PATHWEST POINT-OF-CARE TESTING POLICY

1. POLICY STATEMENT

Point-of-Care Testing (PoCT) refers to pathology testing that is performed in close proximity to a patient, usually outside of a traditional laboratory, providing rapid results for clinical management of acute illness. PathWest Laboratory Medicine WA (PathWest) provides governance over approved PoCT devices utilised in WA Health. PathWest will determine which devices are recommended and which devices have results reported into the PathWest Laboratory Information System (LIS). There are two types of PoCT devices – approved and non-approved PoCT devices.

a) **Approved Devices** are recommended and deemed fit-for-purpose by PathWest. Approved devices may have results reported into the PathWest patient data management system, or not, depending on the complexity of the device and the connectivity available (the current list of PathWest Approved PoCT devices and tests are available in SOP-1237).

   i) **Reported results**: Those results being reported into the PathWest patient data management system. These results are always produced by an approved device. The level of support is higher for an approved device providing reported results than for devices that are not reported by PathWest.

   ii) **Non-reported results**: Results that are not reported into the PathWest patient data management system, but are either appended or transcribed to the patient medical notes.

b) **Non-Approved Devices:** these devices are not endorsed or recommended by the PathWest (out-of-scope for this policy).

2. INTENT

This PoCT Policy provides guidance for the safe, effective management and use of PoCT across WA Health. This is achieved by ensuring devices are fit for their intended purpose and are used by trained and competent individuals. More rapid access to test results provided by use of POCT devices can increase clinical effectiveness and contribute to improved patient outcomes. The expected outcomes for this policy are:

- To provide clear standards for the introduction and management of PoCT in WA Health.
- To ensure that staff using PoCT are competent and confident in using a PoCT device to produce an accurate result.
- To minimise any associated risks, by supporting all operators in implementing PoCT appropriately.
- To meet compliance with relevant regulatory requirements, and achieve and maintain National Association of Testing Authorities, (NATA) accreditation where applicable.
- To ensure principles of quality management and continuous improvement are applied.

This policy applies to all staff involved in the use of approved PoCT devices and aims to facilitate and regulate the appropriate use of PathWest supported PoCT activities across WA Health. All POC device operators must be trained to perform PoCT. It is the responsibility of all health employees who are operating PoCT devices to ensure they have received training and are maintaining their competency to use these devices.

3. SCOPE

The WA Health PoCT Trained User Access Policy is based on standards for performing point-of-care testing and ensuring patient safety. This policy applies to all persons employed in WA Health who perform point-of-care testing, which incorporates the following entities:

- Department of Health
- Metropolitan Health Service Providers (HSPs)
- WA Country Health Service Providers (HSPs)

4. POLICY STATEMENT

Introducing, Modifying, or Changing PoCT devices.

PathWest will endorse the use of approved PoCT devices when there are clear benefits in providing testing outside the central laboratory environment.

- Applications to introduce, modify, or change approved PoCT services or devices in WA Health must be made in writing using the “Point-of-Care Testing (PoCT) Submission Form” (FRM-209) which is submitted to PathWest PoCT, poct.pathwest@health.wa.gov.au
- Clinical areas should seek the assistance of the relevant PathWest Discipline in preparing their application.
- The PoCT Submission Form will identify benefits to WA Health and its patients in providing testing close to the patient and these benefits should be measurable.
- PathWest PoCT staff will progress the application through the approval process with approval being provided by the Designated Person (DP) as a member of the Clinical and Scientific Governance Committee (CSGC). **Cost of PoCT Devices and Consumables.**

No agreement shall be entered into with respect to PathWest supported PoCT before approval has been obtained.

Devices generating results reported into the PathWest Laboratory Information System (LIS):

- The cost of purchasing recommended PoCT devices and providing training will be borne by PathWest.
- PathWest will purchase consumables and provide maintenance, IQC review and EQA review.
- PathWest will recoup these costs from the Health Service via a fee-for-service model.

Devices generating results not recorded in, or reported out of the PathWest LIS:

- The cost of purchasing approved PoCT devices and providing training will be borne by the relevant HSP. (PathWest may use its purchasing power to seek a better price on behalf of the HSP).
- The HSP will purchase all consumables.
- PathWest will not charge the Health Service fees for ongoing support or training.

Responsibilities for reported verses non-reported devices are detailed in PathWest SOP-1229.

Standardisation of PoCT devices.

PathWest supports the use of standardised PoCT devices throughout WA Health. This aims to ensure governance over purchasing devices and reagents, and to simplify staff training requirements.

- The PathWest discipline Principal Scientist will co-ordinate the evaluation of all approved PoCT devices to ensure clinical accuracy and reliability of results (PoCT devices, if appropriate, will be evaluated against accredited laboratory analysers).

As required, new PoCT devices may also be evaluated by the relevant PathWest discipline and any devices that fail to meet accuracy and reliability standards will not be approved for use.

Training and operator competency.

All PoCT device operators must be trained to perform PoCT.

- It is the responsibility of all health employees who are operating PoCT devices to ensure they have received training and maintain their competency to use these devices.
- All approved PoCT devices will have documented training procedures supplied by the relevant PathWest discipline.
- The various mechanisms for PoCT training are detailed in the “Point-of-Care Testing Trained User Access Policy” (POL-226).

Only trained staff with demonstrable competency should operate PoCT devices.

- Training records must be retained by the trainee and the laboratory (where applicable).
- The level of training required will be related to the complexity of the device.

Where applicable for the PoCT device, a central database of trained PoCT operators will be maintained by PathWest.

- For suitable devices (i.e. networkable and with adequate data collection) competency will be reviewed through active monitoring of user error rates. Error Reports will be communicated to PathWest Laboratories, PoCT testing sites, and individual operators as appropriate.
- If device operators with low competency are identified via high error rates on an ongoing basis for non-PathWest staff, the Head of Discipline (HOD) will inform the Scientific and Clinical Governance Committee and the appropriate Pathology Reference Group. (PRG). As the governance of non-PathWest staff resides with the local HSP, they will be

informed by PathWest of any operator competency issues that require further intervention by them.

- WA Health employees must ensure they act on any notifications regarding competency or training issues.
- PathWest will maintain an eLearning training program to ensure all PoCT operators can access training remotely and as required.

All eLearning material will be reviewed and updated by the relevant discipline on a regular basis and in conjunction with device manufacturers as required.

Quality Controls / Quality Assurance / Maintenance

All PathWest approved PoCT devices require ongoing quality control (QC), quality assurance (QA), and maintenance checks to ensure the device is operating optimally and remains fit for purpose.

- QC checks are to be performed at intervals as prescribed by the relevant Laboratory Discipline (e.g. Biochemistry, Haematology).
- All QC/QA/maintenance activities must be documented and retained.
- PathWest Laboratories reporting results from the PoCT device will ensure internal QC testing is performed and acceptable.
- Enrolment in an external QA program is done if required and corrective actions are performed as required.
- Sites using non-approved devices i.e., generating results that are not reported into the PathWest data management system or LIS, may seek advice from PathWest on appropriate QC/QA protocols.

All preventative maintenance performed by the device manufacturer must be documented and should be co-ordinated with the PathWest facility onsite to ensure disruptions to PoCT device availability are minimised.

Reporting PoCT results via PathWest

All PathWest approved devices must be capable of transferring patient results electronically using a standard IT communication protocol (i.e. POCT1A, HL7) to allow the electronic reporting of PoCT results.

- PoCT devices reporting results will be networked to the PathWest LIS and results will be transmitted to the patient's UMRN in the hospital PAS (where available).
- PoCT results reported in the LIS must be clearly identified as being from a PoCT device; the results must include a comment detailing the brand and model of the device and that testing was performed at the point-of-care.
- Where results are not reported using the PathWest LIS, the local area health service staff must ensure that all PoCT results obtained directly from the device are retained in the patient's medical notes. The device print-out must include sufficient identification of the patient to comply with medico-legal investigation and accreditation requirements (if applicable) and be signed by the person who performed the test.

5. OTHER POLICIES RELEVANT TO THIS POLICY

PoCT Managing Low Usage Policy (POL-227)

Summary: The PoCT policy for Managing Low Usage aims to ensure that all operators produce high-quality PoCT results that can be utilised in patient management across a wide range of clinical settings. In order to deliver a safe, clinically effective, and high quality managed PoCT service, training and competency are of key importance. PathWest regularly reviews PoCT devices in terms of meeting minimum testing requirements. This policy aims to manage low device usage as defined by the number of samples being tested on a particular device at a site over a defined period of time, to minimise the effect of low usage on the quality of PoCT results produced. PathWest recommends minimum testing requirements related to the number of patient samples being tested, and also takes into account the level of complexity of the POC testing device.

PoCT Device Endorsement vs Clinical Application Policy (POL-234**)**

Summary: The PoCT policy for Device Endorsement vs Clinical Application aims to ensure that all operators produce high-quality PoCT results for patient management across a wide range of clinical settings.

Device Endorsement: PathWest is responsible for recommending PoCT devices. Ensuring ongoing compliance with the PoCT policy is managed through the PoCT data management system and internal audits. PathWest is also responsible for reviewing submissions to introduce or change PoCT devices in terms of: clinical requirement; training and QC/QA/maintenance requirements.

Clinical Application: The Local Area Health Service is responsible for advising on clinical use of a PoCT device, including the appropriate clinical situations to perform PoCT in accordance with local clinical governance guidelines. PathWest does not stipulate in which clinical situations a PoCT device may be used. The responsibility of PathWest is to ensure the device provided is suitable and that staff are trained to operate the PoCT devices correctly.

6. REFERENCES

AS ISO 15189:2023 *Medical Laboratories – Requirements for Quality and Competence*

TS ISO 22583:2021 *Guidance for supervisors and operators of point-of-care (POCT) devices*

NPAAC *Requirements for point of care testing* (2021)

Appendix 1 POCT Request Process Summary

On-Site Service POCT (OSSPOC)

Request is sent to PathWest POC email account (poct.pathwest@health.wa.gov.au)

Documentation is assembled, signatures and information for 1-3 pages of FRM-209

Provided to the Principal Scientist of the appropriate discipline and GX.

Referred to DPC for endorsement/non endorsement

If not endorsed returned to POC

If endorsed sent to the Delegated Authority of GX for Signature and then forwarded to POC

PathWest POC will then commence the appropriate actions.

PathWest Remote Assisted POCT (PRAPOC)

Request is sent to PathWest POC email account (poct.pathwest@health.wa.gov.au)

Documentation is assembled, signatures and information for 1-3 pages of FRM-209

Provided to the Principal Scientist of the appropriate discipline and GX for sign-off

Sent to the Delegated Authority for Signature of GX and then forwarded to POC

PathWest POC will then commence the appropriate actions.

Information and Reports

Relevant PRG

Up to Date list of current POC sites for HSP

New applications and approval/non approval status

Any CIMS or non-compliant competency actions.

Clinical Scientific Governance Committee

POC CIMs

Summarised Competency Data

New Sites and Applications

New Equipment/Evaluations

Site Reports

Monthly Competency Reports