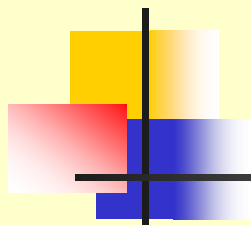


23/12 /2018 third year



Laboratory Quality Control
Edited by:
sagda kamal



Definitions

- **Quality Control - QC** refers to the measures that must be included during each assay run to verify that the test is working properly.
- **Quality Assurance - QA** is defined as the overall program that ensures that the final results reported by the laboratory are correct.



Definitions

- **“The aim of quality control is simply to ensure that the results generated by the test are correct. However, quality assurance is concerned with much more: that the right test is carried out on the right specimen, and that the right result and right interpretation is delivered to the right person at the right time”**



Definitions

- **Quality Assessment - quality assessment (also known as proficiency testing) is a means to determine the quality of the results generated by the laboratory. Quality assessment is a challenge to the effectiveness of the QA and QC programs.**
- **Quality Assessment may be external or internal.**



Variables that affect the quality of results

- **The educational background and training of the laboratory personnel**
- **The condition of the specimens**
- **The controls used in the test runs**
- **Reagents**
- **Equipment**



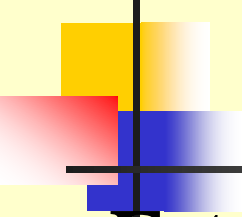
Variables that affect the quality of results

- **The interpretation of the results**
- **The transcription of results**
- **The reporting of results**



Errors in measurement

- **True value - this is an ideal concept which cannot be achieved.**
- **Accepted true value - the value approximating the true value, the difference between the two values is negligible.**
- **Error - the discrepancy between the result of a measurement and the true (or accepted true value).**



Designing a QC Program

- **Establish written Lab policies, Requisition forms, SOPs, Report forms, and Revisions and Corrective action plan**
- **Assure complete documentation and review**
- **Assure proper controls, standards, chemicals and storage**
- **Equipment control and maintenance**
- **Train all staff and periodic retraining**
- **Periodic Internal audits**



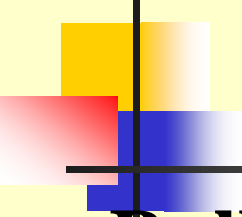
Qualitative vs. Quantitative

- **Qualitative test**
 - **determines whether the substance being tested for is present or absent**
- **Quantitative test**
 - **measures the amount of a substance present**



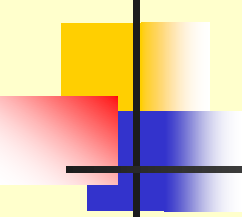
Qualitative QC

- **Quality control is performed for both, system is somewhat different**
- **Controls available**
 - **Agglutination / precipitation controls : Blood Bank / Serology / Micro / Biochemistry.**
 - **Colour change: Pregnancy test.**



Stains, Reagents, Antisera, Media

- **Bulk containers- Date of opening**
- **Prepared contents: Label containers**
 - **Contents**
 - **Concentration**
 - **Date prepared and expiration date/shelf life**
 - **Storage condition**
 - **Placed in service**
 - **Prepared by**



Implementing a QC Program – Quantitative Tests

- **Select high quality controls**
- **Collect *at least* 20 control values over a period of 20-30 days for each level of control**
- **Perform statistical analysis**
- **Develop Levey-Jennings chart**
- **Monitor control values using the Levey-Jennings chart and/or Westgard rules**
- **Take immediate corrective action, if needed**
 - **Record actions taken**



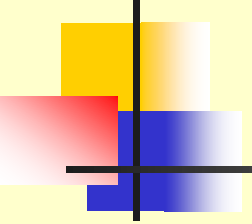
Selecting Control Materials: Calibrators

- **Have a known concentration of the substance (analyte) being measured**
- **Used to adjust instrument, kit, test system in order to standardize the assay**
- **Sometimes called a standard, although usually not a true standard**
- **This is not a control**



Selecting Control Materials: Controls

- **A control also has a known amount of an analyte but is used to monitor the precision and accuracy of an assay method once it has been calibrated.**
 - **Use 2 or three levels of controls**
 - **Include with patient samples when performing a test**
- **Used to validate reliability of the test system**



Sources of QC Samples

- **Appropriate diagnostic samples**
- **Obtained from another laboratory.**
- **Commercial product**



Summary

- **Every one is responsible for Quality of laboratory results**
- **Qualitative QC - In all areas of Medical laboratory**
- **Quantitative QC - Qualitative QC plus determine the control values**
- **Control materials - Reliable source, stable, and enough to last for a year.**