

# Analytical measurement range and limit of quantification:

LOB, LOD, LOQ, LOL → CLSI EP 17

## → Analytical measurement range

the analytical concentration range over which measurements are in declared tolerance for imprecision and bias.

extends from lowest conc. (LOQ) to highest conc. (UOQ)

### (i) Limit of blank (LOB)

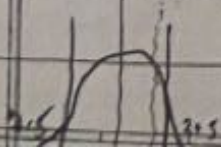
Def: highest apparent analyte conc. expected to be found when replicates of sample containing no analyte (Blank/water) is tested.

Imp: Blank/zero sample can produce analytical signal that might otherwise be consistent low conc. of analyte.

### Measurement

estimated by measuring replicates of blank sample and calculating mean and SD

$$LOB = \text{mean (blanks)} + 1.645 (\text{SD blank})$$





ex  
no measurement of water for glucose

↓  
mean = 0.2

SD = 0.41

$$LOB = 0.2 + (1.65 \times 0.41) \\ = 0.87$$

↓  
Indicates → 95% of time zero sample will give result less than 0.87 mg/dl.  
→ 5% of time even water zero sample will give result more than 0.87

## (2) Limit of Detection (LOD)

Def: lowest analyte conc. that is distinguished from LOB and at which detection is feasible

↓  
Always more than LOB.

Measurement :- LOD estimated by utilizing measured LOB and measuring replicates of sample known to contain very low conc. of analyte

$$LOD = LOB + 1.645 (\text{SD of low conc.})$$



ex. = 20 measurement of sample in very low conc. of glucose

$$\text{mean} = 5.85$$

$$\text{SD} = 0.74$$

$$\text{LOB} = 0.87$$

$$\text{LOD} = \text{LOB} + 1.645 (\text{SD of low conc})$$

$$= 0.87 + 1.645 (0.74)$$

$$= 2.10$$



Indicates

- 95% of time lowest conc. containing sample will give value  $> 2.10$ .
- ~~5%~~ times.

### ③ LOQ (Limit of Quantitation)

Def: lowest conc. at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

ie TE of LOQ should be less than TE of CLIA criteria.

example: mean of replicates of sample measurement at low conc. = 5.85, SD = 0.75, LOD = 2.10

TEA acc of CLIA = 10% of 6 mg/dl

$$\therefore \text{TE}_A = \text{bias} + 1.65 (\text{SD})$$

$$\text{LOD} = 2.10 \quad (\text{SD} \times 3.2) \quad > \quad \text{TE}_A$$

Mem of LOQ: 5.85

↳ LOQ