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Guidance for the assessment of laboratories against EN ISO 15189 and EN ISO 22870 Point-of-Care Testing (POCT)

PURPOSE

This guidance document is intended for accreditation bodies (AB) that assess point-of-care testing (POCT) in the field of laboratory medicine and for medical laboratories (conformity assessment body (CAB)), which are responsible for point-of-care testing. The scope of this document extends to the following:

- a) Medical laboratories including both private institutions and government entities who provide POCT within the boundaries of their own organisation
- b) Medical laboratories that provide POCT to external organisations. Results from POCT remain under overall responsibility of the medical laboratory.

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1. INTRODUCTION

This guidance document is intended for accreditation bodies (AB) that assess point-of-care testing (POCT) in the medical field and for medical laboratories, which are responsible for point-of-care testing seeking accreditation.

The guidance document describes the specific criteria, which an AB and an applicant laboratory should take into account when accrediting a POCT provider. The EA Laboratory Committee (LC) issue the guidance document written by the EA LC Working Group Health Care, Laboratory Medicine.

The scope of POCT continues to develop both in the technologies available and in the amount and complexity of delivery points. In some respect, hospitals, private clinics and even community-based healthcare industries such as pharmaceutical outlets now offer POCT. It is an increasing concern that this POCT is performed with little control or direction.

2. TERMS AND DEFINITIONS

For the purposes of this document, the following terms and definitions apply:

IQA – Internal Quality Assurance: processes established to ensure (and improve) quality of service.

IQC – Internal Quality Control: a measure of precision or how well the measurement system reproduces the same result over time and under varying operating conditions. IQC may also provide a comment on accuracy depending on the IQC material available.

EQA – External Quality Assurance: samples distributed by an external provider with known and/or undisclosed content. Results are statistically analysed to present performance in the context of similar/identical methodologies and/or variance from a known value.

Operator: one who tests the patient by POCT.

POCT – Point-Of-Care Testing: testing that is performed near or at the site of a patient with the result leading to possible change in the care of the patient (ISO 22870:2016)

POCT provider: laboratory providing POCT.

POCT head office: legal registered office of POCT provider.

POCT customer: patient, health care organisation, which contracts POCT provider's services.

Medical laboratory: laboratory for examination of materials derived from the human body for providing information for the diagnosis, management, prevention and treatment of disease in, or assessment of the health of human beings. It may provide a consultant advisory service, covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation (definition in reference to standard EN ISO 15189). In the

context of this guide, the medical laboratory also provides and maintains overall responsibility for POCT and the results.

Site: a building (e.g. such as a hospital), where POCT examinations are performed.

Delivery points: wards, clinics, and emergency care rooms etc. where POCT is delivered.

Cluster: a grouping of POCT delivery points such as wards and clinics, where critical variables such as IT interfaces, purpose of POCT (for example emergency care) are the same. A cluster could be over more than one site. However, the approach should ensure that all the sites are separately considered. See Annex A for an illustration of the application of sites, clusters and delivery points.

Multi-site accreditation: accreditation of a laboratory (CAB) under a single legal entity for activities carried out at more than one site.

Legal entity: an association, corporation, partnership, proprietorship, trust, or an individual, that has legal standing in the eyes of law. A legal entity has legal capacity to enter into agreements or contracts, assume obligations, incur and pay debts, sue and be sued in its own right, and to be held responsible for its actions.

The following definitions apply in understanding how to implement the guideline

- "shall" indicates a **requirement**
- "should" indicates a **recommendation**
- "may" is used to indicate that something is permitted
- "can" is used to indicate that something is possible, for example, that an organization or individual is able to do something

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.3, a **requirement** is defined as an "expression in the content of a document conveying objectively verifiable criteria to be fulfilled and from which no deviation is permitted if compliance with the document is to be claimed."⁽¹⁾

In the ISO/IEC Directives, Part 2, Seventh edition, 2016, 3.3.4, a **recommendation** is defined as an "expression in the content of a document conveying a suggested possible choice or course of action deemed to be particularly suitable without necessarily mentioning or excluding others."⁽¹⁾

3. ACCREDITATION CRITERIA

The accreditation criteria for POCT are:

- Standard EN ISO 15189, Medical laboratories. Requirements for quality and competence (2) in conjunction with
- Standard EN ISO 22870, Point-of-care testing (POCT). Requirements for quality and competence (3).

4. SCOPE OF STANDARDS

The standard EN ISO 22870 applies to POCT when carried out in a hospital, clinic and by a healthcare organization providing ambulatory care. Only medical laboratories can apply the standards EN ISO 15189 and EN ISO 22870. Therefore, the limits to accreditation are defined as only medical laboratories can be accredited according to EN ISO 15189 and EN ISO 22870, as they provide and maintain overall technical and organizational responsibility for POCT. In general, the provision of POCT work is within a clinic or hospital environment. It is performed by clinical/hospital or ideally by specialized laboratory personnel.

Accreditation does not include POCT for patient self-testing in a home or community setting. All ABs shall define and document their own policies concerning POCT accredited to the standard EN ISO 15189 including EN ISO 22870.

5. MULTISITE ACCREDITATION

5.1 Multisite organisation

If the POCT provider operates at different sites, it shall meet multisite accreditation requirements (see EA-2/13 if the sites are in other European countries).

5.2 Basic requirements for multisite accreditation

When assessing a multisite POCT provider the most relevant requirements are:

- personnel.
 - common competence criteria;
 - centralized management of resources and competence;
 - centralized training and education.
- management system.
 - common management system, which is implemented in all sites and delivery points;
 - common policies and procedures, common documentation;
 - centralized quality assurance;
 - implementation of any required corrective action across all sites (as relevant).
- monitoring of the effectiveness of the management system.
 - centralized planning for monitoring the effectiveness of a management system;
 - audit program covering all sites and delivery points, comprehensive analysis of audit outcomes;
 - centralized following up of POCT customer feedback, complaints and non-conformities across all sites.
- records management, review and coordination by the POCT head office.

The initial assessment should include all sites and clusters (with a sampling of the delivery points - see 5.3) to demonstrate that competence in delivering all POCT activities has been established by the POCT provider. Examples of areas for assessment would be:

- planning and managing the operation of POCT,
- evaluation of clinical needs through contract review,
- defining responsibilities,
- defining competence of personnel and key qualifications,
- selecting examination methods and equipment,
- establishing criteria for quality assurance,
- controlling records,
- reviewing results and monitoring the effectiveness of the POCT operation,
- IT management,
- implementation of the POCT examination processes including sampling,
- POCT management including advisory groups and controlling the management system.

5.3 Sampling in multisite POCT accreditation

The AB should have a clear policy for identifying how assessments group delivery points together into clusters and what criteria are to be used. The AB should ensure that the accreditation cycle includes all sites and clusters with a selection of delivery points and critical activities to establish the competence of the POCT provider. Nevertheless, the AB should consider the quality risks in the delivery of POCT, as well as, the performance of the POCT delivery points.

The initial assessment should enable a statement on the overall conformity to standards EN ISO 15189 and EN ISO 22870 for all POCT sites, clusters and/or delivery points, by selecting a representative sample of the examination procedures and devices in use. The AB can use different tools in assessment activities such as:

- an assessment visit,
- a review of records,
- and / or interview of personnel.

The outcome of this assessment, together with the assessment of the medical laboratory taking into account all the clauses of both standards, shall be used to determine the overall conformity to standards EN ISO 15189 and EN ISO 22870. The AB should define criteria to select representative examples of POCT in different POCT sites, clusters, and/or delivery points. The applied selection criteria shall ensure that all measurement principles and critical variables in the equipment and examination procedures plus any key differences in the type of POCT sites, clusters and/or delivery points are assessed at the initial assessment. The primary focus should be on those POCT delivery points, where POCT results are critical to patient care, e.g. in accident and emergency rooms and operating theatres.

6. ORGANISATION/LEGAL ENTITY (EN ISO 15189:4.1; EN ISO 22870 :4.1)

The POCT provider might be in the same legal entity (organization) as its POCT customers (user of the generated POCT results), but it can also be a different legal entity.

The AB accredits the legal entity, which takes responsibility for delivery of POCT, for POCT results and for ensuring conformity to EN ISO 15189 and EN ISO 22870. The legal entity and its scope shall be clearly defined.

If personnel employed by another legal entity operates the POCT devices, there shall be a clear contractual or any other kind of arrangement for the use of these personnel and the necessary competence requirements¹⁾. This shall be managed in accordance with the requirements of the standard EN ISO 15189 as well as those of the standard EN ISO 22870 to ensure that it is evident, that POCT results are issued under the control and responsibility of the accredited POCT provider.

The AB shall assess the POCT provider to standard EN ISO 15189 in conjunction with standard EN ISO 22870 leading to some additional requirements. For example:

- The POCT provider shall be a legal entity or a part of a legal entity having ultimate responsibility for ensuring appropriate measures that are in place to monitor the accuracy and quality of POCT conducted within the healthcare organization.
- The POCT provider shall maintain a health professional grouping (medical counselling) and a multidisciplinary POCT management group (for the management of POCT service).
- The POCT provider shall evaluate the impact of clinical needs, financial implications and technical feasibility, when defining the scope of POCT.
- The POCT provider shall define a health professional group to define the scope of POCT service offered to customers.

The assessment of the AB shall cover the roles and operation of these above mentioned groups.

7. ROLES AND RESPONSIBILITIES IN POCT

7.1 Quality management system (QMS) (EN ISO 15189:4.2, 4.14.6; EN ISO 22870:4.2)

The POCT provider (to be accredited) operates a quality management system that fulfils the requirements of standards EN ISO 15189 and EN ISO 22870. The POCT sites, clusters and/or delivery points under the POCT provider's accreditation follow and respect this quality management system.

The POCT provider shall ensure that staff employed by another legal entity are not exposed to requirements from that legal entity, which are contradictory to the requirements in the QMS

¹⁾ This can be considered as 'contracting in' the appropriate resources.

of the POCT provider. The POCT provider shall be aware of any policies or procedures from the other body which have impact on the delivery of POCT and the staff (such as health and safety requirements, amendments to records and the reporting of non-conforming work). The POCT provider should review this documentation to ensure that the personnel delivering POCT are aware of any additional requirements they shall follow in context of POCT delivery. The POCT provider shall have a system to monitor the effectiveness and correct operation of POCT including internal audits, handling of non-conformities and operator/POCT customer/co-worker feedback. All information regarding the operation of POCT shall be analysed by the POCT provider and necessary actions taken. The role of the multi-disciplinary POCT management group in analysing the information shall be defined.

The AB shall take into consideration and document processes that most directly affect patient safety including all those related to the corresponding POCT performance to enable effective risk management in assessment.

7.2 Document control, record control (EN ISO 15189:4.3, 4.13, 5.6, 5.8; EN ISO 22870:4.3, 4.13, 5.6, 5.8)

All documents referred to and required at each site shall be included and considered in the QMS of the accredited POCT provider with respect to document control.

If the accredited POCT provider is offering POCT in the facilities of another organization and the staff is obliged to comply with in-house policies, then the POCT provider shall show that it has considered and reviewed these documents (as relevant external documents) within its document control process. Where required, these documents should be supplemented by the POCT provider. When required, contractual or any other kind of arrangements with POCT customers shall define responsibilities for the retention of records.

The POCT provider is responsible for all documents within its quality management system. Therefore, competent and responsible personnel shall issue the documents. All POCT documents, like all other laboratory documents, shall be included in the normal, periodic revision process of the quality management system of the POCT provider.

The POCT provider is responsible for the retention and control of all relevant records. The record control shall follow the definitions and requirements set up in cooperation with the POCT customer. All POCT and laboratory results and records shall be included in patient documentation of the hospital/clinic in electronic or paper form. There, the provider and/or publisher of the results shall undertake a clear distinction between POCT and laboratory results/records.

Appropriately qualified personnel of the POCT provider should get the results/records of quality assurance for further evaluation. The POCT provider should trace back the person who generated the results/records, verify the ongoing status of the POCT equipment, analyse the results and determine the expected results of the quality control at the point where and when the results were generated.

7.3 Personnel (EN ISO 15189:5.1, 4.1.1.3; EN ISO 22870:5.1)

Only trained and competent personnel shall carry out POCT work. The multidisciplinary POCT management group shall allocate responsibilities and staff able to undertake POCT. Ethical issues encountered during the daily work of POCT operators shall be considered, as relevant to the pre-analytical, analytical and post-analytical phases.

The POCT provider is responsible for the provision and ongoing management of POCT via an assigned, skilled staff member and/or team, in order to ensure that all POCT work is performed according to the requirements of the standards EN ISO 15189 and EN ISO 22870, with the same assurance as would be expected from the medical laboratory. These services may include, but not be limited to:

- implementation of a quality management system; identification of suitable POCT equipment;
- installation and maintenance;
- training of personnel;
- quality control (internal and external);
- troubleshooting;
- document control;
- record control;
- Identifying of customer satisfaction.

Personnel of the POCT provider shall have training delivered by qualified personnel, authorized by the POCT provider. The training shall at least include:

- patient preparation;
- theoretical basis of the examination;
- the technology used;
- the nature of biological material;
- material/sample collection;
- transportation and disposal of specimens;
- quality control requirements;
- recording and timely transfer of the results;
- interpretation of the results (clinical relevance and appropriate actions with respect to the result, especially in cases of non-valid results and non-valid quality control);
- sources of errors;
- basic maintenance and cleaning of equipment;
- sample and waste disposal;
- health and safety issues;
- witnessing the individual carrying out the POCT;
- education regarding critical limits and actions to be taken.

The competence of personnel of the POCT provider shall be evaluated, monitored and periodically reassessed. Relevant records of this on-going activity shall be maintained. These records may include results of quality assurance activities and information related to identified non-conformities. Retraining of personnel of POCT provider shall occur when necessary.

The POCT provider shall set the criteria by which competence is assessed. Either personnel of the POCT provider and/or not directly employed by the POCT provider shall provide training of operators of POCT services. The POCT provider shall ensure that all training (including that delivered to and by the POCT 'trainers') is effective and be periodically reviewed by it to ensure consistency.

7.4 Equipment (EN ISO 15189:5.3, 5.9, 5.10; EN ISO 22870:5.3)

The POCT provider is responsible for commissioning, installing and verifying new equipment and for implementing a preventive maintenance plan.

POCT providers shall maintain records of all POCT equipment including types, locations and dates of when they put them into operation. When the POCT provider moves equipment between areas, there shall be comprehensive decontamination measures, to avoid accidental cross-contamination. Afterwards, the POCT provider shall check the equipment to the degree necessary to demonstrate that it performs still identical as before.

If the POCT provider is taking new responsibility for POCT, which is already undertaken in a health care unit, it shall ensure that the equipment and methods work correctly and provide correct results. The POCT provider shall study the correlation between test results obtained by the medical laboratory and the POCT delivery point and evaluate the results. The POCT provider shall establish acceptance criteria based on clinical needs.

Whenever operators find that POCT equipment is defective or malfunctioning, it shall be taken out of service. The operators should inform the POCT provider immediately. Troubleshooting procedures shall be available. Only qualified personnel shall be authorized to operate and maintain the POCT equipment. Maintenance records shall be retained with all the relevant information. Operator's manuals and other working instructions shall be part of the quality management system and readily available to users.

Contractual or any other kind of arrangements shall ensure that:

- the facilities and equipment where POCT is provided are appropriate for the testing provided;
- responsibilities for adequate supplies of consumables and reagents are defined;
- responsibilities for calibration, maintenance and service are defined;
- familiarization of POCT personnel with equipment is implemented;
- POCT equipment are connected to the laboratory information system (e.g. within a hospital network), where applicable.

Authorized personnel shall regularly calibrate the POCT equipment. If a metrological calibration is not possible, the confidence in the results shall be provided in other means according to requirements of the standard EN ISO 15189 and with appropriate regard to the importance of traceability.

7.5 Accommodation and environmental conditions (EN ISO 15189:5.2; EN ISO 22870:5.2)

The POCT provider shall determine and manage the work environment in order to establish good working conditions, patient privacy and safety, as well as conformity to POCT requirements and the in vitro diagnostic (IVD) medical device manufacturers' recommendations.

Depending on the type of POCT the operators are carrying out, access to the testing environment shall be restricted to authorized personnel. The provider shall ensure that the working environment at each POCT delivery point is acceptable for the delivery of POCT results taking the above into account. Records to support the review of each POCT delivery point by the POCT provider shall be available.

Work areas shall be clean and tidy. The space allocated shall be commensurate with the volume of analyses and the overall needs of the testing offered (including facilities for staff, patients and storage). National legislation, regulations and guidelines could apply for some types of POCT and the POCT provider shall implement them in an appropriate way.

Where required, the POCT provider shall establish a programme to monitor environmental conditions. The POCT provider and the operators of POCT equipment should pay special attention to sterility, dust, electromagnetic interference, radiation, humidity, electrical supply, temperature, sound and vibration, as appropriate to the technical activities concerned.

7.6 Examination methods (EN ISO 15189:5.5; EN ISO 22870:5.5)

The POCT provider should base its POCT method selection on the needs of its customers (e.g. mostly health care personnel). The POCT provider should consider the performance characteristics of POCT methods during the selection process. Many operators apply POCT methods only for first-hand (screening) information. Therefore, they are not intended to be used for a final diagnosis without confirmation despite they contribute to the clinical evaluation.

POCT methods are mainly performed with closed IVD²⁾ medical device systems. It is the responsibility of the provider of POCT to review the validation (e.g. by verification of specific values generated by the device), initially performed by the manufacturer for the CE-making process, as own part of establishing the fitness for purpose of the method in the applied POCT context. Additionally, the POCT provider shall determine if any further validation of the in vitro medical device system used for POCT is required.³⁾

Verification of an applied CE-marked POCT kit is in the responsibility of the POCT provider. Knowledge of the POCT method and/or underlying technology used in the POCT context together with competence in verification procedures and awareness of corresponding requirements of standard EN ISO 15189 are required when verifying POCT systems. Selection

²⁾ IVD such as reactants/test kits and equipment are from the same manufacturer and closely linked together.

³⁾ It is particularly important to apply IVD that are CE-marked, else the POCT provider shall perform the validation of the POCT system according to the requirement of the regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices (IVDR (4)).

of the verification criteria depends on the specific POCT system. The accuracy and/or precision of POCT results shall be determined with reference to EQA results (when available) and comparisons with medical laboratory results of the POCT provider.

7.7 Quality assurance (EN ISO 15189:5.6; EN ISO 22870:5.6)

The provider of POCT shall monitor the performance of POCT methods according to IVD manufacturer's recommendations (according to recommendation set by the in vitro diagnostic medical device regulation (IVDR) (4)).

In those cases where IVD medical device manufacturers do not provide any control or calibration material, the POCT provider shall establish appropriate own procedures and material for IQC and/or apply alternative EQA procedures to review the accuracy/precision of POCT results and monitor the proper functionality of POCT devices. Plans for IQC and/or EQA should be based on recommendations of medical societies, technical literature and own experience of the POCT provider. Standards EN ISO 15189 and EN ISO 22870 specify requirements for IQC and EQA.

The POCT provider shall establish an overall quality assurance strategy. Furthermore, it shall run the appropriate IQC for the device and/or EQA program for POCT. Together with the multidisciplinary management group, the POCT provider shall review/analyse the IQC and/or EQA results. The POCT provider shall compare IQC and/or EQA data about their consistency between POCT sites, clusters and delivery points.

Included in the quality assurance efforts is the (electronic) transfer of records of IQC and/or EQA from each distinct POCT device to the Laboratory Information System (LIS) of the medical laboratory in order to control the performance of the POCT equipment and helps monitoring the competence of personnel performing POCT in the various delivery points.

7.8 Pre-examination (EN ISO 15189:5.4; EN ISO 22870:5.4)

The POCT provider should define and describe pre-examination procedures in its quality system in accordance with the requirements of the standard EN ISO 15189. The POCT provider shall ensure that personnel, using POCT equipment, implements these procedures. The POCT provider shall set requirements and specific instructions for proper sample collection, identifying, and handling primary samples together with any derived samples. Clear identification of the patient and traceability to the primary samples shall be evident.

In general, requirements for storage and transport of samples do not apply since POCT uses primary samples. However, requirements for pre-testing, preparation and/or condition of the patient before taking primary samples are important. The POCT shall apply and make available documented instructions or information regarding these sample related aspects.

The POCT provider shall define a procedure describing how to submit and complete requests for POCT work.

7.9 Post-examination, reporting results (EN ISO 15189: 5.7, 5.8, 5.9, 5.10; EN ISO 22870:5.7, 5.8)

In general, the POCT provider is responsible for the quality of all established POCT results. The clinician (medical doctor (MD)) is responsible for the manner in which these results are used for further decisions in the treatment of the patient. Therefore, the POCT provider shall ensure that appropriate clinical advisory services are provided to enable the correct interpretation of the results.

The POCT provider usually reviews, accepts, interprets as well as considers and places results in the context of the treatment or the medical history of the patient often right after their availability. The POCT provider should be well aware that POCT results can have an immediate impact in the treatment of the patient and act accordingly.

A software solution and/or an electronic connection to the POCT provider's medical laboratory are desirable, but not essential. However, when the POCT provider issues reports (in hard copy or in electronic form), all related processes shall be defined and documented. The provider of the result should perform plausibility checks before using or transferring them to others in the organization.

8. COMPETENCE OF AN ASSESSMENT TEAM

In addition to medical laboratory experience, the competence of an assessment team (technical assessors and/or experts) should include theoretical and practical knowledge of applied POCT systems, equipment, quality assurance procedures and both pre- and post-examination procedures. The assessment team should also have gained appropriate experience in the field of POCT and be able managing the whole POCT work in the assessment process.

9. PRESENTATION OF A SCOPE

The POCT provider shall clearly distinguish in its accredited scope between examinations undertaken by the laboratory and the POCT sites, clusters and/or delivery points. This means that the scope presentation of the accredited POCT provider should contain sites, clusters and/or delivery points should where POCT is being undertaken by establishing appropriate references to the sites, clusters and delivery points as required by the AB. The scope of accreditation of the POCT provider shall refer to both standards EN ISO 15189 and EN ISO 22870; see also document EA-4/17M (5) for further details in the description of scopes of accredited medical laboratories.

10. REFERENCES

- (1) ISO/IEC DIR 2:2016 - ISO/IEC Directives Part 2 Principles and rules for the structure and drafting of ISO and IEC documents.
- (2) Standard EN ISO 15189:2012, Medical laboratories. Requirements for quality and competence.
- (3) Standard EN ISO 22870:2016, Point-of-care testing (POCT). Requirements for quality and competence.
- (4) In Vitro Diagnostic Medical Devices Regulation 2017/746/EU.
- (5) EA-4/17 M - EA position paper on the description of scopes of accreditation of medical laboratories; current version.

ANNEX A

The example provided below is to illustrate the principles explained in the above text as to how delivery points, 'clusters' and sites could be applied in a sampling strategy, but it is not intended for this to be the definitive approach for all ABs.

Example:

Hospital H has two buildings in the perimeter of 2 km. One building is old (building/site I) with corresponding infrastructure and one is new with very modern infrastructure (building/site II). The hospital H operates several POCT delivery points x and applies for accreditation according to standard EN ISO 15189 including EN ISO 22870 for POCT in the following areas:

Delivery point	POCT equipment; type and total number / measurement principle	Test	Sample type	Number of POCT tests/year in total	IT – type, interfaced with lab or manual transcription	Types of staff delivering POCT
Old Building (building-site I)¹⁾						
Haematology clinic ¹⁾ (2x)	2 AAA/1	Anticoagulant levels (to provide dosing information)	Blood	350	Red system, not interfaced	Nurses
Operating theatre ²⁾ adults (5x) including orthopaedic (1x)	10 BBB/1	Glucose, basic chemistry	Blood	6122	Red system not interfaced	Nurses and operating theatre assistants
Wards ³⁾ (9x): post-OP recovery (1x) orthopaedics (2x) geriatrics (4x) maternity (1x) gynaecology (1x)	20 CCC/2	Electrolytes, urea, kidney function parameters	Blood Urine	8900	Manual transcription	Health-care assistants
Intensive care ward ²⁾ adults (1x)	2 DDD/2	Electrolytes, urea, kidney function parameters	Blood	500	Red system – interfaced	Senior nurses

New Building (building-site II)						
Paediatric theatre ²⁾ (1x)	2 CCC/2	Blood gases	Blood	80	Yellow system - interfaced	Nurses and operating theatre assistants
Intensive care ward ²⁾ adults (1x)	2 DDD/2	Electrolytes, urea, kidney function parameters	Blood	235	Yellow system – interfaced	Senior nurses
Intensive care ward – paediatric ²⁾ (x1)	2 DDD/2	Electrolytes, urea, kidney function parameters	Blood	101	Yellow system – interfaced	Health-care assistants, nurses and clinicians
Wards a, b3), Assessment centres (adults)	4 CCC/2	Electrolytes, urea, kidney function parameters	Blood Urine	5789	Yellow system – interfaced	Healthcare assistants, nurses and clinicians
Haematology clinic ¹⁾ (1x)	2 AAA/1	Anticoagulant levels (to provide dosing information)	Blood	122	Yellow system, interfaced	Nurses and healthcare assistants

- The POCT provider has confirmed that the organisation of the POCT provider in each building uses and implements the same management system.
- The POCT coordinator is responsible for training and establishing appropriate competence of all operators and related POCT personnel in both buildings (site I and II).

¹⁾ **Clinics:** Examples of critical variables within the “cluster” which should be assessed: Laboratory information system (LIS) and the use of healthcare assistants. Critical variables to other clusters that the assessment team of the AB should assessed are e.g. handling of outpatients, use of different analyser type, test and information presented to clinical team to provide dosing information.

²⁾ **Critical care:**

Intensive care and operation theatres – Examples of critical variables within the “cluster” which should be assessed: LIS; paediatrics adult section; purpose of performed POCT (either for diagnostic or for screening); analyser types/tests/measurement principle; different operators doing POCT; high/low use of POCT systems. Critical variables to other clusters the assessment team of the AB should assessed are e.g. emergency and critical care.

³⁾ **Wards:** Examples of critical variables within the “cluster” that should be assessed: Manual versus LIS for data recording; type of patient (e.g. geriatric patients) and their particularities. Critical variables to other clusters that the assessment team of the AB should assessed are e.g. urine as a sample type and a very high use of POCT systems in this area.

Sampling plan for visit:

Planning of assessment based on each site (site I and II), each "cluster" and variables within and between "clusters":

Clinics: 2 delivery points

- Site I - 1x Haematology clinic
- Site II - 1x Haematology clinic

Critical care: 4 delivery points

- Site I - 1x adult (orthopaedic) theatre, 1x Intensive care (adult)
- Site II - 1x paediatric theatre; 1x intensive care paediatric

Wards: 4 delivery points

- Site I - 1x post-OP recovery; 1 x geriatrics; 1 x maternity
- Site II - 1x assessment centre

Clusters	SITE I			SITE: II		
	Critical Care	Wards	Clinics	Critical Care	Wards	Clinics
Delivery points (Number assessed)	adult (orthopaedic) theatre (1x)	post-OP recovery (1x)	Haematology clinic (1x)	Paediatric theatre (1x)	Assessment centre (1x)	Haematology clinic (1x)
	Intensive care (adult) (1x)	geriatrics (1x)		Intensive care paediatric (1x)		
		maternity (1x)				

The planning showed that there are 10 delivery points assessed out of 24 potential delivery points operated by the POCT provider of hospital H.

If every delivery point would be located in one building (e.g. in the new building) and all POCT system would be interfaced to the LIS of the medical laboratory then the sampling could be potentially reduced for the planned assessment.