

# **How to Introduce a New Method**

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**Laboratory Management and Quality Assurance  
(MLS-QUAL-323)  
Lecture NO. (22)**

- 1. Check the linearity :-** analysis of set of serial dilution of STD to define over what range the O.D and concentration linear.
- 2. Check the precision :-** repeat runs to check that results is reproducable from batch to batch or from day to day.

**3. Analysis of normal subject** to confirm the normal values .

This involves performing the previous method a long side the new one and noting whether both agree as to which result are normal and which are abnormal.

**4. Check recovery of the method.**

## **5. Comparison between the results from an old and new method .**

- This done on the same patient sample.
- The analysis by both methods.
- should be performed on the same day.
- Preferably with in 4 hours .
- It recommended that at least 40 samples and preferably 100, be run by both methods.
- After all that it is essential to warn clinical staff.

- When the method become routine, it must renew of STD periodically to a void changes on staying and compare new STD with an old one.
- In enzyme assay, consider that tests are affected by the change of condition.  
(Temp -Time –Light – Rays and so on).

# Method Description

**Analytical method :-** is a set of instructions that describe the procedure – equipments and materials necessary to obtain results.

- To describe any method ,the description must include all the following:-

**1.Principle :-** the base of reaction happened or the relation ship between reactive ingredient in analytical reagent and substance (analyte)to be measure in the sample.

**2. Specification of reagent and instruments being used.**

**3. Calibration of STD:-** necessary to establish whether the beer-lambert law and formula can be applied (i.e whether the absorbance being measured increases in a linear way with its concentration and to what concentration the method is linear.

**4. Procedure of a test.**

**5. Requirements of specimen :-** because some methods affected by different factors so you have to consider the collection time- anticoagulant- preservatives- temperature.

**6. The steps of reaction.**

**7. Calculation.**

**8. Analytical range.**

**9. Safety precaution.**