Quality Control
In
Clinical Biochemistry Laboratory
As per
ISO 15189:2012 & NABL - 112

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Outline - Quality Control

as per ISO 15189:2012 & NABL-112

- Frequency of QC as per NABL - 112
- Finding Mean and SD for New Lot of IQC
- Cumulative Mean & SD
- Alternate Approach of EQAS
  - ***Exchange of samples with other accredited laboratories - Analysis***
- Method of Harmonization of method / instrument.

IQC Frequency as per NABL-112

- **Irrespective of the size of the laboratory**
  - Two levels of IQC atleast once on the day of patient sample testing.
- **24 x 7 Laboratory**
  - Two level IQC = In the peak hour
  - Subsequently One level every 8 hours.
- Daily Levey-Jennings chart
- **CAB shall define its own criteria for accepting or rejecting the run.**

IQC Frequency as per NABL-112

For Blood Gas Analysis

- **For Automatically Calibrating Instrument at predefined internals.**
  - At least one control @ every eight hours.
- **For Automatically Not calibrating Instrument**.
  - At least one control @ every eight hours.
  - Addition, One control - With each patient sample (sample lot)

Example

- XYZ laboratory working 8 am to 8 pm
- Average Sample Load = 40 samples/day
- Average Test Load = 200 tests/day
- Scope
  - Routine Biochemistry
  - Clinical Haematology
  - ABG by cartridge method (sample frequency 1-2 in day)
  - TSH alternate day with ELISA
- **What should be IQC frequency require?**

IQC frequency require for XYZ CAB

- For Routine Biochemistry & Clinical Hematology
  - Normal Level IQC @ 8 AM
  - Abnormal Level IQC @ 2 PM
  - **OR**
  - Two Level IQC @ 8 AM
- For TSH
  - Two Level IQC with each TSH sample lot run
- For ABG
  - One level IQC 8 hourly in day (**????????**)
  - One Level with each lot of sample

When Commercial IQC is not available

- Pool sera
- Re-testing
  - Two sample
  - Normal Sample & Abnormal Sample

Finding Mean for New lot IQC

Establishing Mean :

- Derive own Mean
- Using a minimum of **20 data** points.
- New Lot of IQC and Old Lot IQC - **Parallel run**

Method - I

- **20 data** minimum - obtained on **separate days**.

Method – II

- **< 20 data – Provisional Mean**
- **4 QC data** per day - Atleast **5 different days**.

New Mean should be with-in manufacturer QC range

Finding SD for New lot IQC

Old Data available

- Use old CV% to find SD

Old Data NOT available

- Estimated of SD of 20 data point of new lot.
- Reevaluated periodically.
- Compare with Global / Universal CV%
  - Manufacturer collected CV% from all instrument and all methods

Cumulative Values

- **Cumulative Mean & SD**
  - 20 days
  - 60 days…..
  - 90 days…???
  - Update after Every 60 days
- No Any Fix Guidelines

Cumulative Mean

- Delta SD (SDI)
- Delta SD = $\frac{\text{(New Mean – Old Mean)}}{\text{Old SD in use}}$
- **Example**
- ? SDI > 0.5 than……action decided

Example for Selecting SD

- Old Lot have CV% = 5 % for Serum Glucose
- Global CV% from QC manufacturer = 3%
- After 20 data point of New Lot
  - New Mean = 200 mg%
  - New S.D. = 14.0
  - CLIA TAE = 10%

Example for Selecting SD

- Old Lot have CV% = 5 % for Serum Glucose
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- After 20 data point of New Lot
  - New Mean = 200 mg%
  - New S.D. = 14.0
  - CLIA TAE = 10%
- CAB has following choice for selecting SD
  - **OLD 5 CV%** = Calculated New S.D. = 10.0
  - **From 20 point** New S.D = 14.0 **(X)**
  - **From Global CV%** New S.D. = 6.0

Cumulative SD

- **2SD < TAE** as per CLIA criteria
- SD < half of TAE
- **Make Own Policy** for updation of SD,
  - **Example of policy**
  - 20 % change in new SD
  - Change in method / equipment
  - No. of available data should be >60
- **Update SD after longer period of stable operation.**

EXAMPLE – Correct / Incorrect

Mean & SD value of Drawing L-J for Serum GLUCOSE		
+ 3 SD	236	
+ 2 SD	224	
+ 1 SD	212	
Mean	**200**	
- 1 SD	188	
- 2 SD	176	
- 3 SD	164	

Alternate Approach of EQAS

When to Implement alternate approach

- Non-availability of a formal national PT programme
- Only few laboratories performing the test
- Unstable parameter
  - Blood gases
  - Ammonia
  - G6PD
- Control material of the same matrix is not available
- The sample is completely consumed during performance of the test (e.g. ESR)

Alternate Approach of EQAS

What are alternate approach for proficiency

- Replicate testing
- Examination of split samples
- Use of reference methods & materials
- ***Exchange of samples with other accredited laboratories***

Exchange of samples with other accredited laboratories - Analysis

- Called “ILC” ???
- Comparison of value according to
  - CV %
  - Total allowable error % as per guideline
    - CLIA
    - CAP
- Regression analysis
- **CLSI document EP9 - Measurement Procedure Comparison and Bias Estimation Using Patient Samples**.

Interpretation of ILC for ALT

Sample Id	Your result	Reference Lab result	Differ-ence in %	Acceptable Criteria	Acceptable Yes/No	QM Signature
100022	124	112	10.7%	20% CLIA	Yes	
100114	45	43	4.6%	20% CLIA	Yes	

Method of Harmonization of method / instrument.

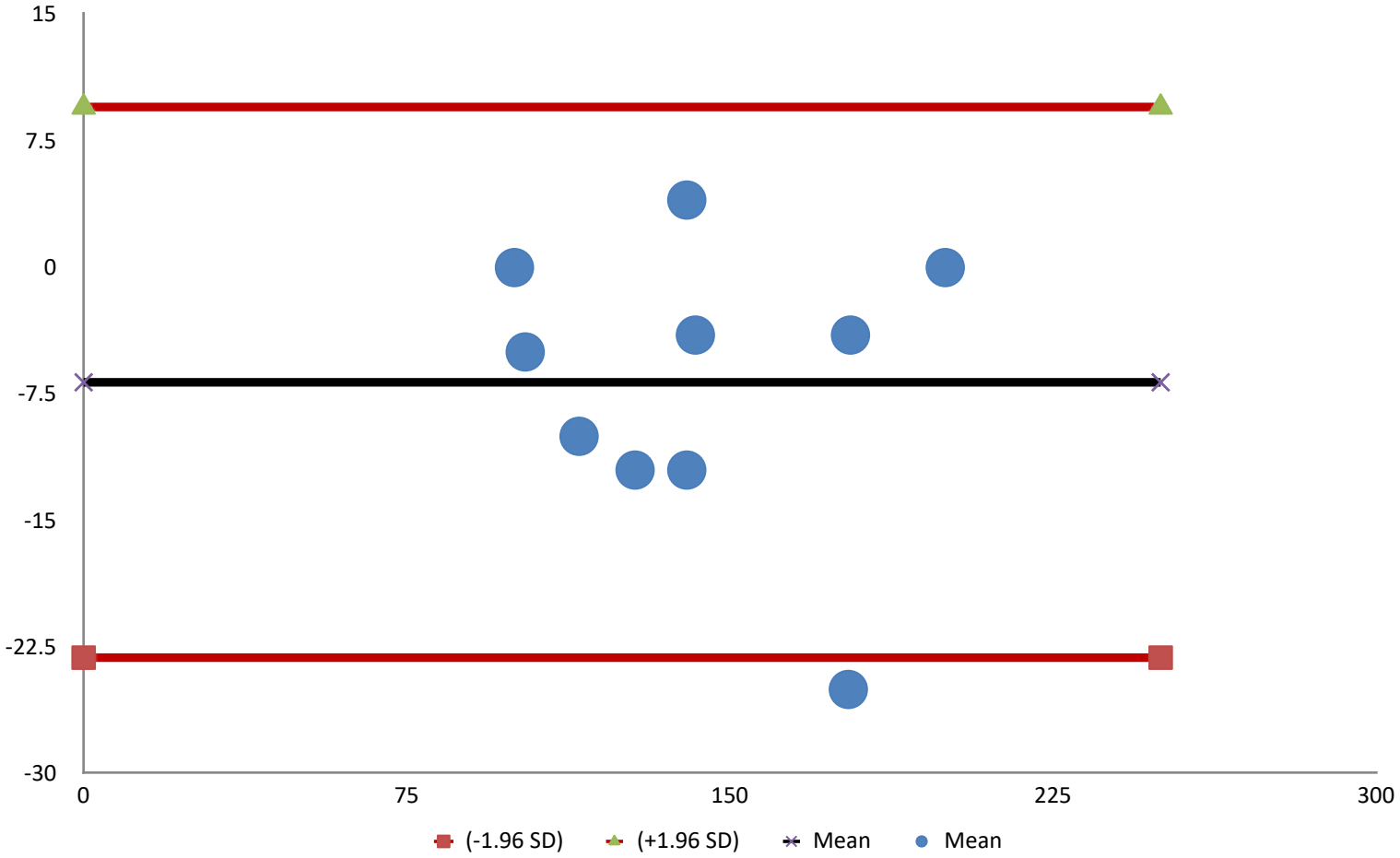
- When More than one measuring system / method
- Performance check for throughout clinical intervals.
- At least twice in a year
- Bland - Altman plot
- Regression analysis.

Harmonization of Instrument A & B for ALT

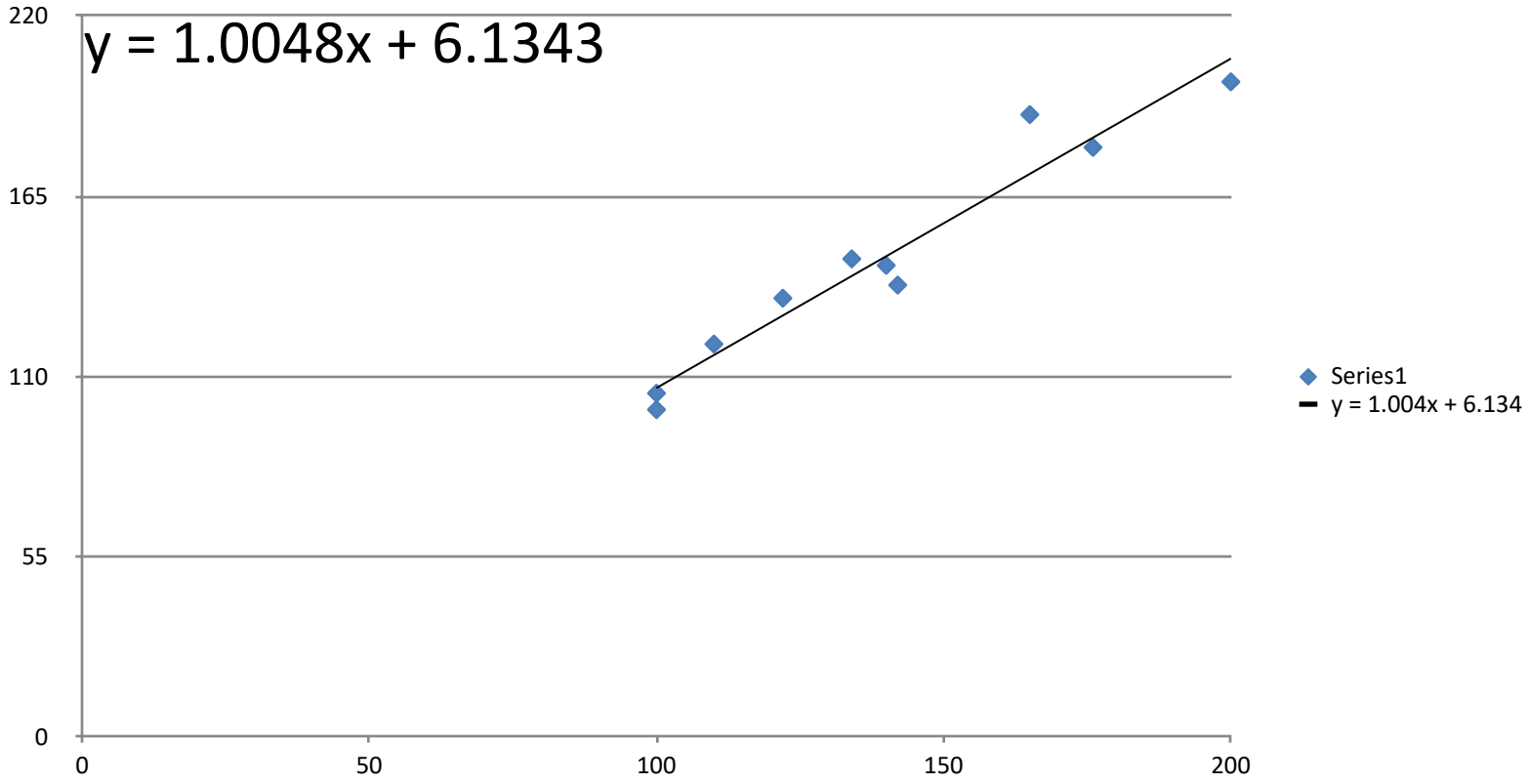
Harmonization of Instrument A & B for ALT

Sample No.	Instrument A	Instrument B	Difference %	Mean
1	100	100	0.00	100
2	100	105	-5.00	102.5
3	110	120	-10.00	115
4	200	200	0.00	200
5	142	138	4.00	140
6	165	190	-25.00	177.5
7	134	146	-12.00	140
8	176	180	-4.00	178
9	122	134	-12.00	128
10	140	144	-4.00	142
Bias			-6.80	
SD			8.32	
Lower limit			-23.11503	
Upper limit			9.5150297	

Bland - Altman plot



Linear Regression Plot



- y = a (x) + b
- a = shall be near to 1.0
- b = shall be less than CV%


Thank
you!