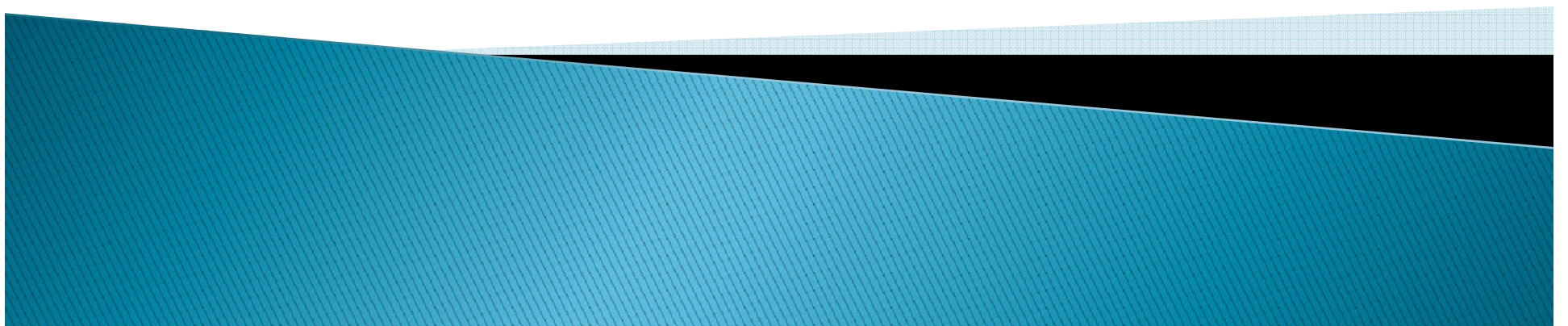
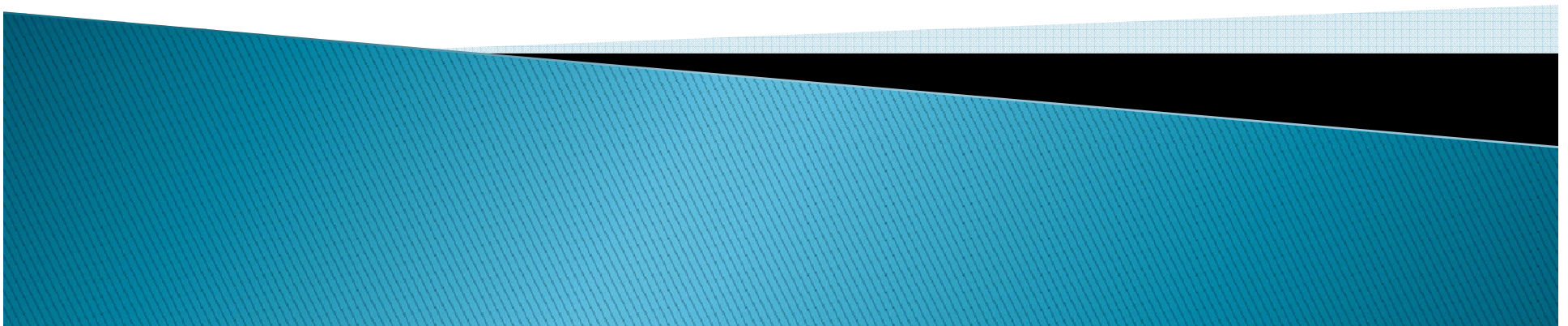


IN THE NAME OF GOD

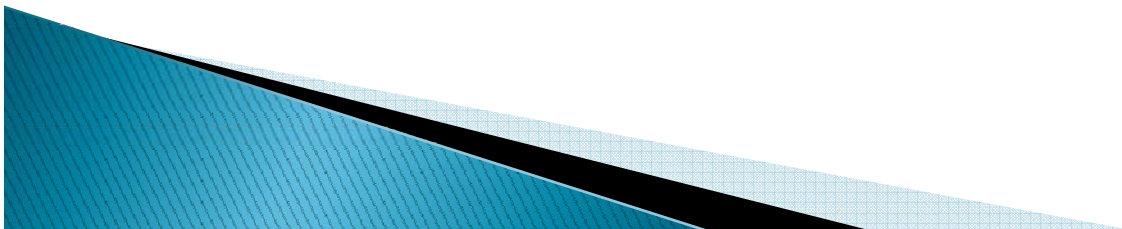
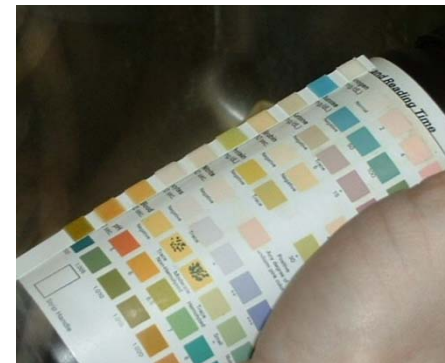


POCT Accreditation

Dr.P.Dahim MD.AP.CP
Reference Health Laboratory



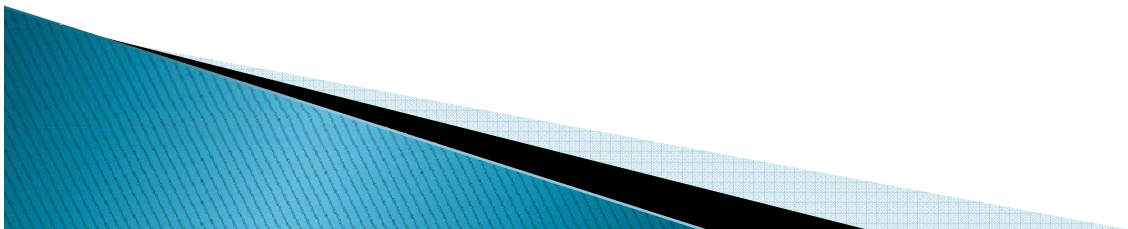
- ▶ Point of care testing (POCT) refers to laboratory testing that occurs close to the patient rather than in a central laboratory.



POCT (near-patient 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 :2006



Analytical patient testing activities provided within the institution , but performed outside the physical facilities of the clinical labs.

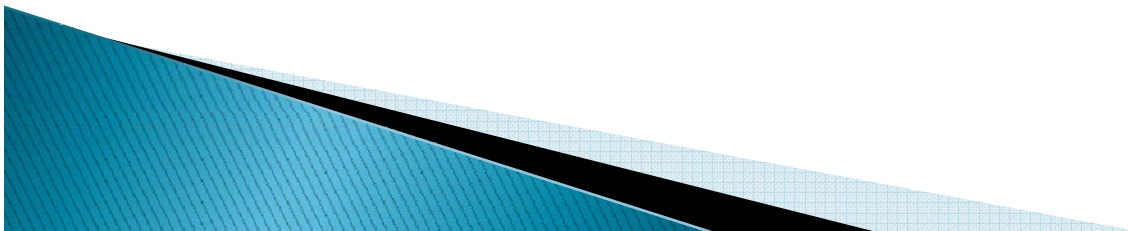
It does not require permanent dedicated space.

College of American Pathologists

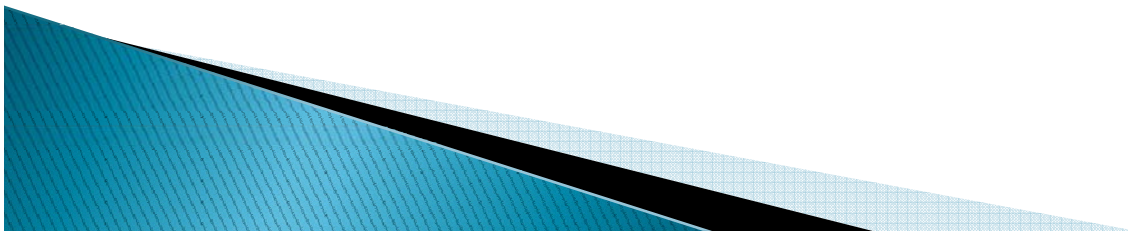


History

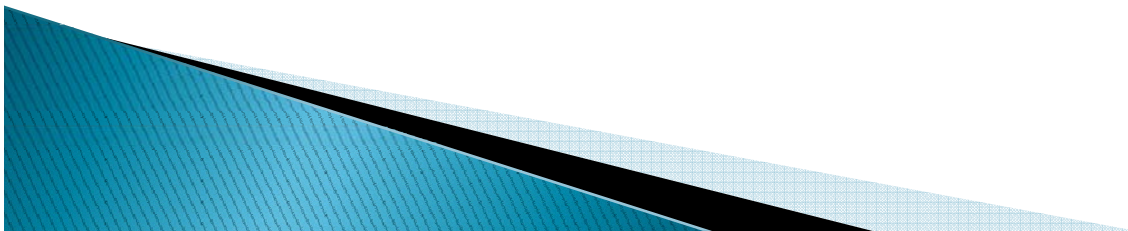
- ▶ The first reported use of POCT is found in papyrus documents dating back to 1550 B.C., which depict Egyptian physicians using ants to determine glycosuria in patients suspected of having diabetes mellitus.



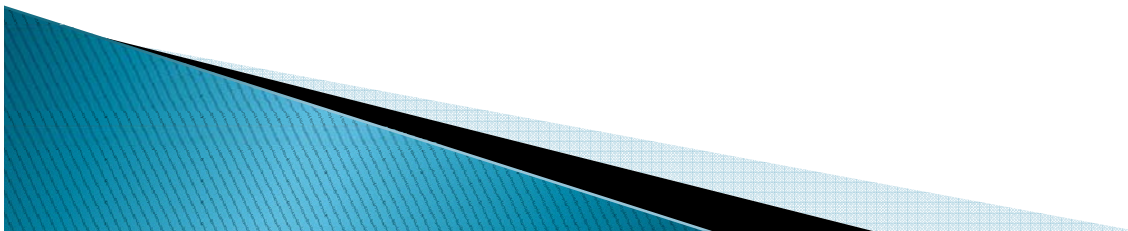
- ▶ POCT is usually performed by non-laboratory trained individuals such as nurses, physicians, respiratory therapists, perfusionists, anesthesia assistants, midwives and paramedics.
- ▶ Patients also perform POCT.



- ▶ A physician may decide to perform laboratory testing in the office.
- ▶ As the physician is ultimately responsible for his/her practice, the authority is implied.

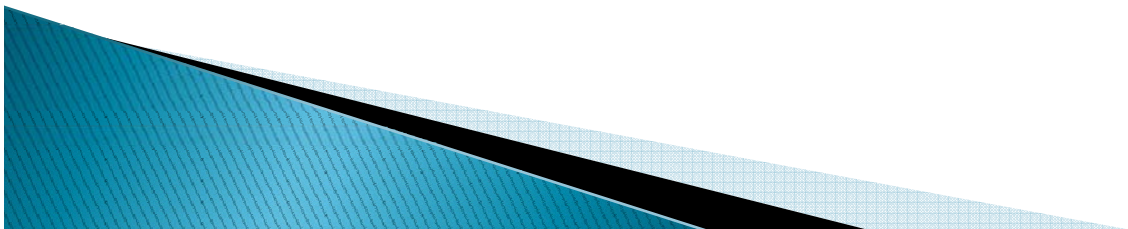


- ▶ The provision of POCT could be within a clinic/hospital by clinical (hospital) or laboratory personnel.



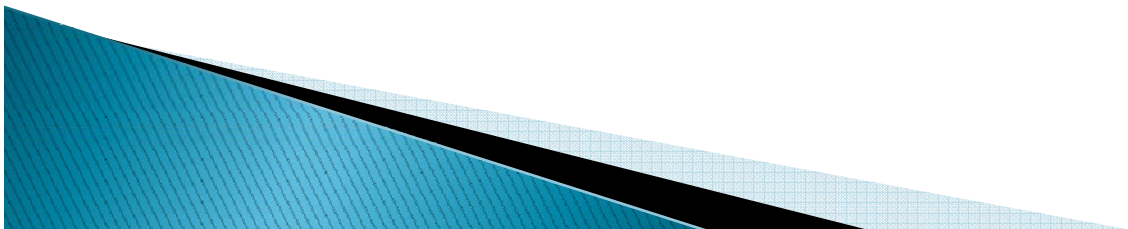
Benefits

- ▶ POCT can be advantageous in situations requiring rapid turnaround time of test results for clinical decision making.
- ▶ Reduction and/or elimination of specimen /sample transport;
- ▶ It generally requires less sample volume than tests performed in the central laboratory
- ▶ Elimination of blood collection tubes and centrifugation with fresh whole blood specimen;



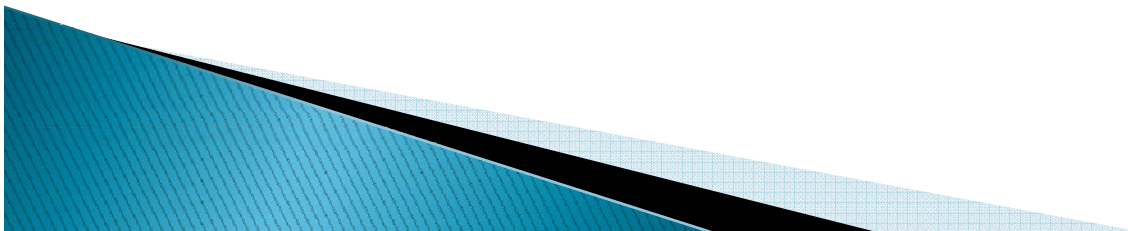
Challenges

- ▶ Major risks derive from the limited competence of users (clinical staff rather than laboratory trained individuals which can lead to errors resulting from a lack of understanding of the importance of quality control and quality assurance practices)
- ▶ There is a limited understanding of requirements for licensure, training, documentation, and procedures.



- ▶ POCT is generally more costly than traditional laboratory based testing.

POCT is usually more expensive than testing performed in the central laboratory and requires a significant amount of support from the laboratory to ensure the quality testing and meet accreditation requirements.



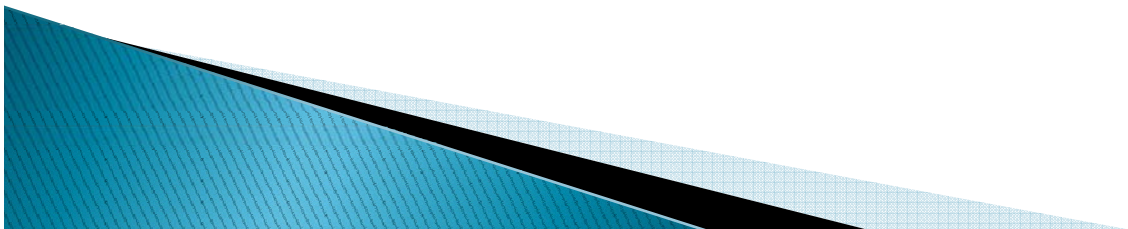
Do not forget...

- ▶ POCT is laboratory testing and must be treated as such, which includes an understanding of the entire testing process from the pre-analytical phase to the post-analytical phase for anyone performing testing
- ▶ POCT results are used to make clinical decisions and the use of POCT requires the implementation of a quality assurance program to ensure the accuracy of results for patient safety



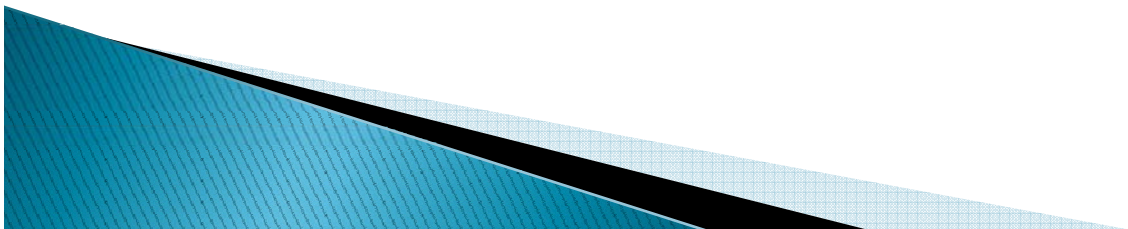
Accreditation

- ▶ The accreditation process ensures that organization, system certification practices are acceptable, typically meaning that they are competent to test and certify third parties, behave ethically and employ suitable quality assurance.

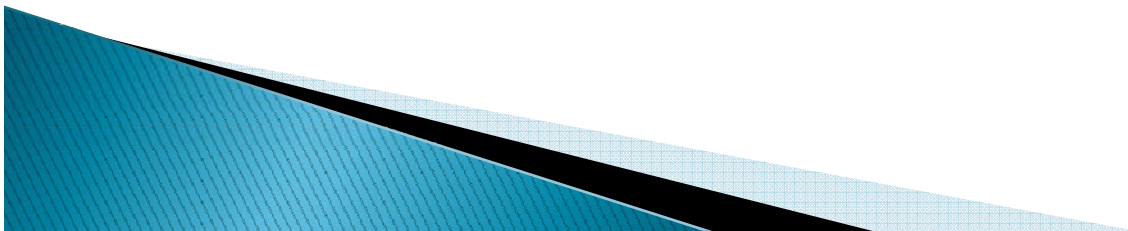


Accreditation

- ▶ Accreditation body
- ▶ Accreditation criteria(Standards)
- ▶ Assessment team
- ▶ Site

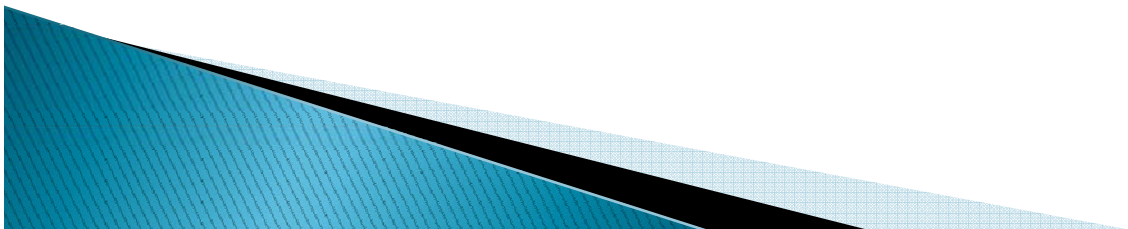


POCT Accreditation



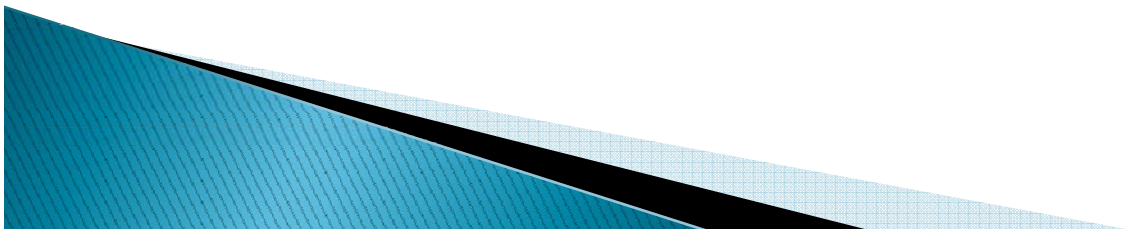
Accreditation body

- ▶ CPA(Clinical Pathology Accreditation)
- ▶ EA(European Accreditation)
- ▶ CAP(College Of American Pathologist)
- ▶ ...



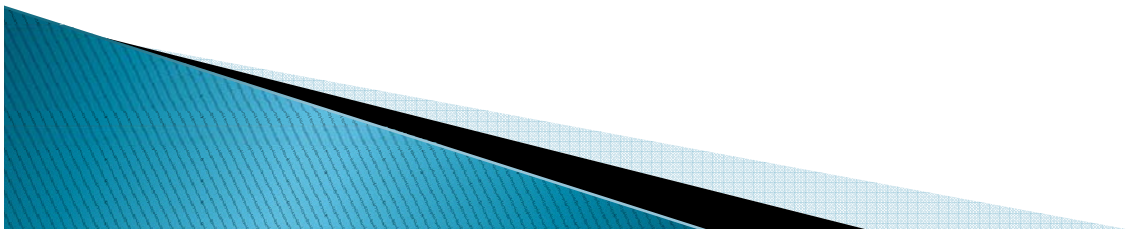
ACCREDITATION CRITERIA

- ▶ The accreditation criteria for POCT are:
- ▶ Standard EN ISO 15189, Medical laboratories. Requirements for quality and competence (1) in conjunction with
- ▶ Standard EN ISO 22870, Point-of-care testing (POCT). Requirements for quality and competence

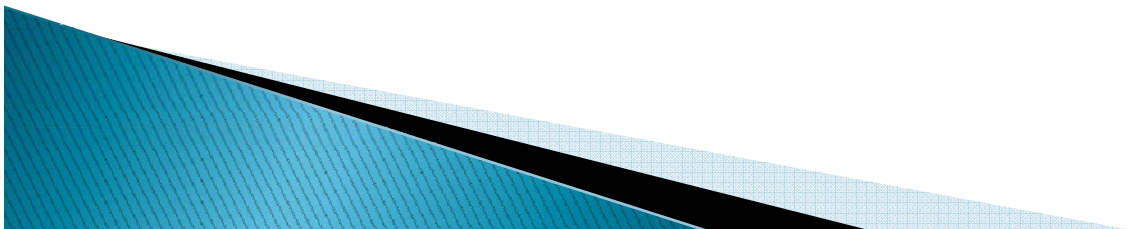


NOTE

- ▶ The standard EN ISO 22870 applies to POCT when carried out in a hospital, clinic and also by a healthcare organization providing ambulatory care.
- ▶ 22870:2006 is not a standalone standard, but seen as a supportive standard, which means that the POCT provider must also be accredited to ISO 15189:2012.
- ▶ It is not intended for patient self-testing in a home or community setting.

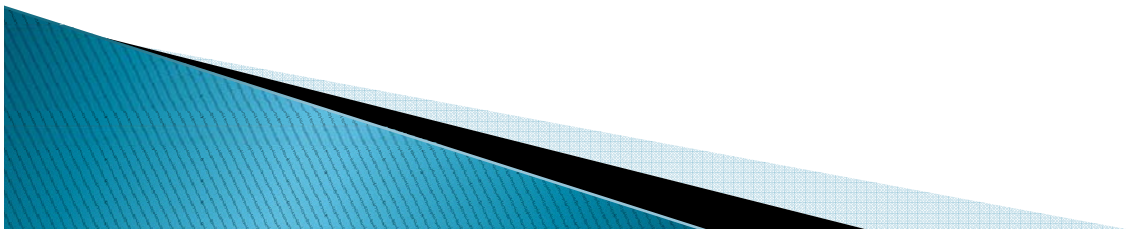


- ▶ EN ISO 15189 and EN ISO 22870 are intended for medical laboratories.
- ▶ Therefore the limits to accreditation are defined as only medical laboratories can be accredited according to EN ISO 15189 and EN ISO 22870, as they provide and maintain overall responsibility for POCT.



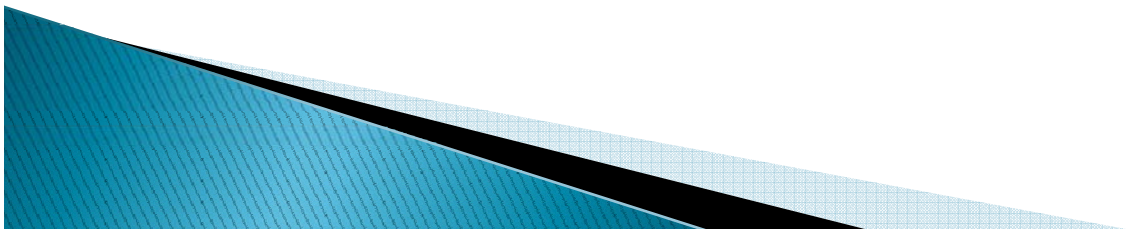
ISO 15189

- ▶ **Management Requirements**
- ▶ Organization and management responsibility
- ▶ Quality management system.
- ▶ Document control
- ▶ Service agreements
- ▶ Examination by referral laboratories
- ▶ External services and supplies
- ▶ Advisory services
- ▶ Resolution of complaints
- ▶ Identification and control of nonconformities
- ▶ Corrective action
- ▶ Preventive action
- ▶ Continual improvement
- ▶ Control of records
- ▶ Evaluation and audits
- ▶ Management review



Technical Requirements

- ▶ Personnel
- ▶ Accommodation and environmental conditions
- ▶ Laboratory equipment, reagents, and consumables
- ▶ Pre-examination processes
- ▶ Examination processes.
- ▶ Ensuring quality of examination results
- ▶ Post-examination processes
- ▶ Reporting of results
- ▶ Release of results
- ▶ Laboratory information



INTERNATIONAL
STANDARD

ISO
22870

First edition
2016-02-01

**Point-of-care testing (POCT) —
Requirements for quality and competence**

*Analyses de biologie médicale (ABM) — Exigences concernant la
qualité et la compétence*



Reference number
ISO 22870:2016(E)

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K ISO 22870

ISO 22870 :

▶ **Management Requirements**

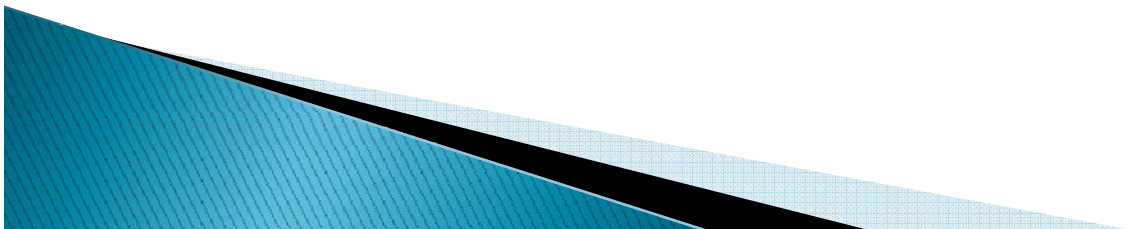
- Organization
- Quality management system
- Document control
- External services and supplies
- Advisory services
- Resolution of complaints
- Identification and control of non-conformities
- Corrective and preventive action
- Continual improvement
- Quality and technical records
- Internal audits
- Management review



ISO 22870

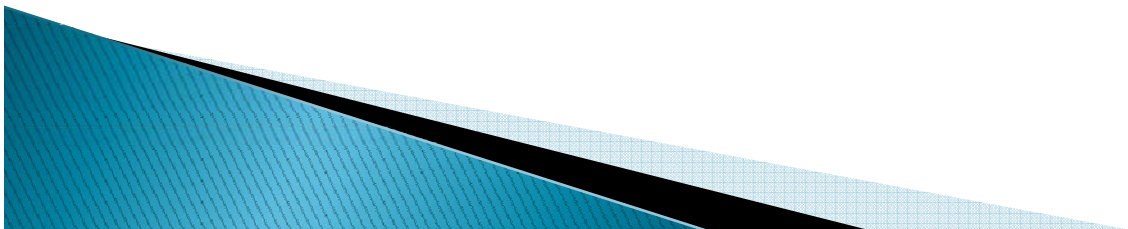
▶ Technical Requirements

- Personnel
- Accommodation and environmental conditions
- Laboratory equipment
- Pre-examination procedures
- Examination procedures
- Assuring the quality of examination procedures
- Post-examination procedure
- Reporting of results



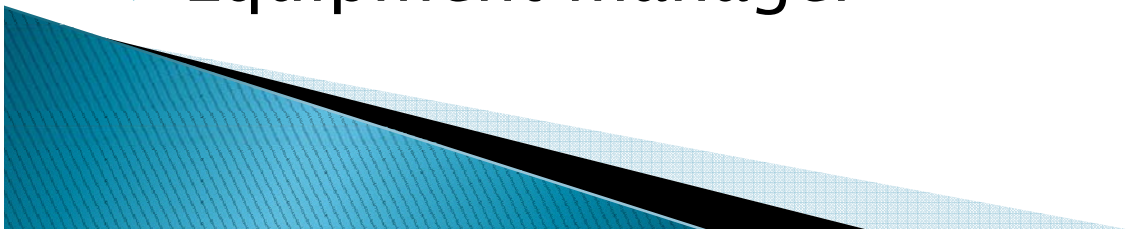
Focusing on :

- ❖ Roles & responsibilities
- ❖ Training & competency
- ❖ Documentation
- ❖ Equipment management
- ❖ Quality assurance



Multidisciplinary POCT Management group

- ▶ Medical director or designee
- ▶ POCT coordinator(s)
- ▶ Clinicians
- ▶ Nurses
- ▶ Pharmacists
- ▶ Safety officer
- ▶ Equipment manager

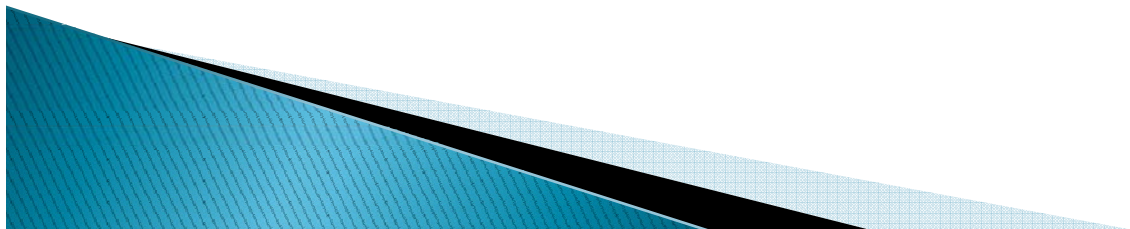


Multidisciplinary POCT Management group :

- ❖ Defining responsibilities & authorities

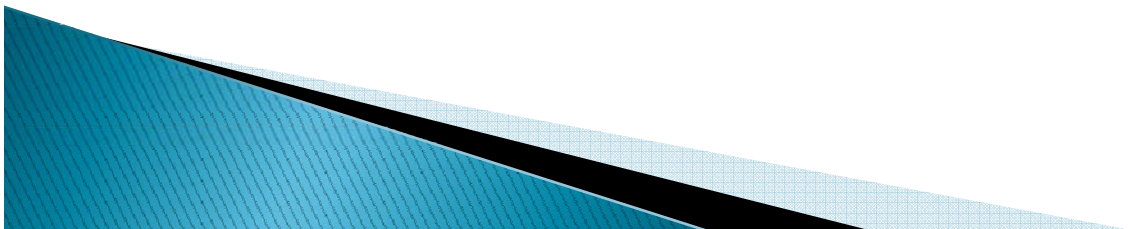
- ❖ Assigning responsibilities for POCT devices and their operation, including defining performance limits, accuracy, and precision

Laboratory director is the main responsible of the group



The management of laboratory services :

- ❖ Ensuring the availability of resources & information
- ❖ Monitoring , Measuring & analyzing these processes
- ❖ Appointing a quality manager responsible for POCT quality



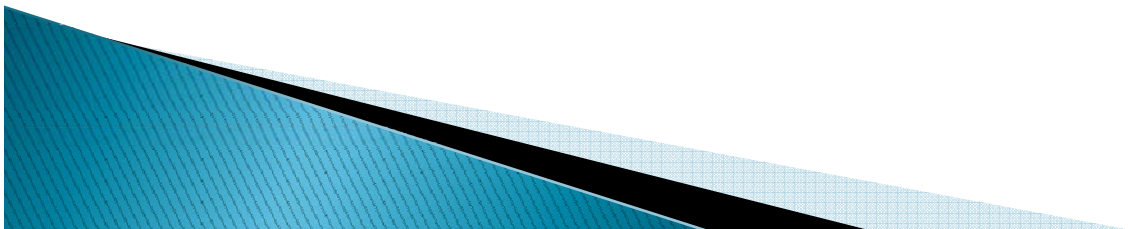
Personnel

- ❖ The staff and their responsibilities
- ❖ Theoretical & practical training programme
(including competency assessment)
- ❖ Specific requirements (based on the tests)
- ❖ Updating programmes
- ❖ Regular competency assessments
- ❖ Certificates



Documentation

- ❖ Procedures and working instructions
 - Encompassing all the process
 - In paper or electronic media
 - Available for all the relevant staff
 - Under control



Documentation

❖ Pre-analytical procedures:

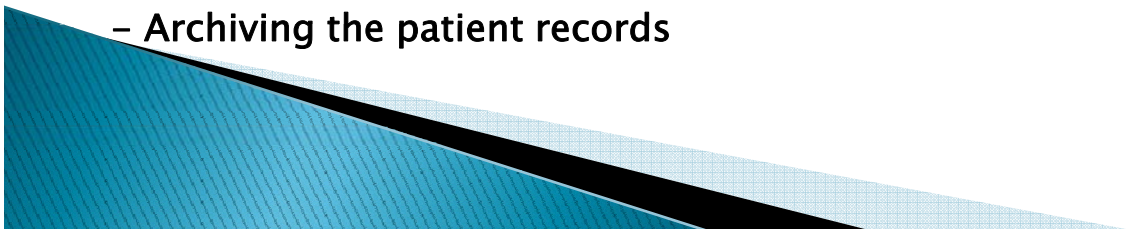
- Patient Identification & preparation
- Sample collection

❖ Analytical procedures:

- Standard Operating Procedures
- Equipment Technical instructions
- Quality control procedures

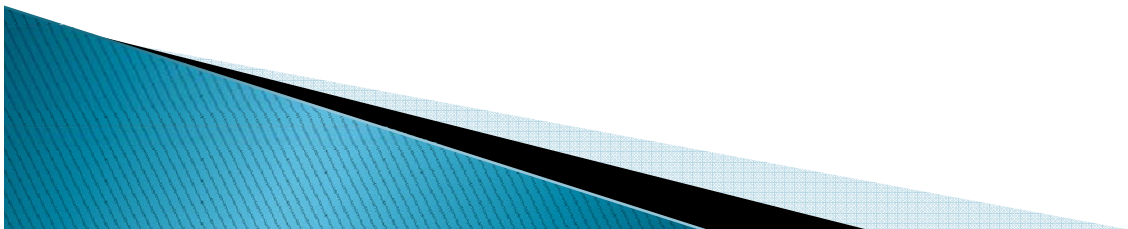
❖ Post-analytical procedures:

- Recording the results
- Reporting the results
- Critical limits & notifying method
- Any unexpected condition
- safe handling & disposal of samples , reagents & kits
- Archiving the patient records



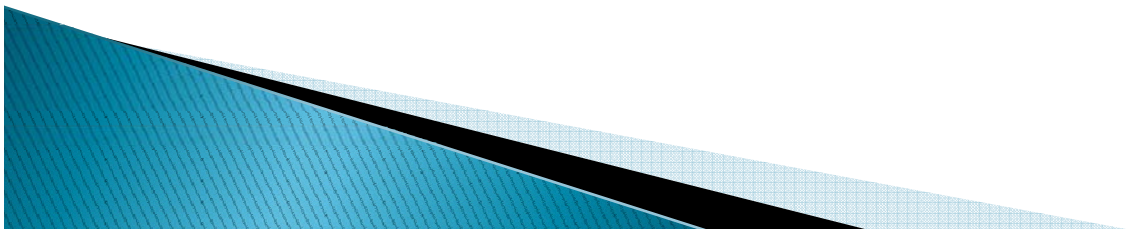
Keeping the evidence of :

- ❖ Training & competence
- ❖ Equipment maintenance
- ❖ Quality control activities
- ❖ Purchasing considerations (device , reagents...)



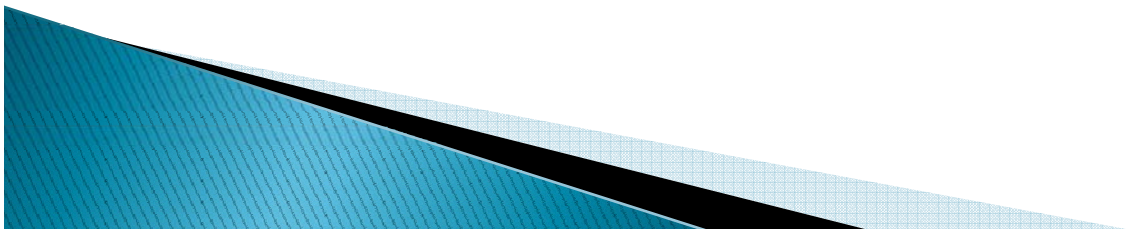
Equipment

- ▶ Technical validation
- ▶ Diagnostic capability
- ▶ Necessary facilities for correct performance
- ▶ Maintenance program



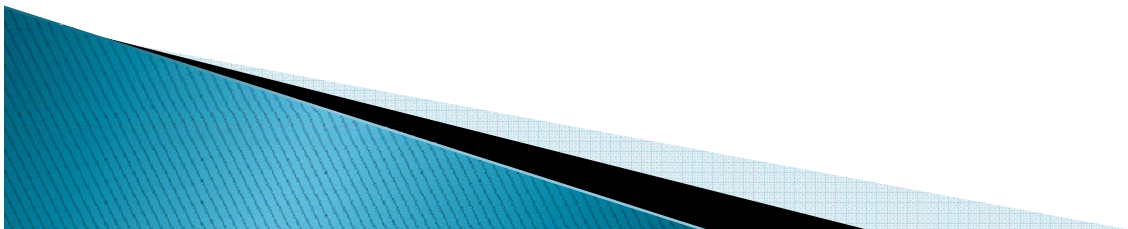
Quality assurance

- ❖ Documented quality control procedure
- ❖ Performing QC activities
- ❖ Performing Corrective & preventive actions
- ❖ Documentation



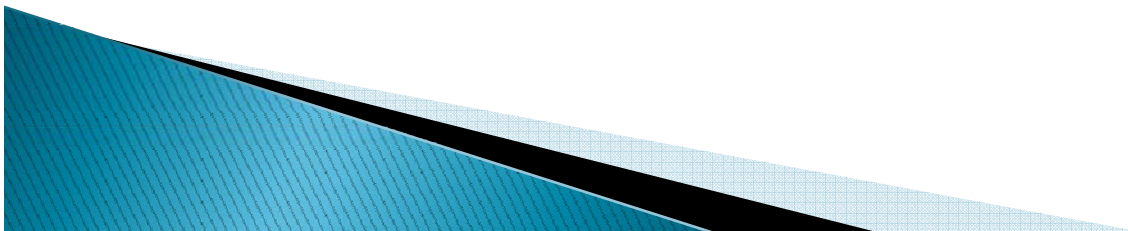
COMPETENCE OF AN ASSESSMENT TEAM

- ▶ In addition to medical laboratory experience, the competence of an assessment team (technical assessors/experts) should include theoretical and practical knowledge of POCT methods, equipment, quality assurance procedures and both pre- and post-examination procedures.
- ▶ The assessors should also have experience of POCT and managing the whole POCT.



Site

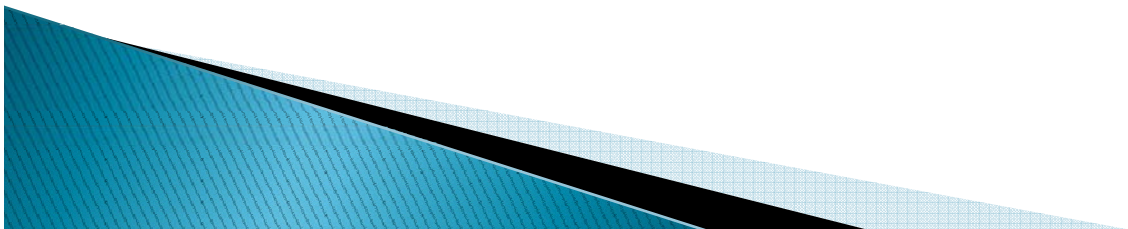
- ▶ A place, where POCT examinations are performed. This can be defined as a ward or clinic e.g. intensive care unit or the location of the clinician e.g. a community physician



MULTISITE ACCREDITATION

Multisite organisation

- ▶ A multisite organisation operates in various sites with one or more sites geographically separated from the head office (Medical laboratory). If the POCT provider operates in different sites, it must meet multisite accreditation criteria.
- ▶ **Multi-site accreditation, Accreditation of a laboratory under a single legal entity for activities carried out at more than one location**



Thank You

