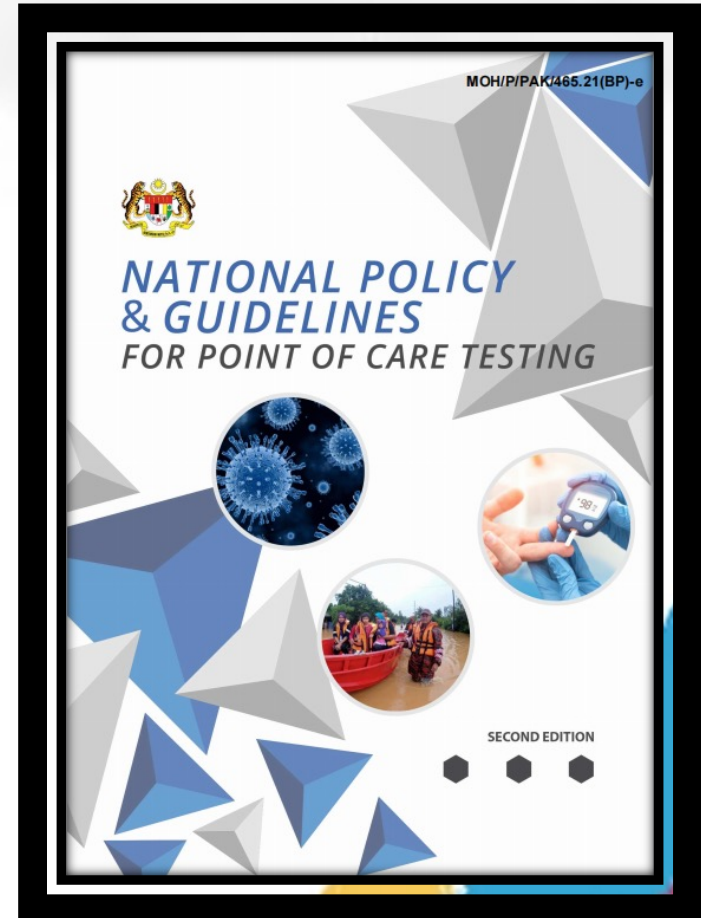# Documentation and Record, Evaluation of POCT Activities

Unit HIV/STI/Hepatitis C
Bahagian Kesihatan Awam
Jabatan Kesihatan Negeri Johor

National Policy & Guidelines For Point of Care Testing (2nd Edition),March 2022

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

NATIONAL POLICY & GUIDELINES
FOR POINT OF CARE TESTING

SECOND EDITION

DOCUMENTATION

1. Standard Operating Procedures (SOPs)
2. POCT device maintenance log
3. Manufacturers Operator Manuals
4. Relevant MDA notices
5. Certified POCT Operator lists.

STANDARD OPERATING PROCEDURES

1. Methodology.
2. Operating and Technical Manual.
3. Health and safety.
4. Specimens required, sample identification criteria (2 unique identifiers)
5. Preparation of reagents (storage & stability)
6. Calibration.
7. Quality control procedures.
8. Sample analysis procedures.

STANDARD OPERATING PROCEDURES

9. Reporting of results, including abnormal results.
10. Documentation/transmission of results.
11. Limitations of the procedure.
12. Reference values.
13. Specimen storage and stability.
14. Disposal of reagents and materials

regular revision

Format & content: POCT Committee

master copy - POCT Coordinator

Copy-retained near the device

RECORD

1. Patient's result
2. Maintenance Log
3. POCT Training Record
4. POCT Operator Competency
5. IQC / EQA Record
6. Remedial / Corrective Action

RESULTS

- Results shall be appropriately recorded-the form of paper report/ electronic
- These records shall include
    1. 2 Unique Identifiers
    2. Date & Time of Analysis
    3. Results Obtained
    4. Identity of Operator
- POCT results shall have clear delineation / be distinguished from the patients' laboratory results.
- Results shall be treated as confidential
- Local rules on access to the system, whether stand-alone or networked, should be maintained.

POCT Operator

RECORDING AND REPORTING OF RESULTS

- Whenever error or non-conformity is detected in the result produced from the POCT devices, the result should be recalled and the requester should be notified as soon as possible.

- Investigation should be carried out and the incident needs to be documented.

Records and Retention Time

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

OTHER RECORDS

- **Request for Approval of New POCT Test/Change of POCT Device Form**
- **Evaluation Checklist for New POCT Test/Change of POCT Device**
- **List of Point of Care Testing Committees**
- **List of Personnel Competency**
- **Master List of Point of Care Testing Devices**
- **Workload**
- **POCT - Training and Competency Record**
- **Internal Quality Control Data Record**
- **Checklist for POCT Audit**
- **Annual POCT Report**

EVALUATION OF POCT ACTIVITIES

Environment	Device Management	Quality Activity
IQC Implementation	EQA/ Peer group comparison	Sample
Results Management	Training and Competency	Storage of Reagents / QC materials / consumables

EVALUATION OF POCT ACTIVITIES

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

EVALUATION OF POCT ACTIVITIES

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

ENVIRONMENT

Suitable location

Adequate space

Suitable temperature for analysis

Accessible by user

DEVICE MANAGEMENT

Maintenance

Daily / weekly / monthly maintenance performed

Maintenance log updated

Plan Preventive Maintenance

Breakdown

Records of breakdown/ downtime (note length of time)

Record and documentation of troubleshooting / corrective action

QUALITY ACTIVITY

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, and acceptable range and mean

EQA/ Peer group comparison

- Participation in EQA
- EQA review - dated and signed
- Corrective action and troubleshooting
- Proper record and documentation

SAMPLE

Proper sample handling

Use of correct container / preservatives

Disposal of sample

RESULTS MANAGEMENT

Reporting of results - at least 2 unique identifier

Results traceability

Recording of results onto patients record/ file

TRAINING & COMPETENCY

All users trained	Training record updated
Competency log updated	List of competent users updated

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

HEALTH AND SAFETY

Appropriate PPE

Biohazard waste bin

- Point-of-Care Testing Activities shall be monitored and evaluated minimally, **at least once a year**; in order to assure that the activity is meeting the needs of its customers

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