

# Traceability

## • Purpose:-

To ensure agreement among methods used for measurement

## • Traceable methods of

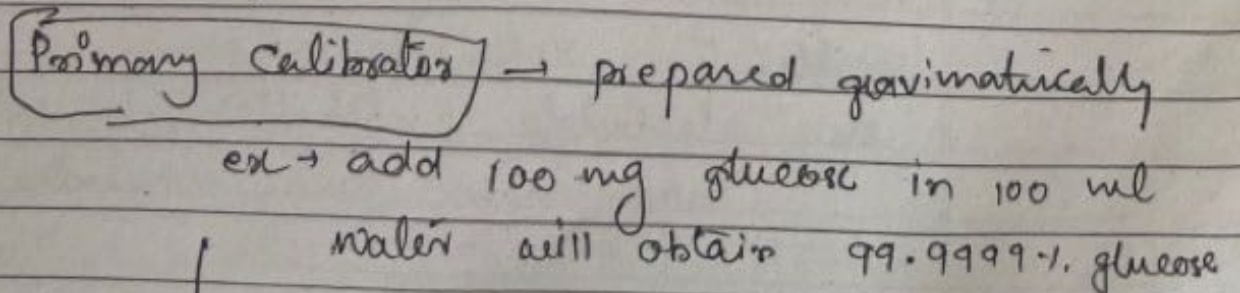
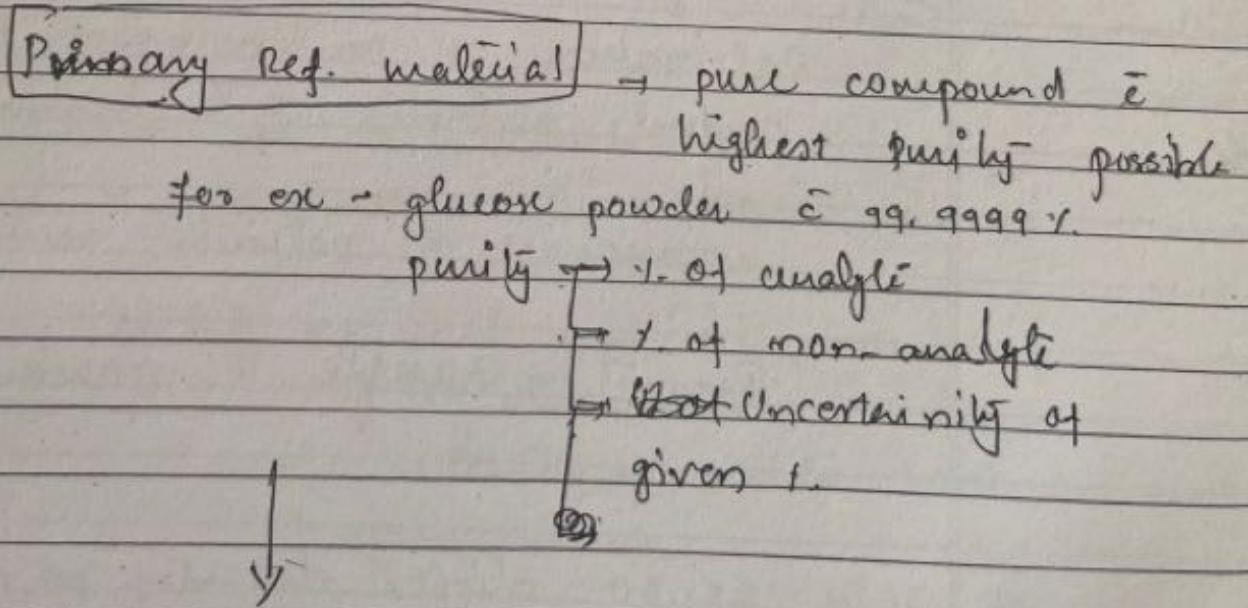
- diff. principle
- diff. Equipments
- diff. laboratories

} → will give same results for same sample

## • Definition

Unbroken chain of comparison of methods and materials leading to known ref. value.

## ⇒ Hierarchical approach for introducing traceability with example



Independent of Sample

↓  
Calibration of Definitive method / Ref. method at Reference laboratory using Primary calibrator

Must be valid & commutability

↓  
Measurement of Secondary Ref. material using Ref / def. method.  
ex. glucose sample having value of 108 mg/dL.

↳ Same as same case measured by routine method

↓  
Use of sec. ref. material as calibrator to assign value of product calibrator using master procedure / selected measurement procedure - at manufacturer site

ex → <sup>supplier</sup> calibrator of random company having target value of 113 mg/dL

↓  
Distribution of product calibrator to end users.

↓  
Calibration of routine method using product calibrator and assigning values of routine measurement of patients sample

↓  
Reports → traceable to primary ref. material

→ Only 25-30 clinical chemistry ex analysis are traceable to SI units  
ex = electrolyte, metabolites like glucose, UA (homogenous pure molecules)

↓  
Not applicable to plasma proteins where their heterogeneity