Analytical measurement range and limit of quantification:

LOB, LOD, LOQ, LOL → CLSI EP 17

→ Analytical measurement range

the analyte concentration range over ≥ 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 with low conc. of analyte.

Measurement

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

LOB = mean(blanks) + 1.645 (SD blank).

eg

20 measurement of water for glucose

↓

mean = 0.2

SD = 0.41

LOB = 0.2 + [1.65 × 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 (SD of low conc.)

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

mean = 5.85 LOB = 0.87

SD = 0.74

LOD = LOB + 1.645 (SD of low sw)

= 0.87 + 1.645 (0.74)

= 2.10

↓

Indicates

- 95% of time lowest conc. containing sample will give value > 2.10.
- ~~Exto tigers.~~

(3) LOQ (Limit of Quantitation).

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

i,e TE of LOQ should be less than TE$_A$ of CLIA acc.

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

TE$_A$ acc. of CLIA = 10% or 6 mg/dl

$\therefore$ TE$_o$ = bias + 1.65 (SD) → Eq. (CLIA)

LOD: 2.10 (SD × 3.2) < (TE$_A$)

• Mean of LOQ: 5.85

↳ LOQ