NABL : 112

ISO (international standard of organization) : medical laboratories - requirement for quality & competence

NABL : 112 -

Describe specific criteria for accreditation of medical laboratories.

- Requirements on specific criteria are based on international standard, ISO 15189 : 2012
- Laboratories compliance to requirements of standard & it's technical competence are assessed by NABL for accreditation.
- The specific criteria document must be used in conjunction with ISO 15189 : 2012
- It provides interpretation of latter document & describe specific requirements.

Differences :- example.

(1) Scope of accreditation is written
e.g. Clinical biochemistry
Hematology
clinical pathology
Microbiology & infectious disease serology
Histopathology
Cytopathology
Cytogenetics
molecular testing
Flow cytometry.

(2) Description & type of laboratory written.

- Small size - Samples size up to 100 subject per day
- Medium size - sample size up to 101 - 400 subject per day
- Large size - Sample size upto 401 - 1000 Subjects per day
- very large size - Sample size more than 1000 Subjects per day.
- Mutiple location - Laboratory with more than one location in same district with same legal identity.

(3) Calibration frequency of equipment Specified.

e.g. Autoclave - one year
Centrifuge - one year
Thermometer - one year.
~~piston coperate~~

(4) IQC (Internal quality control) guideline given
e.g. Design IQC procedure appropriate of size & scope.
- plott result on LJ charts.

- IQC frequency :-

- Irrespective of size of laboratory
↓
2 level QC at least once on day of performing test.

- For 24 x 7 operational laboratories -
2 level control in peak hour
Subsequently one level every 8 hour.

- Derive laboratories own mean & SD using minimum 20 data points to plot on LJ chart
- Define own criteria for accepting or rejecting the run & be able to justify the application
- Analyze QC outliers, their causes, take immediate corrective action
- Calculate monthly mean, SD & CV.
- Employ suitable reference material traceable to international standards for calibration of measuring system & methods
- obtain traceability certificate for calibrator from kit supplier & document appropriately
- For test → Calibration & control material not available
  use - third - party control - not mandatory for accuracy verifying
- For blood gas measurement → at least one control every 8 hours
  - Run one control with each patient sample if instrument automatically does not calibrate

→ Inter laboratory comparison
- EQA [external quality assessment] / PT [proficiency testing participation before gaining accreditation required.

→ Alternative approaches if formal EQA not available for validation of performance:-
Replicate testing
Examination of split sample [within laboratory]
Use of reference method & material where available

- Exchange of sample with other accredited laboratories.

↓

(1) one will function as reference laboratories against which other will be compared. Document as MoU.

(2) When several laboratories, compare result against reference laboratory.

→ Other quality assurance procedure

↓

Review of daily mean
Delta check
Clinical correlation
correlation with other laboratory results.