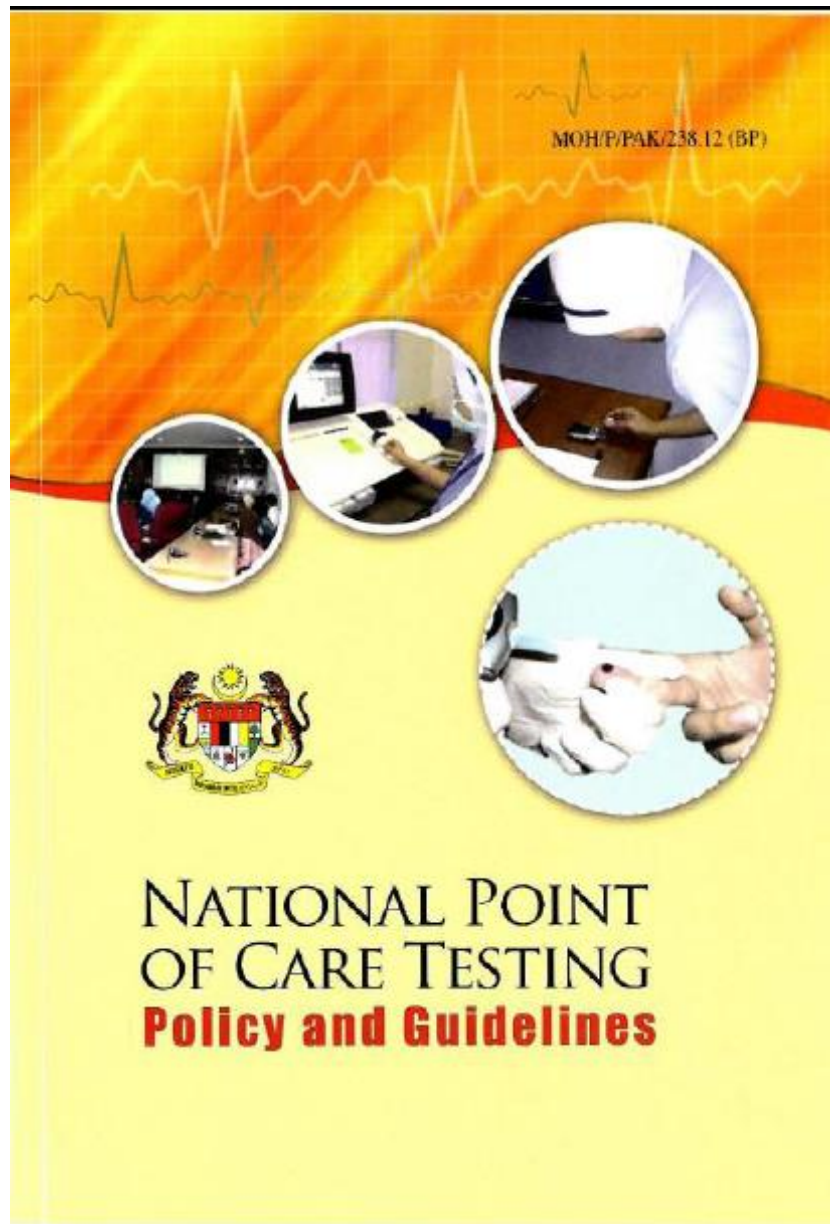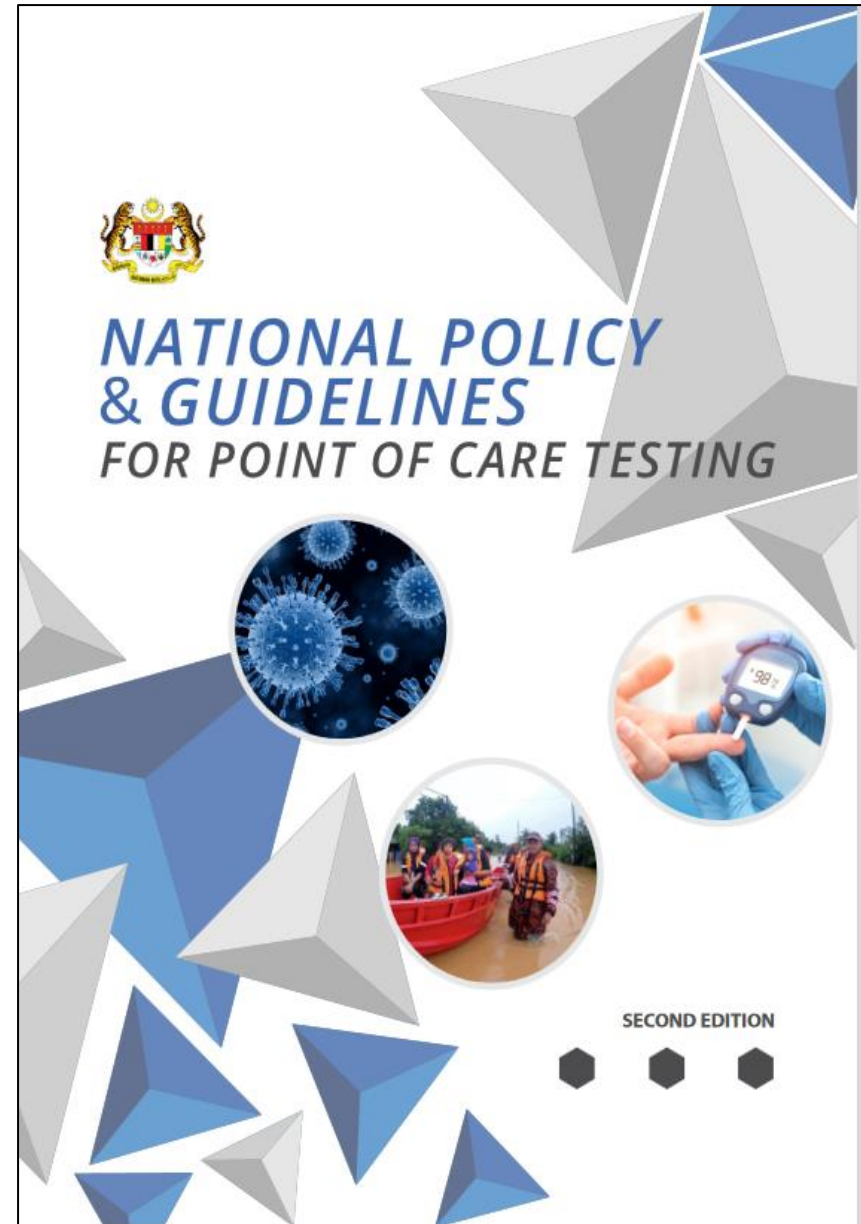# POCT Management in Malaysia

Dr Hanisah Abdul Hamid

1st edition   July 2012

2nd edition April 2022

ACCREDITATION

ISO/TS 22583:2019   MSQH 6THEDITION   ISO 15189 : 2022

TECHNICAL SPECIFICATION   ISO/TS 22583

First edition 2019-11

Guidance for supervisors and operators of point-of-care testing (POCT) devices

Reference number ISO/TS 22583:2019(E)

© ISO 2019

MSQH
EDUCATOR
ENABLER
EVALUATOR

STANDARDS MALAYSIA

Annexes (Informative)

Annex A
Correlation between

ISO 15189:202x &

ISO 15189:2012 &

ISO/IEC 17025:2017

Annex B
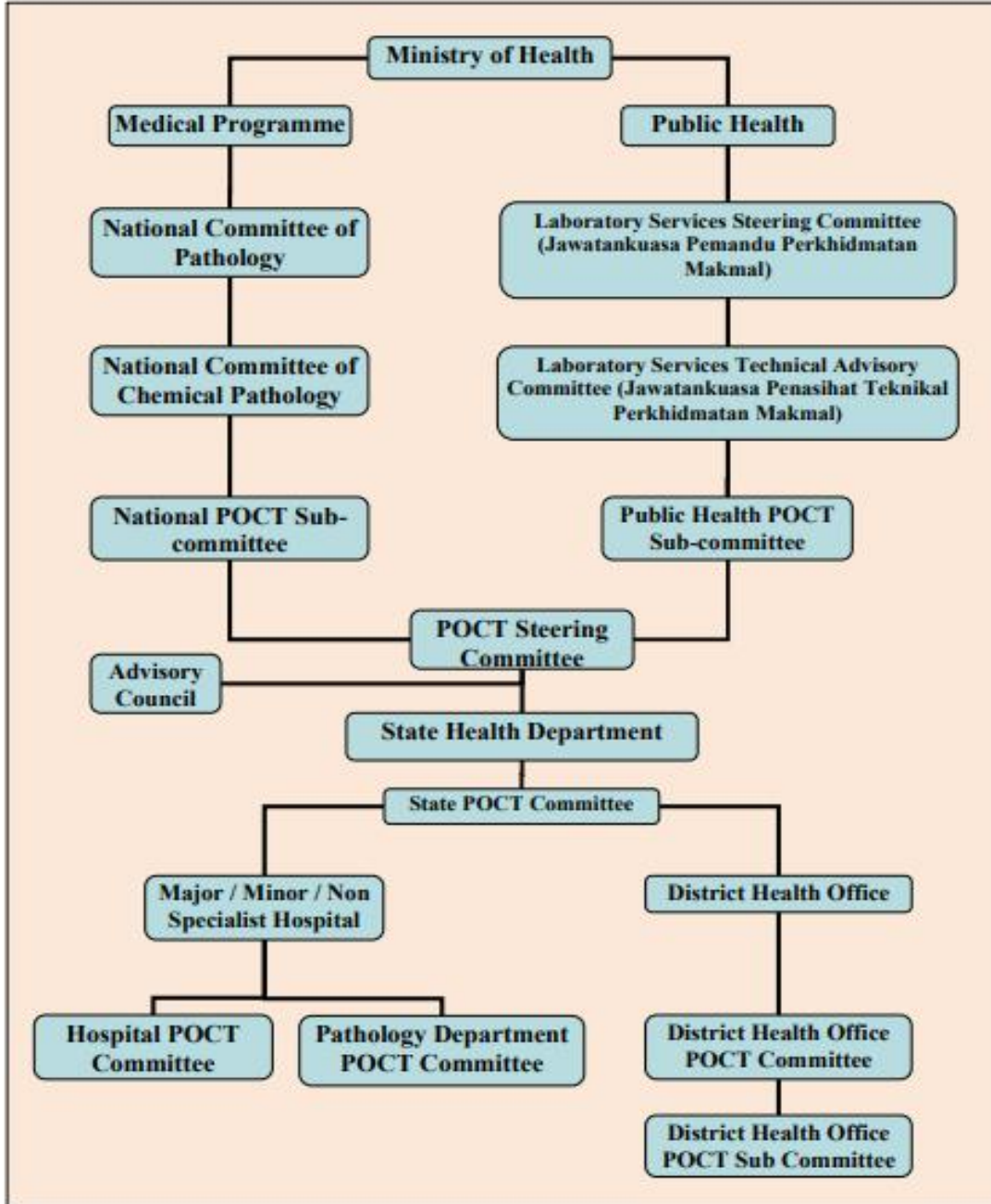Additional Requirement for Point of Care Testing (PoCT)

23

1st edition

Figure 1: National Level POCT Committee Organization Chart

2nd edition
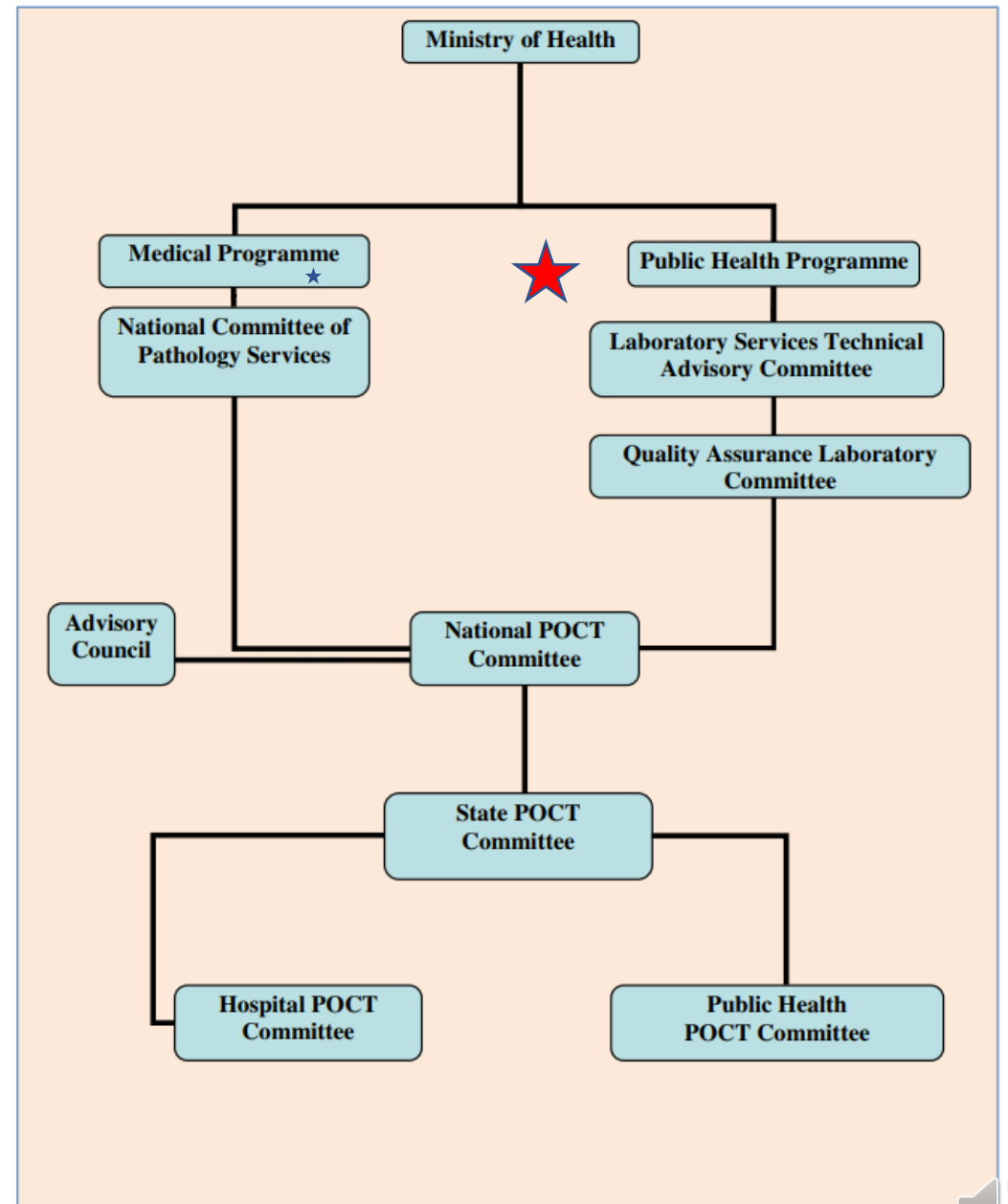
Figure 1: National POCT Committee Organisation Chart

Quality Assurance Lab Sub-committee

National Technical Advisory Committee

on Health Laboratories

Quality Assurance Lab Committee

Secretariate : National Public Health Laboratory

Accreditation Working Group

Evaluation Working Group

POCT Working Group

EQA Working Group
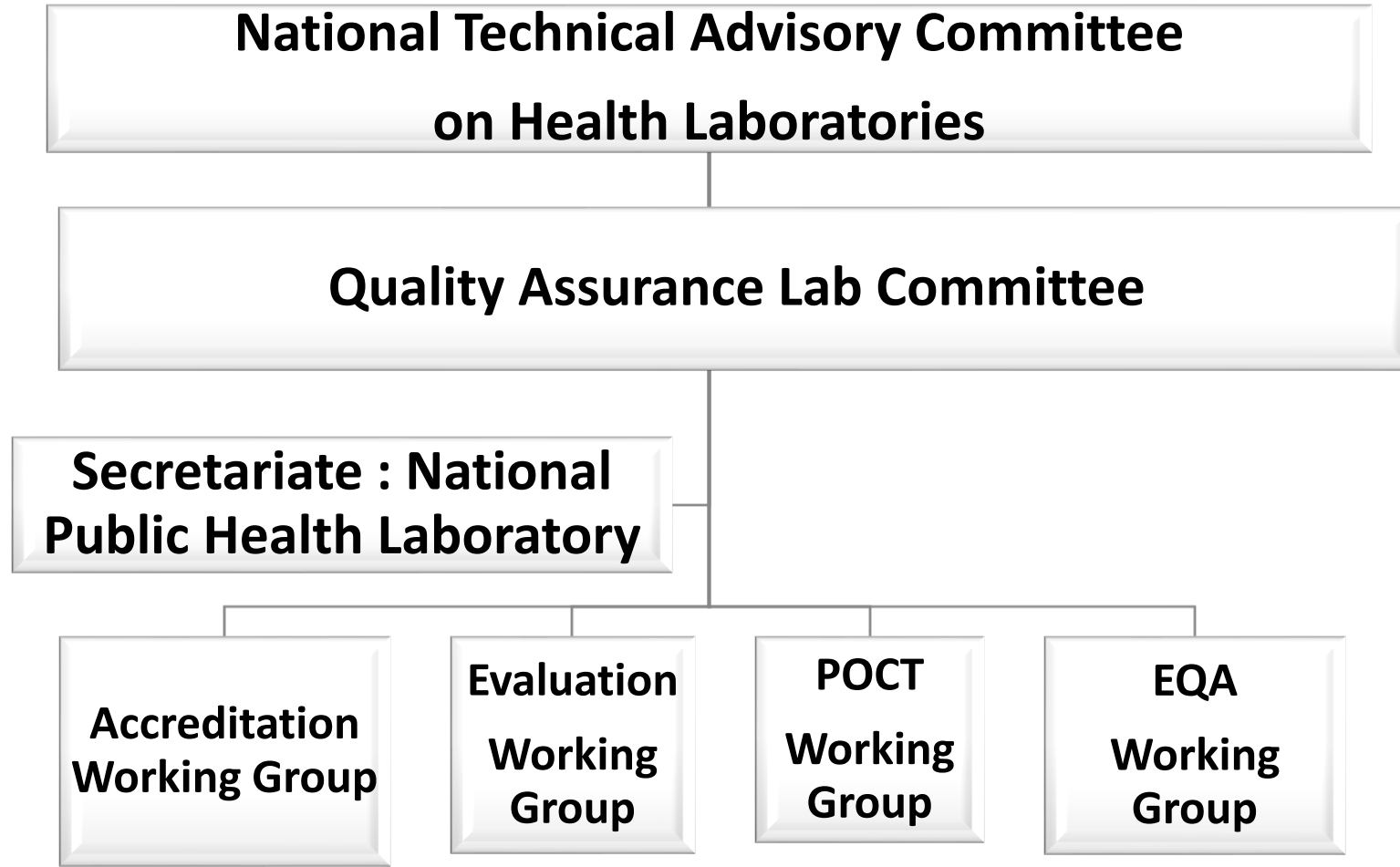
National POCT COMMITTEE

Chemical Pathology

Haematology

Microbiology

Public Health (DCD, FHDD, NPHL)

Institute Medical Research

PADLET POCT COMMITTEE
(Sub-Committee of National POCT Committee)

https://padlet.com/kkmPOCT/kebangsaan

Formation of Hospital POCT committee

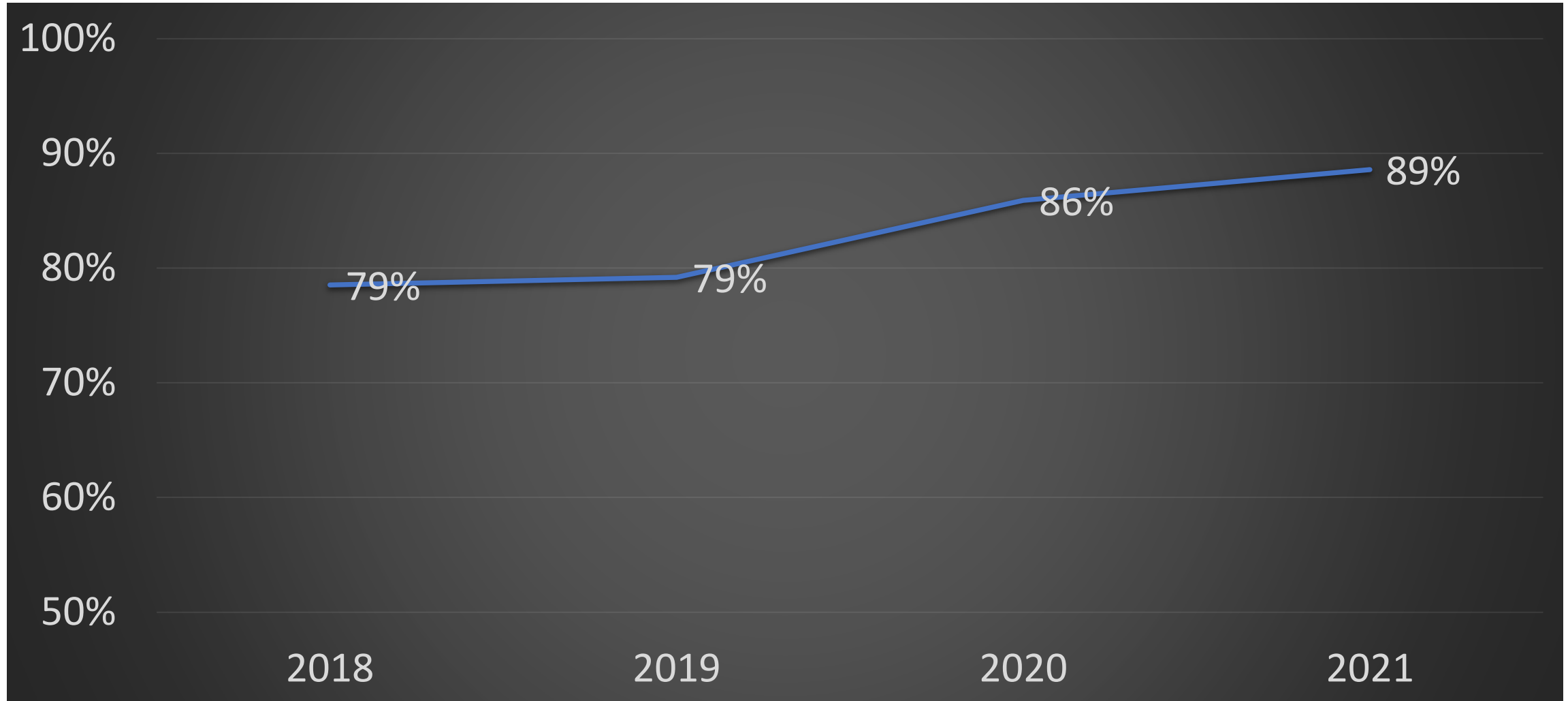# FORMATION OF PUBLIC HEALTH POCT COMMITTEE 2022

District Health Office (158)	
(a)Klinik Kesihatan	1064
(b)Klinik Kesihatan Ibu & Anak	84
(c)Klinik Desa	1741

Total 2889

34%

66%

■ Yes ■ No
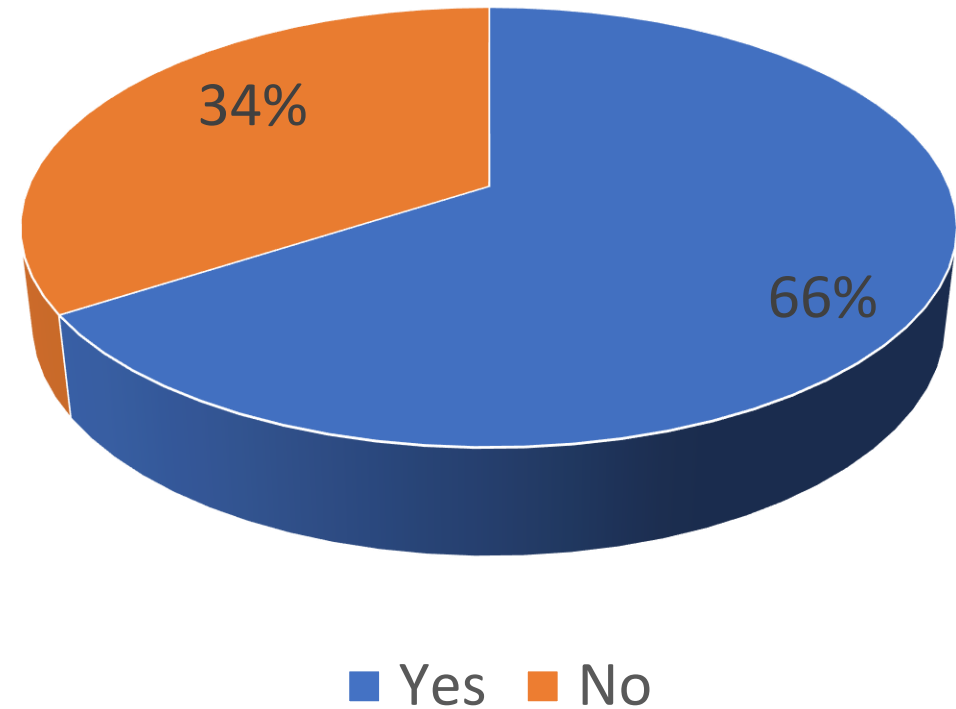
National POCT POLICY

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 and during disaster, performed by **competent personnel, on the correct patient with documented quality results**; in order to provide high quality patient care through a standardized POCT services. POCT services shall be coordinated by the POCT committee at all levels.

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

STATE POCT COMMITTEE
- State Health Director (Chairperson)
- State Pathologist
- State POCT Coordinator (Pathologist/Science Officer)
- Specialists
- Pathologists
- Hospital & 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 & Public Health)
- Matron (Medical & Public Health)
- MLT (Medical & Public Health)

HOSPITAL POCT COMMITTEE

PUBLIC HEALTH POCT COMMITTEE
- District Health Officer (DHO)
- District Primer Medical Officer
- Coordinator (Assistant Medical Officer / MLT)
- Family Medicine Specialist
- Assistant Medical Officer
- Matron
- MLT
- Pharmacist

Chairperson shall be appointed from amongst committee members by the DHO

HOSPITAL POCT COMMITTEE WITH PATHOLOGIST
- Hospital Director (Chairperson)
- HOD of Pathology
- Hospital POCT Coordinator (Pathologist/Science Officer)
- Specialists
- Pathologist
- Medical Officer (Pathology)
- Science Officers
- MLT
- *Matrons, Sisters or Staff Nurses
- Assistant Medical Officer
- *Pharmacist
- *Concession Company

Where applicable

HOSPITAL POCT COMMITTEE WITHOUT PATHOLOGIST
- Hospital Director (Chairperson)
- Supervising Pathologist (Advisor)
- HOU of Pathology (Coordinator)
- *Specialists
- Science Officers
- MLT
- *Matrons, Sisters or Staff Nurses
- Assistant Medical Officer
- *Pharmacist
- *Concession Company

Where applicable

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

State POCT Committee

1st edition	2nd edition
• State Health Director (Advisor) • State Pathologist (Chairperson) • Clinical And *Public Health Specialists • Pathologists • Scientific Officers - Hosp& MKA/K • State Assistant Medical Officers • State Medical Laboratory Technologists (PH) • Matron (Medical & Public Health) • *Consisting of Family Medicine Specialist (FHDD) And Public Health Specialist (Quality Unit).	• State Health Director (Chairperson) • State Pathologist • State POCT Coordinator (Pathologist/Science Officer) • Specialists From Major Clinical Disciplines • Pathologists • Hospital & 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 & Public Health) • Matron (Medical & Public Health) • Medical Laboratory Technologist (Medical & Public Health)

Public Health POCT Committee (PHPC)

1ˢᵗ edition

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

2ⁿᵈ edition

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

* *Chairperson shall be appointed from amongst committee   members by the DHO*

Roles & Responsibilities of POCT committee

POCT Activity	National POCT Committee	State POCT Committee	Public Health POCT Committee	Hospital POCT Committee
POCT Equipment & Device Procurement				
Review of Current Technology	/	/	/	/
Specification	/	/	/	/
Technical Evaluation & Selection	/	/	/	/
Procurement Management	/	/	/	/
POCT Device User Training & Competency				
Coordinate Training		/	/	/
Coordinate Competency Assessment			/	/
POCT Quality Assurance Program				
Review IQC			/	/
Plan and implement EQA			/	/
Review Corrective Action			/	/
POCT Documentations, Records & Audit				
Review SOP			/	/
Review and Report Data Collections			/	/
Coordinate Audit & report			/	/

National POCT Guideline

TERM OF REFERENCE OF POCT COORDINATOR

Ensure POCT site complies with National POCT Policy	Ensure relevant departments are represented	Delegate duties to committee members
Liaise with the management	Ensure relevant department have copy of policy	Schedule meeting & Plan Audit
	Submit report	

# Implementation of specific forms for POCT activities

Appendix I	BPOCT001A/2022	Request for Approval of New POCT Test / Change of POCT Device Form
Appendix II	BPOCT001B/2022	Evaluation Checklist for New POCT Test / Change of POCT Device
Appendix III	BPOCT002/2022	List of Point-of-Care Testing Committees
Appendix IV	BPOCT003/2022	Checklist for POCT Audit
Appendix V	BPOCT004A/2022	Registry of POCT Devices / Kits in MOH Facilities
Appendix VI	BPOCT005/2022	Workload
Appendix VII	BPOCT006/2022	POCT - Training and Competency Record
Appendix VIII	BPOCT007/2022	List of Personnel Competency
Appendix IX	BPOCT008/2022	Maintenance Log for Point-of-Care Testing Device
Appendix X	BPOCT009A/2022	Internal Quality Control Data Record (Quantitative)
Appendix XI	BPOCT009B/2022	Internal Quality Control Data Record (Qualitative)

Request for POCT Service

[Request for Approval of New POCT Test / Change of POCT Device form (Appendix I)](#)
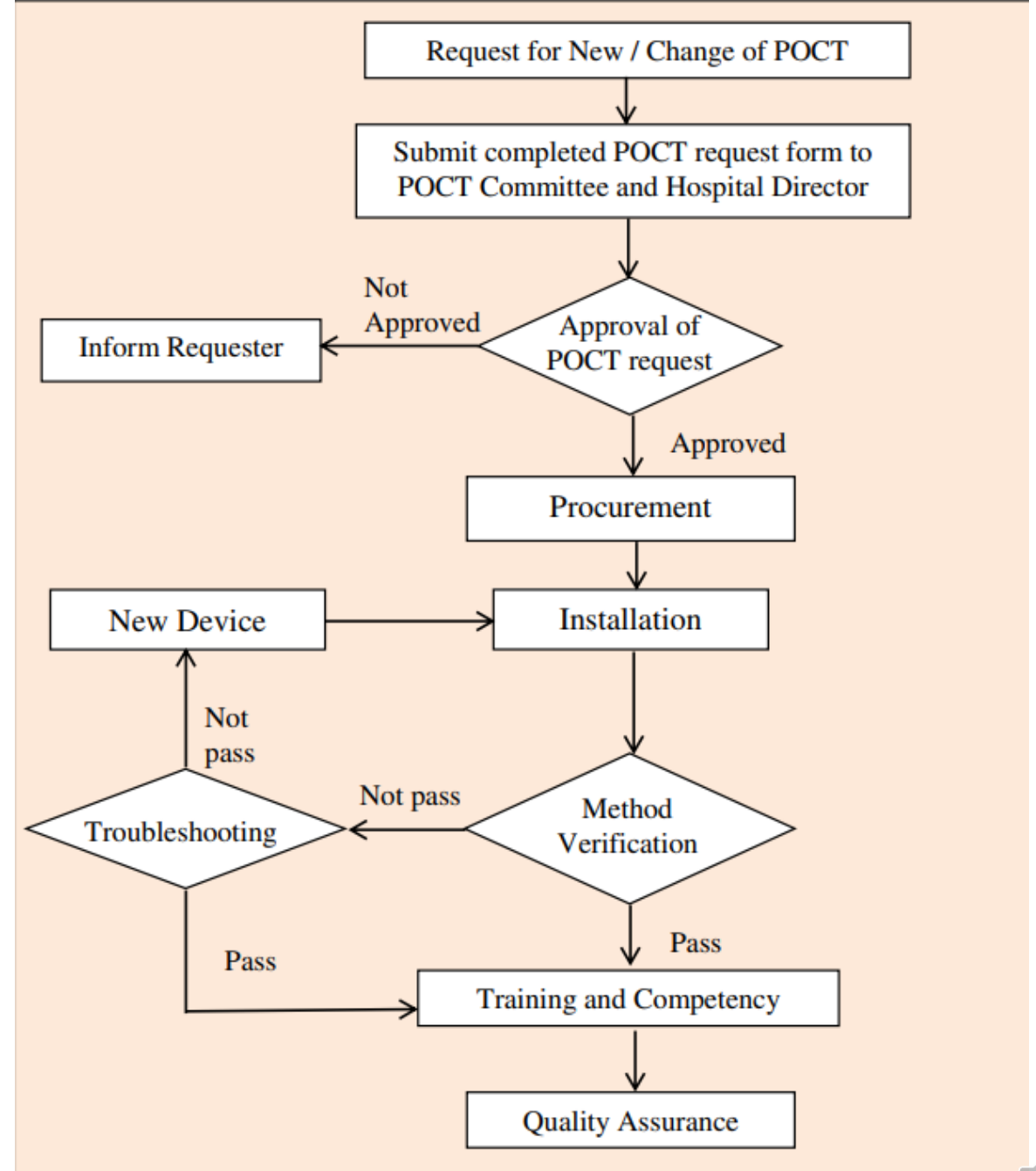
Figure 3: Flowchart on Implementation of POCT Service

Request for Approval of New POCT Test / Change of POCT Device Form

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:

Evaluation of Proposed POCT Device

a) New POCT test

b) Change of POCT device

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			

POCT Training & Competency Record

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			

Records and Retention Time

1st edition

2nd edition

Records of patient results, POCT device maintenance logs, training records, POCT operator competency and assessment records, quality control / quality assessment (IQC / EQA) and remedial / corrective action log should all be retained for the length of time specified in the guideline on retention of pathology records and materials version 1/2005.

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

Based on new version of Guideline on Retention of Pathology Records

Evaluation of POCT Activities

POCT Activities shall be monitored and evaluated minimally, at least once a year

Checklist For POCT Audit

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

New chapter

3rd Chapter

POCT In Emergency And Disaster Preparedness, Response & Recovery

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.

PADLET POCT PROGRAMME

National POCT Registry

Annual POCT Report

https://padlet.com/kkmPOCT/kebangsaan

OBJECTIVES OF DATA COLLECTION

1. Collection of POCT devices/ kits data will assist in:
   a) Planning of POCT service delivery
   b) Quality management
   c) Replacement of equipment
   d) Procurement

2. POCT disaster management plan

Data collection : POCT Padlet

Annual POCT Report 2021 & 2022
POCT Registry 2022

Before 13ᵗʰ Mac 2023

Annual POCT report

ANNUAL POCT REPORT

YEAR		DISTRICT HEALTH OFFICE / HOSPITAL/PKRC	
STATE			

TOTAL NUMBER OF POCT SITES IN PUBLIC HEALTH FACILITIES	KK		KD	
	KKIA		KKOM	

TOTAL NUMBER OF POCT SITES IN HOSPITAL	WARD	
	CLINICS	

FORMATION OF POCT COMMITTEE	STATE	YES	1
	HOSPITAL	YES	1
	PUBLIC HEALTH		0

NO	INFORMATION ON OFFERED POCT TESTS	NUMBER OF DEVICES	WORKLOAD	No of POCT sites	No. POCT sites with SOP	SOP (%)	No. Trained POCT Operator
1	Blood Gases					#DIV/0!	
2	Glucose					#DIV/0!	
3	Bilirubin (Bilirubinometer)					#DIV/0!	
4	Bilirubin (Transcutaneous Bilirubinometer)					#DIV/0!	
5	Cholesterol					#DIV/0!	
6	Creatinine					#DIV/0!	

POCT DATA

ANNUAL POCT REPORT

a) Total number of POCT sites in public health facilities – KK/KKIA/KD/KKOM
b) Total number of POCT sites in hospital- ward/Clinic
c) Formation of POCT committee - State / Hospital/Public Health

- Activities (yes/ no)
a) Audit conducted by POCT committee
b) POCT meeting conducted

- Issues
- Incident reports related to POCT test
- Issues related to implementation on policy & procedure
- Issues related to budget allocation

- Other issues issues related to POCT testing.

INFORMATION ON OFFERED POCT TESTS

1	Blood Gases	22	Urine drug of abuse test
2	Glucose	23	Urine alcohol
3	Bilirubin (Bilirubinometer)	24	Full Blood Count (3 part)
4	Bilirubin (Transcutaneous Bilirubinometer)	25	Full Blood Count (5 part)
5	Cholesterol	26	Hemoglobin
6	Creatinine	27	PT/INR
7	Ketone	28	CD4 test
8	Lactate	29	ROTEM/TEG
9	C-Reactive protein	30	HIV 1/2 rapid test
10	Creatine kinase-MB	31	Dengue rapid test (NS1 antigen)
11	Cardiac Troponin I	32	Dengue rapid test (IgG/IgM)
12	Cardiac Troponin T	33	Dengue rapid test (NS1 antigen/IgG/IgM)
13	Beta Natriuretic Peptide (BNP)	34	Hepatitis Bs antigen rapid test
14	NT-proBNP	35	Hepatitis C antibody rapid test
15	HbA1c	36	Covid-19 antigen rapid test
16	Urine biochemistry (Protein, glucose)	37	Leptospira rapid test
17	Urine biochemistry (Albumin, creatinine)	38	Chikugunya antibody rapid test
18	Urine biochemistry (Albumin,glucose, ketone)	39	Syphilis rapid test
19	Urine biochemistry (5 parameters)	40	SARS COV2 antibody rapid test
20	Urine biochemistry (>=10 parameters)	41	Measles antibody rapid test
21	Urine pregnancy test	42	Others (please specify)

ANNUAL POCT REPORT

Information on offered POCT tests
- Number of devices
- Workload
- Number of POCT sites
- Number of POCT sites with sop
- Total number of POCT operator
- Number of trained POCT operator
- Number of competent POCT operator
- Number of devices with IQC monitoring
- Number of devices with EQA monitoring
- Number of devices with maintenance

POCT REGISTRY

GUIDELINE ON DATA COLLECTION FOR REGISTRY OF POINT-OF-CARE TESTING (POCT) DEVICES/ KITS IN MINISTRY OF HEALTH (MOH) FACILITIES

REGISTRY OF POCT DEVICES/ KITS IN MOH FACILITIES (BPOCT004A/2022)

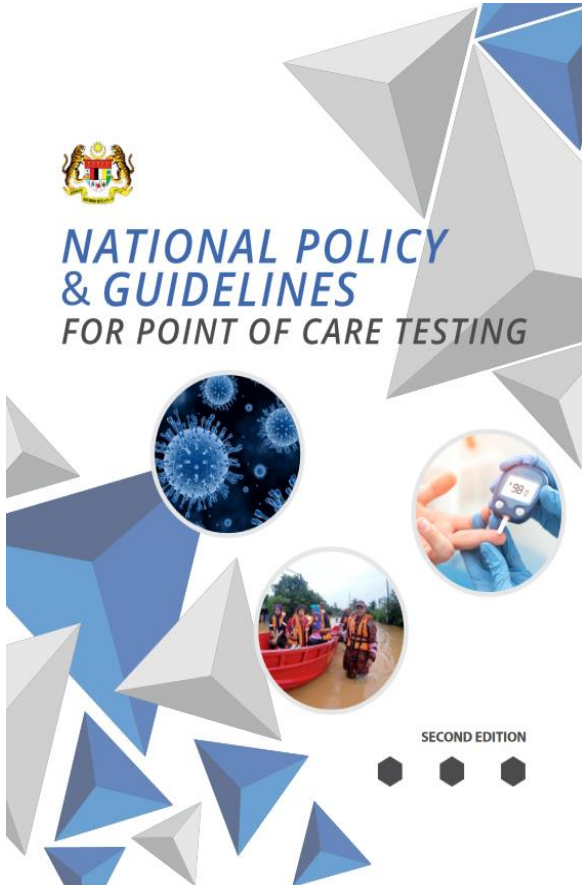REGISTRY OF POCT DEVICES/ KITS IN MOH FACILITIES   BPOCT004A/2022

(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

- All POCT devices/ kits used at each MOH facility shall be registered/updated using BPOCT004A/2022 form
- Form shall be updated whenever there is new/ change in POCT devices/ kits used in the facility

Summary

+

Padlet POCT Programme

National POCT Registry	**+**	Annual POCT Report

THANK YOU