

Quality Management in FSL-

Testing and calibration

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Introduction

- ❑ All laboratory accreditation activities are administrated under direction of National Accreditation Board for testing & calibration Laboratories (NABL).
- ❑ The laboratory are required to comply with all requirements listed in international standard ISO 15189:2007

Scope

The scope of accreditation is applicable to following medical laboratory services-

1. Clinical pathology
2. Haematology
3. Cytopathology
4. Histology

Description of laboratories

Following classification shall be used for determining structure-

- 1.Small laboratory
- 2.Medium laboratory
- 3.Large laboratory

Classification is done according to the level at which they function..

Three stages of testing

Pre-test examination procedure- Specific instructions for proper collection & handling of primary samples shall be documented in primary sample collection manual.

- 1.Sampling-Transport and storage
- 2.Sample handling-All records are maintained.

Examination procedure-According, to clause ISO 15189-2007 actual test is performed.It uses standard methods which are maintained by laboratories.

It includes

- 1.Sample identification
- 2.Results interpretation in positive and negative controls.
- 3.Disposal of contaminated waste for safety purpose. Test is carried out by 2 methods

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- 1.Routine test
- 2.Special test

Post -test examination procedure- 1.Assuring quality of results

- 2.Reporting results.

Conditions for laboratory

1. There must be adequate space and storage facility to carry out test.
2. Laboratory testing area should have appropriate lighting and ventilation.

Calibration

Laboratories perform calibration means comparison between reference standard and measuring instruments. This process must be documented. It should be maintained.

Calibration report

Results of calibrations may be recorded in document called calibration certificate or calibration report.

Calibration of Equipments

Equipments used for test must be calibrated properly. Including equipment used for subsidiary measurements have significant effect on accuracy of test results.

The equipment shall be calibrated or otherwise verified before being put into service & shall be subjected to program of recalibration.

Laboratory equipments

All the reagents, media, kits should be stored as recommended by manufacturer and used within expiry dates.

The label should bear following information-content and quantity, date of opening, storage requirements, expiry dates.

Merits of testing and calibrations

- 1.To measure reliability of equipment.
- 2.One can perform test with small quantity of sample.

Demerits

1. Test laboratory requires adequate space.

References

Clause 4.7 NABL

THANK YOU