Quality Assurance

Dr. Mohamed.A.Mahdi

Laboratory Management and Quality Assurance

(MLS-QUAL-323)

Lecture NO. (16)

Quality Assurance

- This describe all the steps taken both in and out side the laboratory to achieve reliable results, starting with the patient preparation and collection and specimens and ending with correct interpretation of results.
- Quality control is one component of the quality assurance system.

Quality control

Each laboratory system for recognizing and minimizing analytic errors –or it describe the steps taken by the laboratory to ensure that tests are performed correctly.

The quality assurance system is encompasses pre-analytical, analytical and post- analytical factors:

1. Pre analytic factors

1. Selection of appropriate investigations.
2. Preparation of patients :- is critical- for example nutritional status (fasting –random), arecent meal ,alcohol, etc .

- The lab must provide instructions ,usually in the form of manual procedure for proper patient preparation and this should be found in all nursing units and be available to all medical personnel .

3. Correct collection:-

a. Collection methods:- (ex: how to avoid haemolysis and venous stasis when collecting blood samples).

b. Types of container to use .(tube-bottle).

c. Suitable anticoagulant –preservative or stabilizer.

d. Stability of different substances in samples and time with in which a specimen should reach the lab.

e. Special precautions which need to be taken for certain specimens .(ex:- protect blood specimen from light and heat → testing for biliurbin).

f. Methods of sample transport:- (reception staff must have medical background)-separation and storage.

g. Labeling of specimens:-

-patient name-lab number-request form, labeling container.

4. Correct filling in of a request form :-

- Should be as simple and clear as possible and provide essential information such as :- drug therapy are supplied.
- Specify the actual test required and avoid general request such as (liver function tests).

- Date and time of specimen collected must be written.

- Pre-analytical factors are difficult to monitor and control because most occur outside the laboratory.

2/ Analytic factors

1. **Training** laboratory workers to perform tests correctly.

(workshops- conferences- lectures- presentation)

- The reference lab should provide the laboratories by:

(STD solutions –control sera- test reagent).

2. **Reception** :- check that specimen is useful to do the test .(for example no hemolysis) .

3. **Reliability** :-

a. Accuracy :- means closeness between the value obtained and true value .

b. Precision :- means (reproducibility)of the value obtained.

c. Specificity :- hasn't any interference substances.

d. Sensitivity :- detect small a mounts of substances.

Accuracy # inaccuracy. Precisions # imprecision

Specifity # interference. Sensitivity #detection limit.

4. **Practicability:** (cost – precautions – speed – experience).

5. **Comparison** :- compare the result with clinical remarks of patient.

6. **Correct calculation**.

7. **Making sure that equipmen**t such as analytical balance ,colorimeters ,water bath ,etc **are being used correctly**.

3/ Post analytical factors

1. **Reporting results** :- results should be reported careful.

- The writing should be clear ,particularly figures ,and decimal points must be correctly placed.

2. **Careful recording of results.**

3. **Correct interpretation of test results**:- to assist in the interpretation of results the laboratory should provide reference (normal ranges for each of the test it performs according to the method used).

4. **Dispatch** :- the result should sent as soon as possible to the doctor.

Routine Quality Assurance

- Should be performed every 3 weeks as:

1. Calibration of instruments.
2. Checking the validity of reagents.
3. Checking the validity of STDs.
4. Checking the validity of anticoagulants.

5. Training of the lab staff periodically.

6. Checking the control materials.

7. Using control test daily with in each batch of specimens.

8. Using external quality control every 1 to 3 months.

9. Checking the statistical program of control system.