Policy for accreditation of Point of Care Testing (POCT) PS31

1 Purpose

The purpose of this document is to outline the accreditation requirements for applicant and accredited laboratories using Point of Care testing. This document is supplementary to ISO 15189 and ISO 22870.

2 References

EA 4/20 2018 - Guidance for the Assessment of Laboratories against ISO 15189 and ISO 22870. (Due to be issued in 2020)
PS24 - INAB policy statement on minimum verification requirements.
PS19 - INAB policy statement on multisite accreditation.
ISO 15189 - Medical laboratories - Requirements for quality and competence
ISO 22870 - Point-of-care testing (POCT) — Requirements for quality and competence

3 Definitions

POCT
Point of care testing is testing which is performed near or at the location of a patient with the result leading to possible change of care of the patient.
POCT Provider
Organisation / legal entity providing POCT, accredited to ISO 15189.
Delivery points
An area such as wards, clinics, emergency care etc., where POCT is delivered.
Cluster
A cluster is defined as a group of delivery points that have a similar purpose; for example outpatient clinics, emergency care, critical care, wards.
POCT site
A building or buildings where POCT is performed by the accredited legal entity

4 Policy

4.1 It is INAB's policy to assess POCT, sites, clusters and delivery points according to a sampling plan specific to each POCT provider. This sampling plan shall ensure full coverage of all POCT activities of the accredited laboratory over the five-year accreditation cycle. The legal entity of the POCT provider shall maintain responsibility for the results of all POCT activities.

4.2 To facilitate the assessment of the POCT testing, the accredited or applicant laboratory shall compile and maintain information on all equipment and its location for the accreditation scope of the laboratory. See Appendix I for a sample template to record this

information. The information captured shall include delivery point location, description of measurement technique, equipment description, type of interface to the POCT quality system recording of results and description of the test, at a minimum.

4.3 The laboratory shall ensure the information in Appendix I is maintained and updated for every change in equipment / location / interface on a real time basis. When equipment is moved / replaced to / from its original 'cluster' the laboratory shall ensure appropriate verification is carried out. See PS24 for minimum verification requirements. The INAB assessment team shall review the submitted information as per Appendix I.

4.4 This information shall also be provided to INAB with the PS10 documentation in advance of each on site visit or at the initial assessment in the case of a new applicant.

4.5 The laboratory shall designate key personnel to manage the POCT system. Deputies shall also be in place. INAB shall be informed of any changes to these key personnel.

4.6 INAB will assign an assessor to POCT at the on-site visits and the time involved in the assessment will depend on the nature and extent of POCT activities in each individual laboratory. This assessment effort will be agreed in advance with the INAB assessment manager on a case-by-case basis and may result in extra assessment time at the INAB onsite visit.

4.7 The sampling plan for POCT activities shall be agreed with the INAB assessment team and shall ensure the following:

- All measurement principles shall be assessed over the accreditation cycle for each discipline (i.e. Haematology, Clinical Chemistry).
- Each method of recording results / IT interface shall also be assessed at least once over the accreditation cycle, i.e. manual transcription, interface with laboratory IT system, interface with other IT systems as defined by the laboratory.
- If there is more than one site involved in POCT testing, each site shall also be assessed over the five-year accreditation period, at a frequency to be determined depending on the activity, (see INAB policy statement PS19).
- Clusters will be assessed on a sampling basis over the five year accreditation cycle.

4.8 A method comparison shall be completed between analysis in the main laboratory and the POCT instruments and the provider shall be aware of any differences in results and take the necessary steps in response to this.

4.9 The laboratory may choose not to report POCT results separately. If this is the case the POCT-instruments' results shall be included in the overall measurement uncertainty of the method. For example: If glucose is run on a lab instrument and there are a number of POC instruments in the hospital on which glucose can be run. If these two methods are reported separately, (e g Glucose and POCT-Glucose) the measurement uncertainty will be calculated separately. If the lab and POCT methods are reported simply as Glucose, the total measurement uncertainty (lab and POCT MOU combined) needs to be calculated and reported.

5 Implementation

The requirements in this policy will apply from January 2021.

Immediate implementation for future revisions.

For further information, please contact your assigned Assessment Manager.

Appendix I

Delivery point	Cluster	POCT measurement principle	Test	Interface / Manual transcription	Equipment name / asset numbers
Intensive care room 1	ICU		Electrolytes, kidney function	Manual transcription	XZZ 12345