consumables, quality control and service contract. Cost benefit analysis shall include all indirect costs for the POCT Committee's involvement including support, training, IQC / EQA monitoring and inevitable backup costs.

4.1.4 The cost benefit analysis shall recognise the need for device compatibility with existing POCT devices in both laboratory and other areas of the hospital. The NPC / State / Hospital POCT Committee shall be consulted by Health Programmes / Facilities / Hospital respectively about the compatibility of all POCT devices.

4.1.5 Any POCT device being considered **shall be compliant** with the POCT Committee's technical requirements.

4.2 Risk Management

4.2.1 Any POCT device introduced will have its merits and/or limitations. The POCT Operator shall recognise this and maintain accountability for any undesirable consequences or outcomes of its use, especially medicolegal implications.

4.2.2 It is essential that the risks associated with the use and interpretation of results obtained are effectively managed by training and support from the respective Public Health and Hospital POCT Committees concerned.

4.3 Health and Safety

4.3.1 The Heads of Department of clinical services in hospitals, Public Health and Pathology shall jointly develop and enforce policies consistent with current legislation and guidance. This includes 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.

4.3.2 There shall be close liaison between the Safety Officers of the testing site and the respective POCT Committees. Any untoward health and safety issues shall be forwarded to the respective Safety Officer.

4.3.3 POCT devices shall be commissioned by the Concession Company and POCT Committee according to set specifications.

4.4 Training

4.4.1 The POCT Operators' training logs and competency assessments shall be exercised. Only competent staff shall be authorised to use the POCT device.

4.4.2 Training and certification of POCT Operators shall be overseen and monitored by the POCT Committee.

4.4.3 The training course shall be specified and supervised by a qualified person provided by the Supplier of the POCT device or a trained and certified staff who has been appointed by the Hospital POCT Committee or Public Health POCT Committee to oversee training.

4.4.4 Training shall include other issues such as patient preparation, pre-analytical aspects of the test and interpretation of results.

4.4.5 Retraining / refresher courses where necessary, shall be made available to POCT Operators to maintain competency. Records of such training, retraining and competency shall be retained at the POCT site.

4.4.6 The State POCT Committee must ensure that appropriate training is provided.

4.5 Standard Operating Procedure (SOP)

4.5.1 Only authorised personnel shall carry out testing on the POCT device.

4.5.2 SOP shall be written and produced in accordance with the standards required by the National Policy and Guideline for POCT or equivalent accreditation agencies. This shall be available to users at the POCT site.

4.5.3 This document shall have instructions on safe operating practices, interpretation of error messages and results, recording of data and relevant quality control procedures.

4.5.4 The POCT Committee shall provide a standard SOP format for the POCT Operators to customise accordingly.

4.5.5 The SOP shall be authorised for use by personnel appointed by the POCT Committee. Copies of the SOP shall be made available for audits.

4.5.6 POCT sites shall work towards accreditation.

4.6 Recording and Reporting of Results

4.6.1 All patient results, IQC and EQA results shall be recorded. Records shall be traceable based on two unique identifiers, date and time of analysis, patient results, relevant QC results and the identity of the POCT Operator.

4.6.2 The POCT Operator shall ensure results are transcribed legibly without errors and informed to the authorised relevant personnel.

4.6.3 The POCT Operator shall have written procedures on the formatting, transferring, recording and reporting of results.

4.6.4 Notification and action taken on critical results shall be documented. Records shall include date, time, responsible POCT Operator, person notified and the critical result. Any difficulty encountered in meeting this requirement shall be recorded and reviewed during audits.

4.6.5 The POCT Operator shall have written procedures regarding the alteration of results showing the time, date and name of the person responsible for the change. Original entries/electronic records shall be retained and remain legible and traceable.

4.6.6 All patient results shall be treated as confidential and kept in a secure place.

4.7 Logbook: Maintenance / Training

4.7.1 The POCT site shall maintain a maintenance history of all POCT devices in accordance with MS ISO 22870 and MS ISO 15189 for management of POCT device.

4.7.2 The POCT site shall maintain a maintenance history of all POCT devices in accordance with accreditation requirements.

4.7.3 POCT Operators shall maintain all records and have them reviewed by the POCT Committee in a timely manner.

4.7.4 POCT Operators shall ensure all POCT devices are maintained on schedule to ensure safe, accurate and reliable operations. Maintenance shall be documented in a logbook.

4.7.5 All POCT Operators shall have a logbook with frequent updates on operation training and competency assessments.

4.7.6 The performance of suppliers shall be monitored and documented. Any issues related to POCT suppliers shall be reported to the POCT Committee.

4.7.7 Each device shall have a device maintenance logbook in either paper or electronic form in which details including daily maintenance, IQC results, errors, corrective actions and repairs by named individuals are documented. POCT Committee members shall have free access to these logbooks.

4.8 POCT Service Management

4.8.1 There shall be an agreement between the POCT Operators and concession companies or suppliers defining the responsibilities for maintenance, troubleshooting and repairs.

4.8.2 An inventory shall be maintained for POCT devices including serial number and unique identification, manufacturer or supplier identification, date of purchase, service history and dates when the device is out-of-service (Appendix V: BPOCT004A/2022: Registry of POCT Devices / Kits in MOH Facilities).

4.8.3 Designated POCT Operators shall be responsible for:

4.8.3.1 Day-to-day care of the device including control of environmental conditions that may affect POCT performance.

4.8.3.2 Inventory monitoring of reagents, consumables and other accessories.

4.8.4 The respective POCT Committee shall recommend the withdrawal of any POCT device or system if the device fails to meet specified analytical, critical, safety or maintenance requirements. The device shall be withdrawn from service immediately until full remedial action has been undertaken. Concession companies or suppliers shall have the responsibility of removing the device from service.

4.8.5 Users shall be informed immediately of any quality shortfalls by the respective POCT Committee.

4.8.6 The POCT Operators shall ensure that alternative sites for analysis are arranged / available in the event of device failure. It should have been agreed upon and documented.

4.9 Quality Assurance

4.9.1 General

4.9.1.1 Quality Assurance Programme (QAP) shall be the integral component of any POCT device and includes all measures taken to ensure reliable and accurate patient results.

4.9.1.2 Point-of-care testing shall comply with accreditation requirements which requires participation of POCT sites in recognised EQA schemes relevant to their test repertoire.

4.9.1.3 The State / Hospital / Public Health POCT Coordinator shall be responsible for the implementation and management of analytical quality assurance in POCT sites and provide feedback to the State POCT Committee.

4.9.1.4 The appointed POCT Committee shall be involved in clinical governance and shall carry out regular audits to ascertain the reliability and effectiveness of tests being carried out.

4.9.1.5 POCT Committee members shall have free access to IQC / EQA results.

4.9.1.6 The POCT Operator shall be responsible for purchasing of IQC and EQA scheme with the advice of the POCT Committee.

4.9.1.7 The POCT Operator shall be responsible for ensuring that the performance of the device is checked against appropriate IQC and EQA assessments.

4.9.1.8 The POCT Operator shall report any related quality issues to the respective POCT Committee as there may be legal implications.

4.9.2 Internal Quality Control (IQC)

4.9.2.1 IQC shall be performed by the POCT Operator to ensure that the POCT device performs according to technical requirements at that specific time.

4.9.2.2 The IQC material shall be stored and handled according to the manufacturer's recommendations. Calibration and IQC of the POCT devices shall be performed according to the National Policy and Guideline for POCT.

4.9.2.3 The IQC results shall be recorded and reviewed. Corrective actions shall be taken and recorded for all results that fall outside the IQC range or as presented in Levey-Jennings (LJ) chart.

4.9.2.4 The POCT Operators are responsible in documenting and keeping IQC data for monitoring and review by the POCT Committee.

4.9.2.5 The POCT Committee shall coordinate training for POCT Operators to ensure competency in performing IQC and tests.

4.9.3 External Quality Assurance (EQA)

4.9.3.1 The POCT Operator shall be responsible for the enrolment in EQA schemes where applicable (e.g., Intensive Care Unit and Emergency & Trauma).

4.9.3.2 The POCT Committee shall review the performance of EQA and discuss with the users on the appropriate action to be taken should there be any shortfalls in quality standards.

4.10 Budgetary Planning and Monitoring

4.10.1 Prior to procurement, there shall be a budget proposal inclusive of operational costs such as reagent, consumables, quality control materials (IQC & EQA), maintenance, training, technical support and other inevitable costs.

4.10.2 The State / Hospital / Public Health POCT Committee shall be responsible in monitoring and reporting cost implications to their respective Managements.

4.10.3 The POCT Operator shall be responsible in procuring POCT devices and monitoring inventory.

4.11 Complaints

4.11.1 All written complaints shall be directed to the POCT Committee for documentation purposes.

4.11.2 The Management shall be responsible for all relevant issues and take appropriate corrective actions.

POINT-OF-CARE TESTING (POCT) GUIDELINE

POINT-OF-CARE TESTING (POCT) GUIDELINE

1.0 SCOPE / USE

The scope of the present guideline relates to the management philosophy of POCT, the venues where POCT may be undertaken by any health facility, the range of results, the qualifications of 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, devices, 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 minimised. It is recommended that every MOH facility in Malaysia enforce this POCT guideline which is consistent with the POCT policy. This guideline should also be applied during disaster or crisis when applicable.

Any non-MOH regulated or private health facility is urged to use this guideline as a reference for POCT practices.

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

2.1 Formation of POCT Committee

2.1.1 Obtaining Authorisation to Coordinate POCT Services

POCT Committees shall be formed at State, Public Health and Hospital levels. Management (State Director / Public Health Officer / Hospital Director) acts as a chairperson and should be involved in point-of-care programmes. Their involvement is needed as multiple departments and budgets are involved.

2.1.2 Selecting Members of State / Hospital and Public Health POCT Committee (PHPC)

A POCT Committee shall be established in every state, hospital and Public Health facility to be responsible for all POCT services and to ensure effective monitoring of quality assurance.

The State POCT Committee, Hospital POCT Committee and Public Health POCT Committee (PHPC) will aim for accreditation. Documents published by various accreditation and regulatory agencies propose that an interdisciplinary committee be instated in any site performing POCT.

State Pathologist / HOD of Pathology / HOU of Pathology / Public Health Officer shall initiate formation of the POCT Committees. The State / Hospital / Public Health POCT Committees shall be multidisciplinary which include laboratory staffs, clinicians, nursing staffs and other non-laboratory staffs.

2.1.3 Terms of Reference

2.1.3.1 The POCT Coordinator shall:

a) Ensure that the POCT site complies with the National Policy and Guideline for POCT.

b) Ensure that relevant departments are represented and play active roles in the POCT Committee.

c) Delegate duties to all committee members and enforce the rules and requirements, as stated in the National Policy and Guideline for POCT.

d) Liaise with the Management to ensure the success and continuity of POCT services.

e) Ensure that relevant departments in the hospital / public health facility have a copy of the National Policy and Guideline for POCT which can be downloaded from the Pathology website (www.patologi.gov.my).

f) Ensure that the selection and evaluation of instruments, staff training and competency assessments, surveillance of the entire testing process, quality control and quality assurance procedures, and troubleshooting are compliant to the policy.

g) Schedule meetings with the POCT Committee and plan audits to ensure continuous compliance to the requirements.

h) Submit reports to the State POCT Committee.

2.1.3.1 Terms of Reference for Science Officer (SO) / Medical Laboratory Technologist (MLT) / PHPC

SO / MLT / PHPC shall ensure that:

a) They are responsible for the preparation of specifications, evaluations and requirements of POCT devices.

b) Training on handling of POCT devices, IQC, maintenance and troubleshooting are provided.

c) IQC / EQA / Peer Group Comparison are monitored and reviewed.

d) All activities (e.g., quality control, maintenance, troubleshooting) are recorded and the relevant documents are made available.

2.1.3.2 Terms of Reference for HOD / Person-in-Charge

HOD / Person-in-Charge shall:

a) Obtain approval for new requests for POCT tests or change of POCT devices from their respective POCT Committee.

b) Ensure there is adequate budget allocated for the running of POCT services.

c) Ensure all new POCT devices acquired at POCT sites are evaluated and verified upon commissioning.

d) Ensure all Operators are trained and competent to perform testing according to SOP.

e) Ensure daily IQC, EQA and maintenance activities are performed as scheduled.

f) Ensure all related POCT activities are recorded, documented and maintained.

g) Be involved in all Quality Assurance activities suggested by the Committee to improve on-site analysis for better patient management.

h) Review and verify all data submitted to the respective Hospital POCT Committee or PHPC.

2.1.3.3 Terms of Reference for POCT Operator

POCT Operator shall:

a) Attend training and competency sessions to ensure that testing is performed in accordance with the SOP.

b) Be responsible for the purchasing of reagents, consumables, IQC and EQA; and monitoring of inventory.

c) Perform IQC and EQA as scheduled.

d) Carry out maintenance activities as recommended.

e) Report any problems related to the devices to their respective HOD / Person-in-Charge.

f) Record and document all activities including patient results, IQC and EQA results, maintenance, troubleshooting and corrective action.

g) Ensure all records and related documents are maintained.

h) Collect all required data and submit to the respective Hospital POCT Committee or PHPC.

2.1.3.4 Terms of Reference for Supplier / Concession companies of POCT devices and materials

Suppliers / *Concession companies shall adhere to the National Policy and Guideline for POCT for the following:

a) Procurement of POCT devices.

b) Provision of training to all POCT Operators.

c) Provision of scheduled preventive maintenance and troubleshooting whenever required as part of the after sales services. Supplier / Concession companies shall be fully responsible for the preventive and corrective maintenance, where applicable.

d) Provision or supply of IQC and EQA; or peer group comparison programmes to POCT sites with no EQA programme.

*(a) and (d) not applicable

2.2 Review of POCT Devices at All Sites by the POCT Committee

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

2.3 Request for POCT Service

2.3.1 Evaluation of Proposed POCT Device

2.3.1.1 Selection Criteria of POCT device

There is a wide variety of POCT devices available for measuring tests. However, the sheer number and diversity of instruments can lead to confusion, incorrect decisions, and inappropriate applications. This can result in financial inefficiency and loss of opportunity to improve patient care.

Before a POCT device is placed, a request shall be made through the POCT Committee, using the workflow below (**Figure 3**). BPOCT001A/2022: Request for Approval of New POCT Test / Change of POCT Device form (Appendix I) shall be utilised for any new POCT request or change in POCT device.

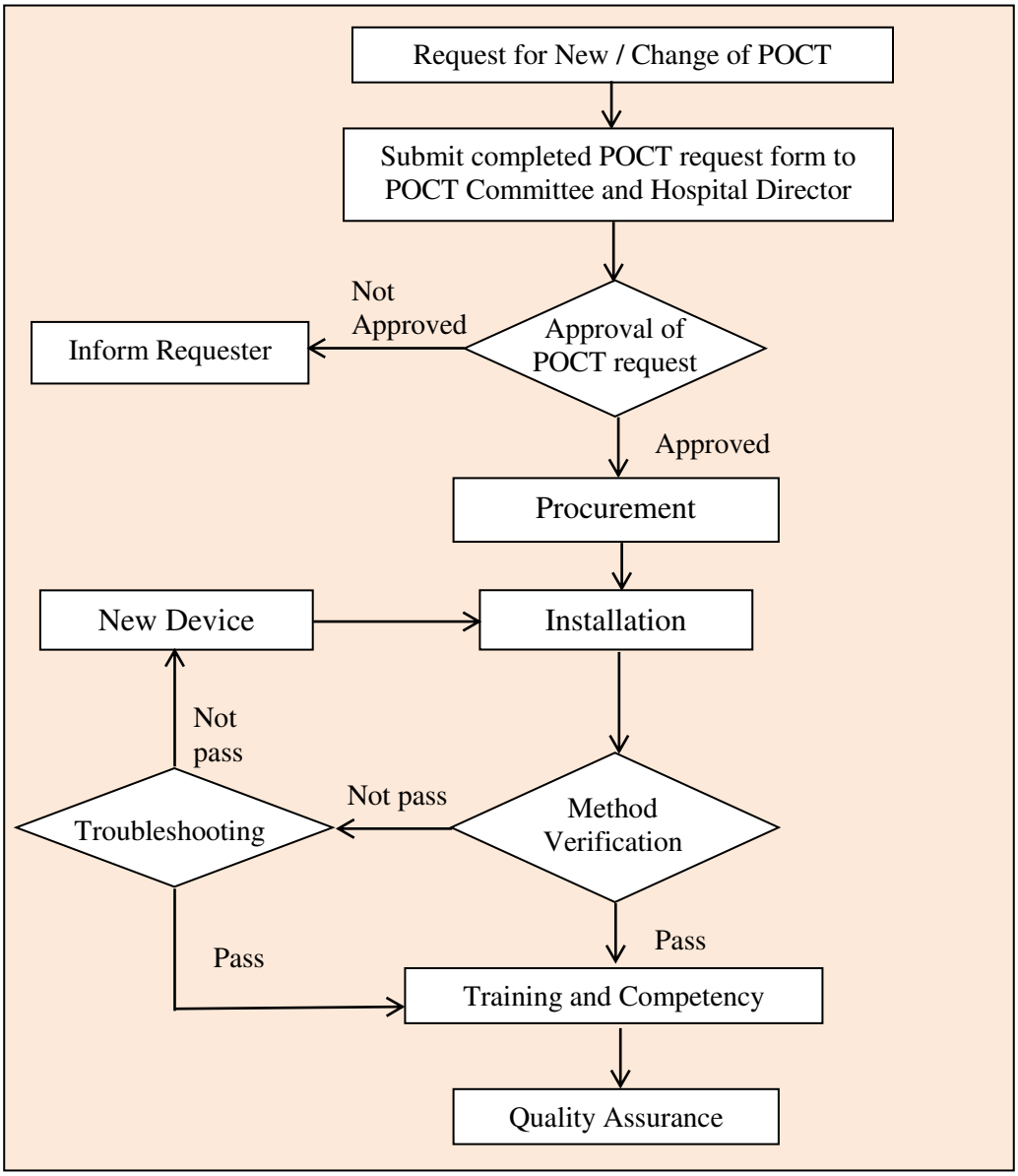

Figure 3: Flowchart on Implementation of POCT Service

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

Criteria		Concerns
1	Justification to introduce POCT service	Short turnaround time
		Improves patient care: • Reduced length of stay • Patient convenience
		Number of tests available
		Methodology
		Sample stability
2	Sufficient space availability	The amount of space available for instruments, consumables, storage and paperwork should be considered including fridge / freezer.
3	Ease of use	User friendly to operators
		Power / network requirements
		Minimal maintenance required
4	Sample type	Whole blood preferred
5	Sample volume	Minimum volume required
6	Expiry date of consumables	Adequate workload to ensure that consumables / reagents shall be used before expiry
7	Testing throughput	Sufficient workload to ensure ongoing operator competency
8	Peer comparison	Results comparability with local laboratory. This is particularly important if both laboratory and POCT results are used to assess the same patient.
9	Connectivity	Results can be transferred electronically to patient records
10	Barcode	Barcoding capability for patients, operator and consumables
11	Quality	Precision and accuracy should be appropriate for clinical needs
		Appropriate internal quality control materials are available
		Appropriate external quality assurance programmes are available
12	Portability	If moving of device is required, portability should meet requirements
13	Services contract	Access to ongoing services and support and terms of contract
		Training and training materials are provided by the supplier
		What is the length and terms of warranty offered for the device?
		Provision of after sales service
14	Supplier evaluation	Reliability of supplier
		Availability of helpline
		Training available post-procurement e.g., refresher course
15	Budget	Capital expenditure
		Affordability
		Sufficient running costs including maintenance, consumables, quality control, quality assurance materials and connectivity

Table 2: Criteria for Selection of POCT Device / System

2.3.1.2 Technical Evaluation of Proposed POCT Device

Evaluation	Criteria
Methodology: What methodology is used for each test? Further evaluation for its fitness for purpose shall be carried out by the Pathology Department	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
Certification and registration	a. Device must be approved by a certified body e.g., CE, FDA b. Device shall be registered under the Medical Device Act 2012
Cost	a. Reduction in admission rate b. Reduction in length of patient stay following early treatment c. Costs of training operators and maintenance of competency d. Labour costs associated with processing and analysing specimens e. Labour associated with device maintenance f. Annual reagent, control, maintenance and depreciation costs g. Costs of EQA / proficiency programmes

Table 3: Criteria for Technical Evaluation of Proposed POCT Device

2.3.2 Approval and Procurement

2.3.2.1 Procurement of all POCT devices is subject to the criteria described in clauses 2.3.1.1 and 2.3.1.2 of this document irrespective of whether the device is purchased (including from endowment funds), hired, loaned, reagent rented, placed or received as a donation.

2.3.2.2 Any proposal of POCT service shall be presented to the POCT Committee for evaluation and approval before submission to the Hospital Director, State Health Department or Ministry of Health for financial support.

2.3.2.3 The Quality & Benefit Analysis of proposed POCT service shall detail all the quality and financial 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 POCT sites in providing 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.

2.3.2.4 When funding has been identified, operational specifications (technical and clinical) shall be drawn up jointly by the POCT Committee and the proposed HOD / Person-in-Charge.

2.3.2.5 The supplier shall then be invited to submit their tender participation. Short-listed suppliers shall be allowed to perform demonstration and/or trial of their POCT device at the proposed POCT site or laboratory.

2.3.2.6 The POCT Committee shall evaluate the technical quality of the device and any interfacing requirements.

2.3.2.7 The final selection shall be vetted by the POCT Committee.

2.3.2.8 Once the selected POCT device has been installed, a complete verification process shall be performed assisted by the POCT Committee using the suggested protocol.

2.4 Training and Competency

2.4.1 Staff Training

2.4.1.1 All POCT Operators shall be trained and be competent to use the POCT device. The training and competency shall be overseen and monitored by the HOD / Person-in-Charge.

2.4.1.2 Training and certification of POCT Operators shall be regularly assessed by the POCT Committee.

2.4.1.3 There shall be training and competency records at the POCT site to ensure training, registry of staff trained, competency assessments, monitoring of training and retraining are documented.

2.4.1.4 Components of POCT staff training programmes shall include pre-analytical, analytical and post-analytical aspects of the testing.

2.4.1.5 Supplier shall modify and deliver training programs to suit local needs.

2.4.1.6 Training shall cover the following (but not limited to) topics listed in **Table 4**:

No	SCOPE	
1	THEORY	
	1.1	Method / principle of test
	1.2	Handling and preparation of reagent / test strip / cassette
	1.3	Proper storage conditions for strips / cassette / reagent
	1.4	Calibration
	1.5	Internal Quality Control
	1.6	External Quality Programme / Peer Group comparison
	1.7	Maintenance
	1.8	Understanding error messages
	1.9	Basic troubleshooting
	1.10	Test limitations and interferences
	1.11	Health and Safety regulations and compliance
	1.12	Patient preparation requirements
	1.13	Sample collection procedures
	1.14	Result interpretation & clinical decision limits
	1.15	Incident reporting and adverse event
2	PRACTICAL SESSION	
	2.1	Maintenance
	2.2	Calibration
	2.3	Internal Quality Control
	2.4	Sample collection procedures
	2.5	Sample analysis – how to perform the test on the device according to manufacturer's instructions
	2.6	Interpretation and recording of POCT results

Table 4: Scopes of Training

2.4.2 Training Manual

2.4.2.1 A training manual, either in hard copy and/or electronic form, should be provided to all POCT Operators attending training.

2.4.2.2 Training manuals shall include simple instructions rather than scientific and analytical concepts that can be readily understood by non-laboratory staffs.

2.4.2.3 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 IQC and EQA testing procedures into a practical, workable format can also be used effectively as part of a training package.

2.4.3 POCT Operator Competency

2.4.3.1 Successful trainees shall receive a competency certificate on completion of training and competency assessment.

2.4.3.2 Only trained and competent staff shall be permitted to perform the POCT test.

2.4.3.3 Post-training surveillance of competency shall be undertaken by conducting regular reviews of quality control and quality assurance testing results.

2.4.3.4 Competency shall be determined by written and/or practical assessments and documented in a logbook.

2.4.3.5 Competency shall be assessed in a practical sense by both the successful conduct of a routine POCT test (ideally the entire testing procedure and not just analytical) in the presence of the POCT Operator and by a written assessment through a series of short questions to ensure key theoretical concepts have been grasped.

2.4.3.6 Competency shall be formally and regularly reviewed through retraining, reassessments and participation in education updates.

2.4.3.7 Echo training shall be conducted by certified POCT Operators to provide practical hands-on experience and confidence to the trainee prior to commencing patient testing.

2.4.3.8 Attendance at training and retraining sessions is mandatory. These sessions may be conducted on-site, at regional workshops or at annual workshops.

2.4.3.9 If the POCT Operator fails a competency review (e.g., poor IQC / EQA performance, level of testing activity below minimum requirements or high rate of analytical errors), retraining should be conducted prior to re-certification.

2.4.3.10 Registry of trained staff and renewed competency certificates should be prepared and maintained by the POCT Committee.

2.5 Monitoring QAP and Troubleshooting

2.5.1 Internal Quality Control (IQC)

2.5.1.1 IQC is defined as a set of planned and systematic activities focused on assessing the whole testing process to provide accurate and reliable results.

2.5.1.2 IQC protocols for POCT should be defined based on risk management. The protocol is dependent on device complexity and availability of inbuilt system checks, and the risks associated with release of an incorrect patient result.

2.5.1.3 Low complexity devices include testing that provides qualitative, semi-quantitative or quantitative results utilising cassettes, strips or cards.

2.5.1.4 Moderate complexity devices have multifaceted internal parts and/or interface and produce quantitative results.

2.5.1.5 IQC processes differ between quantitative and qualitative methodologies.

2.5.1.6 IQC for quantitative and qualitative testing shall be performed when:

- The lot number of consumables changes
- There is a new delivery of consumables
- An operator lacks confidence in a patient result
- The healthcare professional deems that the POCT result does not fit the patient's clinical picture
- Substantial maintenance procedures have been carried out on the device
- The device has suffered a physical insult (e.g., dropped, undergone temperature extremes)

2.5.1.7 Electronic QC is a check of the device's measurement signal only and does not check the analytical part of the system. Therefore, it is complementary to liquid QC requirements and not a substitute for the minimum QC requirements outlined in this document.

2.5.1.8 IQC for Quantitative POCT

a. In general, instead of testing on the patient's sample, the test is done using IQC material.

b. IQC material may be provided either by the manufacturer of the POCT device (first party IQC) or by a registered external provider of quality assurance program (third party IQC).

c. IQC material has a target value and range to assess the acceptability and performance of the test being measured. The target value and range can be either predetermined by the manufacturer or established by the POCT Operator.

d. Different IQC lots may have different target values and ranges.

e. The results of IQC testing shall be within the range before it can be used for testing of patient sample.

f. However, if the IQC result falls outside the range, corrective action shall be carried out.

g. All IQC results and corrective action taken shall be recorded electronically or manually for traceability.

h. For the set of IQC data obtained, mean and standard deviation can be calculated. Levey-Jennings Chart can be plotted either manually by the Operator or automatically by devices that have auto-plotting feature.

i. The key performance indicator for IQC testing is imprecision, which is the degree of reproducibility expressed as coefficient of variation (CV).

j. Coefficient of variation (CV) is calculated using the formula:

1. CV% = (Standard Deviation / Mean) × 100%; where:

2. Mean, $\bar{x} = \frac{\Sigma x_i}{N}$

3. Standard Deviation, SD = $\sqrt{\frac{\Sigma (x_i - \bar{x})^2}{n - 1}}$

Some devices may calculate CV% automatically based on the data stored in the device.

k. As a general rule, the smaller the CV%, the better the performance of the device.

2.5.1.9 IQC for Qualitative POCTs

a) In general, qualitative POCT (e.g., HIV, Hepatitis, Dengue, Malaria, Urine Pregnancy Tests, Urine Chemistry Dipstick) do not yield any numerical values and only show qualitative results such as Positive/Detected/Reactive, Negative/Not Detected/Non-Reactive or Equivocal.

b) These tests utilise immunochromatographic method with inbuilt IQC.

c) Inbuilt IQC ensures adequacy of specimen volume and solution flow.

d) When the inbuilt IQC line does not develop, the test result for the patient is invalid thus shall not be reported. Institute corrective action and repeat the test. If a second invalid result occurs, evaluate with external or known controls.

e) External control (positive and negative controls) is available from the manufacturer supplying the qualitative POCT device. These known controls are used to evaluate the performance of the device and to check if the test is performed correctly.

2.5.2 Documentation of IQC Results

2.5.2.1 IQC results must be recorded and monitored. (Appendix X: BPOCT009A/2022: Internal Quality Control Data Record (Quantitative) and Appendix XI: BPOCT009B/2022: Internal Quality Control Data Record (Qualitative) is/are to be used where applicable).

2.5.2.2 When the POCT device provides incorrect IQC results, corrective action shall be taken and the subsequent results/findings after retesting shall be recorded in the IQC monitoring log.

2.5.2.3 The POCT Committee shall be informed and is responsible in assisting if required. Troubleshooting assistance from the supplier of the POCT device shall be sought when necessary. All corrective actions shall be documented.

2.5.3 Frequency of IQC Testing

IQC testing frequency is based on device complexity (refer Table 5).

2.5.3.1 For low complexity devices, a minimum of one liquid quality control (QC) sample shall be tested each month or as suggested by the manufacturer or based on risk assessment done by the facility. It is recommended that if only one QC sample is run, it should have a concentration in the clinically relevant range for the analyte being measured. If two levels of QC are available, then control samples with both normal and abnormal levels should be run.

2.5.3.2 For moderate complexity devices, a minimum of two liquid QC samples should be tested each month or as suggested by the manufacturer or based on risk assessment done by the facility. These two QC samples should include normal and abnormal levels.

2.5.3.3 For higher complexity devices, daily multilevel QC equivalent to laboratory-based system shall be performed.

Low Complexity (Strip Technology)		Moderate Complexity (Cartridge Technology)	High Complexity
Without automatic reader	With automatic reader		
Urine Biochemistry (Dipstick)	Glucose (Glucometer)	Creatinine (Cartridge)	Blood Gases
Urine Pregnancy Test	Cholesterol (Cholesterol Meter)	Lactate	Full Blood Count
Urine Drug of Abuse Test	Creatinine (Creatinine Meter)	C-Reactive Protein	Bilirubin (Bilirubinometer)
Urine Alcohol	Ketone (Ketone Meter)	Creatine Kinase-MB	Urine Biochemistry (Urine Analyser)
HIV 1/2 Rapid Test	Haemoglobin (Haemoglobinometer)	Cardiac Troponin	
Dengue Rapid Test	PT/INR (Coagulometer)	Beta Natriuretic Peptide (BNP / NT-ProBNP	
Hepatitis B Surface Antigen Rapid Test		Viscoelastic assays (Thromboelastography Thromboelastometry and Sonoclot)	
Hepatitis C Antibody Rapid Test		CD4	
COVID-19 Antigen Rapid Test		HbA1c	
Leptospira Rapid Test			
Chikungunya Antibody Rapid Test			
Syphilis Rapid Test			
SARS-CoV-2 Antibody Rapid Test			
Measles Antibody Rapid Test			

Table 5: Type of POCT Device / Kit Based on Test Complexity

2.5.4 External Quality Assurance (EQA)

2.5.4.1 EQA, sometimes referred to as Proficiency Testing, is an essential part of assuring the quality (accuracy) of the overall testing process.

2.5.4.2 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.

2.5.4.3 All participating POCT sites are required to analyse an identical unknown specimen on their POCT device and submit obtained results to the EQA provider.

2.5.4.4 In return, the EQA provider sends a report to the HOD / Person-in-Charge detailing their performance.

2.5.4.5 EQA complements IQC in assuring the POCT Operator and patient on test result validity.

2.5.4.6 If there is any shortfall in EQA performance, immediate corrective action shall be taken.

2.5.4.7 All EQA results and corrective action taken must be reviewed, recorded and documented.

2.6 Documentation and Records

2.6.1 Standard Operating Procedures (SOPs) and Additional Supporting Documents

2.6.1.1 SOPs shall conform to ISO standards or National Policy and Guideline for POCT with a mechanism for regular revision. A copy shall be retained near the device for convenient access.

It should provide clear and precise instructions on:

a) Methodology
b) Technical operations
c) Health and safety
d) Specimens required, request/sample identification criteria (two 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

2.6.1.2 The format and content of SOPs should follow recommendations by the POCT Committee. A master copy of the SOP shall be held by the POCT Coordinator and be available to the POCT Committee, ISO auditor or equivalent accreditation agencies.

N.B., when necessary, the SOP format may be customised accordingly depending on the device and location of testing.

2.6.1.3 Other documents shall be stored together with the SOP i.e., POCT device maintenance log, Manufacturer Operator Manuals, National Institute for Occupational Safety and Health and Risk Assessments, relevant MDA notices and list of certified POCT Operators.

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

2.6.2 Recording and Reporting of Results

2.6.2.1 All patient results shall be appropriately recorded.

2.6.2.2 Records shall include unequivocal patient identity with 2 unique identifiers (patient name and registration number or Identity Card number), date and time of analysis, test results obtained, relevant QC results and the identity of the Operator. Management of these records is the responsibility of the POCT Operator and the POCT Coordinator / Committee shall have free access to all data.

2.6.2.3 A more permanent record of documentation in the patient notes or a standard worksheet shall replace reports issued by POCT devices. Reports may be in the form of paper or electronic in the case of devices with information management connectivity.

2.6.2.4 All patient results shall be treated as confidential and kept in a secure place. If results are stored in a computer system, local rules on access to the system, whether stand-alone or networked, should be maintained.

2.6.2.5 Whenever error or non-conformity is detected in the result produced from the POCT device, the result shall be recalled and the requester notified as soon as possible. Investigation shall be carried out and the incident documented.

2.6.2.6 POCT results shall have clear delineation / be distinguished from the patients' laboratory results.

2.6.3 Records and Retention Time

All records shall be retained for the length of time specified in the latest edition of Guideline on Retention of Pathology Records and Materials.

Type of Record	**Retention Time**
Standard operating procedure	Lifetime of SOP in use + 1 year
Maintenance, service & repair report	Lifetime of POCT device + 1 year
Daily, weekly and monthly maintenance logs	1 year
POCT training record	Period of employment
POCT Operator competency	7 years
All IQC & EQA records	3 years
Specimen	Discard after issuance of result
Cartridge/strip/card	Discard after issuance of result

Table 6: Retention Time of Records

3.0 EVALUATION OF POCT ACTIVITIES

Point-of-care testing activities shall be monitored and evaluated minimally, at least once a year to assure that the activity is meeting customer needs. The POCT Committee may accomplish this by monitoring and reviewing areas as detailed in the following table:

NO	AREAS	DETAILS OF ASSESSMENT
1	Environment	Suitable location
		Adequate space
		Suitable temperature for analysis
		Accessible by POCT Operator
2	Device Management	
	2.1 SOP	Available on site
	2.2 Maintenance	Daily / weekly / monthly maintenance performed
		Maintenance log updated
		Planned preventive maintenance
	2.3 Breakdown	Record of breakdown / downtime (length of time)
		Record and documentation of troubleshooting / corrective action
3	Quality Activity	
	3.1 IQC Implementation	Frequency of IQC – following recommendation in guideline
		IQC review – dated and signed
		Corrective action and troubleshooting
		Proper record and documentation of QC lot, and acceptable range and mean
	3.2 EQA / Peer Group Comparison	Participation in EQA / peer group comparison programs
		EQA review – dated and signed
		Corrective action and troubleshooting
		Proper record and documentation
4	Sample	Proper sample handling
		Use of correct container / preservative
		Disposal of sample
5	Results Management	Reporting of results – at least 2 unique identifiers
		Results traceability
		Recording of results onto patients record / file
6	Training and Competency	All operators trained
		Updated training records
		Updated competency records
		Updated list of competent operators
7	Storage of Reagents / QC Materials / Consumables	Appropriate storage temperature
		Monitoring and charting of storage temperature
		Updated bin card / KEW card
		Recorded open date
		Recorded expiry date
8	Health and Safety	Appropriate Personal Protective Equipment (PPE)
		Biohazard waste bin

Table 7: Audit Checklist

4.0 CONCLUSION

It is important that each hospital or health clinic has a clearly defined and well-structured approach to running and maintaining POCT services to ensure accordance with the POCT policy.

It is recommended that this guideline is adopted by not only hospitals and public health facilities in MOH, but also private health institutions, university hospitals and military health facilities. 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 to achieve accreditation standards.

POCT IN EMERGENCY AND DISASTER PREPAREDNESS, RESPONSE AND RECOVERY

POCT IN EMERGENCY AND DISASTER PREPAREDNESS, RESPONSE & RECOVERY

1.0 INTRODUCTION

Malaysia potentially faces public health adverse events and new health threats such as emerging and re-emerging infectious agents (emerging diseases e.g., pandemic Influenza, MERS-CoV, Ebola, Zika; re-emerging diseases e.g., Polio and Tuberculosis) as well as sudden environmental changes. Floods and landslides are also significant although their effects are limited to prone areas. Radiation disaster is covered in other guidelines.

Enhanced healthcare delivery in complex emergencies and disasters can improve crisis standard of care. Recent events in other countries have emphasised the role and feasibility of POCT as a diagnostic tool during times of disaster. During a disaster, the health system may be overwhelmed or disrupted hence healthcare delivery can be augmented by efficient POCT services. The utilisation of POCT by emergency medical responders provides rapid diagnostic data that facilitate triage and improve management of victims.

2.0 SCOPE

This chapter covers the roles played by the National POCT Committee (NPC) in assisting POCT management during Emergency and Disaster and ensuring compliance to POCT Policy and Guidelines.

3.0 DEFINITIONS

Disaster is a serious disruption of the functioning of society, causing widespread human, material or environmental losses, that exceeds the local capacity to respond, and calls for external assistance (CDC Atlanta).

4.0 TYPES OF DISASTER

4.1 Communicable Disease Outbreak / Pandemic Event

Disaster due to communicable disease outbreak relates to any outbreak incident which is caused by communicable diseases occurring suddenly and in an unprecedented manner with negative implications on health, social well-being and economy.

4.2 Mass Casualty Incident (MCI)

MCI-linked disasters are incidents involving a large number of victims, substantial loss of lives and associated disruption and breakdown of health service infrastructure.

4.3 Environmentally Linked Disaster

Environmentally linked disasters result from an incident or series of natural geophysical events such as volcanic eruptions, landslides, floods, haze, storms, tsunami and human activities. These incidents cause disruptions to societal activities and government businesses, loss of lives, destruction of property, economic losses and environmental disturbance beyond the human capacity to overcome requiring intensive utilisation of resources.

4.4 Chemical, Biological, Radiological and Nuclear Explosives (CBRNe)

Any incident involving the use of CBRNe agents such as chemical and/or biological and/or radioactive and/or explosive materials which can threaten the lives and health of a large number of people.

4.5 Health-related Crisis

Sequence of events following a public health threat, where limited time for decision-making and large degree of uncertainty lead to overburdening of normal responses and undermining of authority.

5.0 PHASES OF DISASTER

There are four phases of disaster:

1. Mitigation Phase
2. Preparedness Phase
3. Response Phase
4. Recovery Phase

6.0 Terms of Reference for National POCT Committee (NPC) during Emergency & Disaster

a) To assist in preparedness of POCT management during emergency and disaster.
b) To provide related consultation and technical input on POCT devices utilised during emergency and disaster.
c) To offer guidance on standardisation of POCT devices.
d) To ensure that the masterlist of POCT devices / supplier registry is available and updated.
e) To assist in the procurement of relevant POCT devices.
f) To advise on the appropriate use of POCT tests and device utilisation.

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8.0 ABBREVIATIONS

AMO	Assistant Medical Officer
CE	*Conformité Européenne*, meaning "European Conformity"
CPRC	Crisis Preparedness and Response Centre
DCD	Disease Control Division
DHO	District Health Office
EQA	External Quality Assurance
FBC	Full Blood Count
FDA	US Food and Drug Administration
FHDD	Family Health Development Division
FMS	Family Medicine Specialist
HOU	Head of Unit
ICT	Information & Communication Technology
IQC	Internal Quality Control
LIS	Laboratory Information System
MKA/K	Makmal Kesihatan Awam/Kebangsaan (National Public Health Laboratory)
MLT	Medical Laboratory Technologist
MO	Medical Officer
MOH	Ministry of Health
MSQH	Malaysian Society for Quality in Hospitals
POCT	Point-of-Care Testing
NPC	National POCT Committee
PHPC	Public Health POCT Committee
QAP	Quality Assurance Programme
SHD	State Health Department
SO	Science Officer
SOP	Standard Operating Procedure
TAT	Turnaround Time

9.0 GLOSSARY

POCT Advisor	A person who provides advisory support on POCT services through regular contact with POCT Committees and Operators.
Concession company	Company with the right to operate a specific business within the government's jurisdiction subject to certain terms.
POCT Coordinator	A person who is responsible in organising, managing and planning POCT events or activities to ensure POCT services run smoothly and effectively.
POCT Device	Equipment used outside the laboratory to perform medical diagnostic testing.
Person-in-Charge	A person who is responsible in leading and managing POCT activities to achieve the highest possible standards of excellence in all its activities.
POCT Operator	Any person who is trained and competent in handling a POCT device whether it is used directly to produce results, for maintenance or for quality control. This includes clinicians, nursing staff, healthcare assistants and healthcare scientists.
Supplier	A person or organisation that provides and delivers products / services to the requester.

10.0 APPENDICES

Appendix I

BPOCT001A/2022

REQUEST FOR APPROVAL OF NEW POCT TEST/CHANGE OF POCT DEVICE FORM

All point-of-care testing must be evaluated and approved by (NAME OF HOSPITAL) POCT Committee to ensure that it meets institutional goals as well as state and national regulations. To expedite your request, please complete all information below. Please attach all pertinent documents (brochure/pamphlet/journals etc) and supplier/vendor profile to this form and submit to:

(NAME OF HOSPITAL) POCT Coordinator, Attn: …….....

1) Test and device requested (Please tick)

☐ Device (please specify): _____ Quantity: _____

☐ Test (please specify): _____

2) Justification

_____

_____

_____

(*To be filled if requesting for change of POCT device*)

☐ Name(s) of current device(s): _____

3) Method of procurement:

☐ Reagent rental

☐ Asset

4) POCT device/analyser/rapid test kit specifications*

☐ Easy to use: YES / NO

☐ Size (dimension): _____

☐ Portability: YES / NO

☐ Maintenance requirement: YES / NO

☐ Storage temperature: _____

☐ Internal Quality Control availability: YES / NO

*Where applicable

5) Reagent/strip/consumable specifications*

☐ Ready to use: YES / NO

☐ Shelf-life duration: _____

☐ Onboard stability duration: _____

☐ Storage temperature: _____

☐ Internal Quality Control availability: YES / NO

*Where applicable

6) Location of POCT device

☐ Space availability: _____

☐ Electrical requirements: _____

☐ Network requirement (if applicable): _____

☐ Other requirements: _____

7) Estimated annual test volume:

8) Personnel

- Estimated number of potential users: _____
- Job categories of potential users: _____

_____

9) Estimated cost (inclusive of verification study) _____

- One-off

1	Device cost	
2	Renovation (if any)	
	Total	

- Operational cost (Annually)*

1	Reagents	
2	Calibrators	
3	Internal Quality Control Material	
4	External Quality Assurance Programme	
5	Consumables	
6	Maintenance	
7	Training	
	Total	

*Where applicable

Requester:

Name: _____ Signature and Stamp:

Designation: _____

Department: _____

Telephone No.: _____

E-mail: _____

Date: _____

For POCT Committee Use Only

(To be completed in 2 weeks after receipt)

Reference Number

Date of receipt: _____ Signature and stamp:

Name: _____

Designation: _____

Date of evaluation: _____ Signature and stamp:

Name: _____

Designation: _____

Request Approved: YES / NO

Comments:

_____

_____

_____

Name: _____ Signature and stamp:

Designation: _____

Date: _____

Appendix I (Example)

BPOCT001A/2022

REQUEST FOR APPROVAL OF NEW POCT TEST / CHANGE OF POCT DEVICE FORM

All point-of-care testing must be evaluated and approved by (NAME OF HOSPITAL) POCT Committee to ensure that it meets institutional goals as well as state and national regulations. To expedite your request, please complete all information below. Please attach all pertinent documents (brochure/pamphlet/journals etc.) and supplier/vendor profile to this form and submit to:

(NAME OF HOSPITAL) POCT Coordinator, Attn: Dr Ahmad Kamal

1) Test and device requested (Please tick)
   - [√] Device (please specify): i STAT Quantity: 1
   - [√] Test (please specify): Blood Gases & Electrolytes

2) Justification
   To be used in participated international medical event i.e., Motor GP (yearly event) and Critical Patient Escort and Retrieval (CPERT) ambulance service.

   (*To be filled if requesting for change of POCT device*)
   - ☐ Name (s) of current device (s): Not applicable (NA)

3) Method of procurement:
   - [√] Reagent rental
   - [ ] Asset

4) POCT device/analyser/rapid test kit specifications*
   - ☐ Easy to use: YES / ~~NO~~
   - ☐ Size (dimension): 7.68 (W) x 23.48 (L) x 7.24 (D) in cm
   - ☐ Portability: YES / ~~NO~~
   - ☐ Maintenance requirement: ~~YES~~ / NO
   - ☐ Storage temperature: Room Temperature
   - ☐ Internal Quality Control availability: YES / ~~NO~~

   *Where applicable

5) Reagent/strip/consumable specifications*
   - ☐ Ready to use: YES / ~~NO~~
   - ☐ Shelf-life duration: 3 to 5 months
   - ☐ On board stability duration: 2 weeks to 2 months
   - ☐ Storage temperature: Room Temperature

   *Where applicable

6) Location of POCT device
   - ☐ Space availability: Minimal space is needed
   - ☐ Electrical requirements: Battery operated
   - ☐ Network requirements (if applicable): Not required
   - ☐ Other requirements: Nil

7) Estimated annual test volume: 1500
8) Personnel
   - ☐ Estimated number of potential users: 50 staffs
   - ☐ Job categories of potential users: CPERT ambulance service personnel,

9) Estimated cost (inclusive of verification study)

☐ One-off

1	Device cost	RM 41,000.00
2	Renovation (if any)	N/A
Total		

☐ Operational cost (Annually)*

1	Reagents	RM 60,000.00
2	Calibrators	N/A
3	Internal Quality Control Material	Blood gas & RP: RM7200 for 3 boxes (2 levels)
4	External Quality Assurance Programme	N/A
5	Consumables	Printer paper : RM67/pkt Ultralife Battery: RM546 for 2 boxes
6	Maintenance	FOC
7	Training	FOC
Total		RM 65,013.00

*Where applicable

Requester:

Name	Dr Alina Ahmad	Signature and Stamp:
Designation	Emergency Physician UD56	
Department	Emergency and Trauma	
Telephone No.	03-33338890 ext 3452	
E-mail	alina@yahoo.com	
Date:	20th March 2017	

For POCT Committee Use Only
(To be completed in 2 weeks after receipt)

Reference Number: 2/2017

Date of receipt:	20th March 2017	Signature and stamp:
Name:	Dr Alidah Hashim	
Designation:	Chemical Pathologist UD54	
Date of evaluation:	30th March 2017	Signature and stamp:
Name:	Pn Halimah Daud	
Designation:	Science Officer C48	

Request Approved: YES / ~~NO~~

Comments:

Requested test is justified. Running budget is borne by the Department. Technical evaluation findings show good performance and user-friendly device.

Name:	Dr Farid Kamil	Signature and stamp:
Designation:	POCT Coordinator, Head of Department of Pathology, HTAR	
Date:	20th April 2017	

Appendix II

BPOCT001B/2022

EVALUATION CHECKLIST FOR NEW POCT TEST / CHANGE OF POCT DEVICE

(To be filled up by the POCT Committee)

Name of requester :
Location and name of facility :
Proposed POCT Device :
Proposed Test :
Date of Request :

No	Criteria	Concerns	Yes	No	Remark / Comment
1	Patient related - immediate and improved patient care	Turnaround time			
		Reduction of length of stay			
		Patient convenience			
2	Technical specifications	Method			
		Precision			
		Sensitivity			
		Specificity			
		Interference			
		Linearity			
		Batch vs discrete technology			
		Reagent and control stability			
		Reagent and control storage requirements			
		Quality control requirements			
		Correlation			
3	Location of device	Space availability (the amount of space available for instruments, consumables, storage and paperwork should be considered, including fridge / freezer space required)			
		Environmental (temperature/humidity etc.)			
		Electrical requirements			
		Network requirements (if applicable)			
4	Device specifications	Ease of use			
		Size			
		Throughput			
		Number of test menu			
		Portability of POCT device			
		Barcode capability for patients, operator and consumables			
		Minimal maintenance requirements			
		Results can be transferred electronically to patient records			
5	Reagent/strip/consumable specifications	Ready to use			
		Expiry date			

		On board stability. Adequate workload to ensure that consumables / reagents shall be used before expiry			
6	Sample requirements	Sample type: Serum/Plasma /Whole blood /Urine/Body Fluid			
		Sample volume: Adult/Paediatric patients			
		Sample stability			
7	Workload per year	Estimated annual test volume			
8	Quality Assurance	Peer comparison (Related documents i.e., journal, evaluation reports)			
		Availability of appropriate internal quality control materials			
		Availability of appropriate external quality assurance program			
9	Services contract	Access to ongoing services and support			
		Training and training materials provided by supplier			
		Maintenance			
		After sales service			
10	Supplier evaluation	Reliability of supplier			
		Availability of supplier helpline			
		Training available post-procurement e.g.: refresher course			
11	Budget	Capital expenditure			
		Affordability			
		Operational costs (including maintenance, consumables, quality control, quality assurance materials and connectivity costs)			
12	Certification and registration	Device must be from a certified body e.g., CE, FDA			
		Device shall be registered under Medical Device Act 2012			

COMMENT/ RECOMMENDATION

Evaluated by :	Verified by :	Approved by :
Name :	Name :	Name :
Designation :	Designation :	Designation :
Date :	Date :	Date :

Appendix III

BPOCT002/2022

LIST OF POINT-OF-CARE TESTING COMMITTEES

Location and name of facility: _____

No	Name	Designation	Contact Number	Email Address

Prepared by :

Name :

Designation :

Date :

Approved by :

Name :

Designation :

Date :

CHECKLIST FOR POCT AUDIT **BPOCT003/2022**

Name & Location: _____

Name of Auditor*: _____

**Auditor for Health Facilities = Competent personnel assigned by Officer-in-Charge*

Date: _____

	POCT Device:		**Device 1**	**Device 2**	**Device 3**	**Device 4**
No	**Areas**	**Details of Assessment**	****Findings & Comments**			
1	Environment					
		Suitable location				
		Adequate space				
		Suitable temperature for analysis				
		Accessible by user				
2	Device Management					
	2.1 Maintenance	Daily / weekly / monthly maintenance performed				
		Maintenance log updated				
		Planned Preventive Maintenance				
	2.2 Breakdown	Records of breakdown / downtime (note length of time)				
		Record and documentation of troubleshooting / corrective action				
3	Quality Activity					
	3.1 IQC Implementation	Frequency of IQC - following recommendation in guidelines				
		IQC review - dated and signed				
		Corrective action and troubleshooting				
		Proper record and documentation of QC lot, acceptable range and mean				
	3.2 EQA / Peer group comparison	Participation in EQA				
		EQA review - dated and signed				
		Corrective action and troubleshooting				
		Proper record and documentation				

4	Sample					
		Proper sample handling				
		Use of correct container / preservative				
		Disposal of sample				
5	Results Management					
		Reporting of results - at least 2 unique identifiers				
		Results traceability				
		Recording of results onto patients record / file				
6	Training and Competency					
		All users trained				
		Training records updated				
		Competency log updated				
		List of competent users updated				
7	Storage of Reagents / QC materials / Consumables					
		Appropriate storage temperature				
		Monitoring and charting of storage temperature				
		Updated Bin Card/KEW Card				
		Opened date - recorded				
		Expiry date - recorded				
8	Health and Safety					
		Appropriate PPE				
		Biohazard waste bin				

Name of Auditee :

Designation :

Date :

Name of Auditor :

Designation :

Date :

Registry of POCT Devices / Kits in MOH Facilities

(A) **Year** :
(B) **Name of Facility** :
(C) **Category** :
(D) **Prepared by** :
(E) **Checked by** :
(F) **Verified by** :

(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)
No	**Location**	**Name Of Test**	**Brand**	**Model**	**Asset/ Rental**	**Serial No.**	**Asset Registration No.**	**Concession Company Registration No.**	**Method of Procurement**	**Date of Procurement**	**Name of Supplier**	**Remark**

WORKLOAD

Appendix VI
BPOCT005/2022

No	POCT device	Workload												Total Workload
		Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec	
1	Glucometer													
2	Cholesterol meter													
3	Haemoglobinometer													
4	Bilirubinometer													
5	Full Blood Count													
6	Blood Gases													
7	Urine Pregnancy													
8	Urine Biochemistry Dipstick													
9	HIV Test													
10	CD4/CD8													
11	Coagulometer													
12	Dengue Combo													
13	Leptospirosis													
14	Cardiac Markers													
15	Malaria													
16	Others													

Prepared by :

Name :
Designation :
Date :

Approved by :

Name :
Designation :
Date :

Appendix VII
BPOCT006/2022

POCT - TRAINING AND COMPETENCY RECORD

Name of Trainee : _____
Designation : _____
Contact No. : _____
Location : _____

N.B: This record should be kept by the Supervisor / Training Officer

No.	Scope	**Score	Date of Training	Signature of Trainer
1.0	**THEORY**			
1.1	Method/principle of test			
1.2	Handling and preparation of reagent/test strips/cassette			
1.3	Proper storage conditions for strips/cassette/reagents			
1.4	Calibration			
1.5	Internal Quality Controls			
1.6	External Quality Programme/Peer group comparison			
1.7	Maintenance			
1.8	Understanding error messages			
1.9	Basic troubleshooting			
1.10	Test limitation(s) and interference(s)			
1.11	Health and safety regulations & compliance			
1.12	Patient preparation requirements			
1.13	Sample collection procedures			
1.14	Result interpretation & clinical decision limits			
1.15	Incident reporting and adverse events			
2.0	**PRACTICAL SESSION**			
2.1	Maintenance			
2.2	Calibration			
2.3	IQC			
2.4	Sample collection procedures			
2.5	Sample analysis			
TOTAL SCORE (%)				

**SCORE:	TOTAL SCORE	
1 = Poor	>90 %	= Competent, able to train and audit
2 = Below average	80 -90%	= Competent and able to run test
3 = Average	60 - 79%	= Require supervision and re-training
4 = Good	<60%	= Not competent and cannot perform test. Require re-training
5 = Excellent		

SUMMARY / COMMENT

Assessed by :

Name :

Designation :

Date :

Verified by :

Name :

Designation :

Date :

Appendix VIII
BPOCT007/2022

LIST OF PERSONNEL COMPETENCY

Device: _____
Location and name of facility: _____
Contact Person: _____

No	Name	Designation	Date

Prepared by :
Name :
Designation :
Date :

Approved by :
Name :
Designation :
Date :

MAINTENANCE LOG FOR POINT-OF-CARE TESTING DEVICE (Where applicable)

Appendix IX
BPOCT008/2022

Analyser : _____
Asset / Serial number : _____
Location and name of facility : _____
Month : _____

a) Daily

Item \ Date	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31
Operator initials																															

b) Weekly

Item \ Date	1	2	3	4
Operator initials				

c) Monthly

Item \ Date	
Operator initials	

Reviewed by:
Name :
Designation :
Date :

Appendix X
BPOCT009A/2022

INTERNAL QUALITY CONTROL DATA RECORD
(QUANTITATIVE)

Month: Year:

Location	
Test	
Device ID / Serial number	

Date	QC / Strip Lot Number	Range Level 1	Range Level 2	Range Level 3	Pass / Fail	Performed by	Remarks
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		
					L1 : L2 : L3 :		

Appendix XI
BPOCT009B/2022

INTERNAL QUALITY CONTROL DATA RECORD
(QUALITATIVE)

Month: Year:

Location	
Test	

Date	Box/Vial/Bottle Lot Number	Level 1	Level 2	Pass / Fail	Performed by	Remarks *
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		
				L1 : L2 :		

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