EXTERNAL QUALITY ASSESSMENT (EQA) REPORTS AND THEIR INTERPRETATION

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SAACB Education Day 2010

EXTERNAL QUALITY ASSESSMENT SCHEME (EQAS)

- External agency
- Evaluation is performed on several Labs that analyse the same specialised samples
- Performed at regular intervals
- Frequency may vary between schemes
- Retrospective assessment

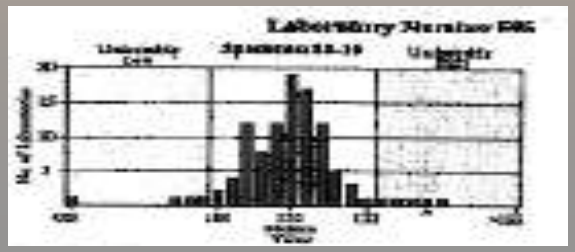
- Compares performance between labs

- National/regional basis – several:
  NHLS EQAS, Thistle, UKNEQAS, BIORAD EQAS, RIQAS, CAP, RCPA etc

“Blind” samples

Analysis same as patient samples

results are returned to EQAS organiser



Statistical analysis

NHLS EQAS (2001)

NHLS labs, public sector, Southern African countries

Clinical Chemistry
Blood gases
TDM

} monthly

Target values for most

THISTLE – SA

National and International

Central values – Consensus means

EQAS of European countries vary widely in the frequency and type of specimen analysed, traget values/consensus means as well as in the criteria for acceptable performance

USA (CAP)

Proficiency testing became a legal requirement in 1988 when the CLIA (Clinical Laboratories Improvement Amendments) were approved

- Frequency of sampling (up to 5 specimens 3x per annum)

EQA GOALS

1. An objective external (independent) assessment of the lab's long term performance

2. To alert the lab of problems with accuracy (aimed to at preventing the reporting of incorrect patient results. (failure of internal alerts)

3. To provide Management and clients with the confidence that the on-going processes for monitoring analytical processes is sound

4. Identification of group problems – (affecting specific anaysers/ reagents/ kits)

5. Complimentary to the IQC which monitors daily accuracy of the lab’s methods

BASIC STATISTICS

- **Mean** $= \dfrac{\sum \mathbf{x}}{n}$

  is the sum of all the measurements divided by the number of measurements

- **Median** is the point on the scale that has an equal number of observations above and below.

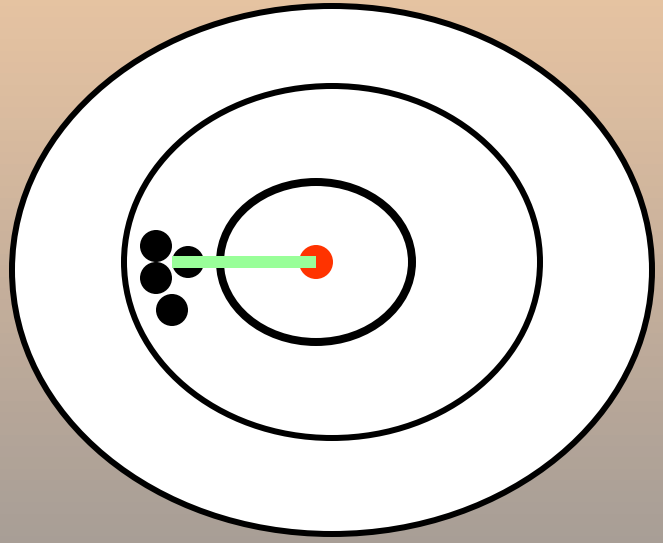
- **Mode** is the most frequently occurring result.

- **TRUENESS**

defined as the **closeness** of the agreement between the mean of a large series of measured results and the true concentration

BIAS

Is the mathematical **difference** between the mean value of a series of measurements and the true value



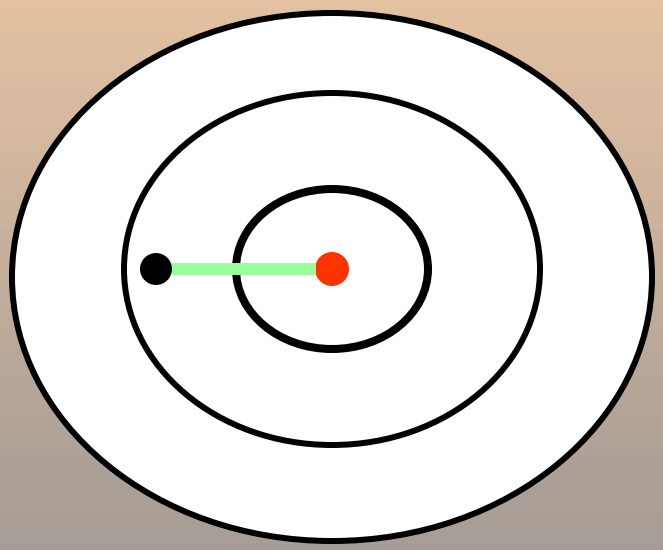
and is a measurement of **SYSTEMATIC ERROR**

% Bias

$$= \frac{\text{Result} - \text{True value}}{\text{TV}} \times 100$$

ACCURACY

defined as the **closeness** of the agreement between a **SINGLE** observed measurement and the true concentration and is inversely related to the UOM

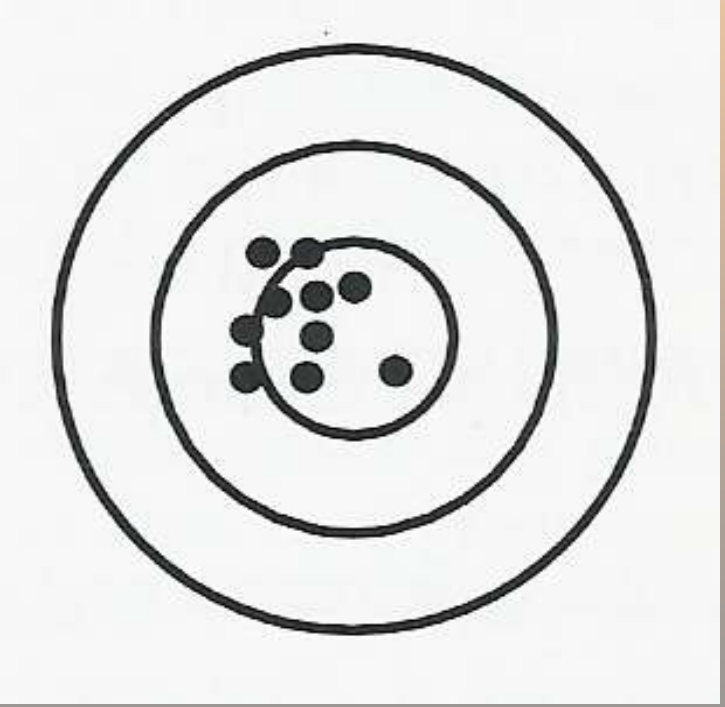


Influenced by both bias and imprecision

and is therefore an expression of Total Error

PRECISION

refers to the **closeness** of agreement of a series of independent measurements



PRECISION

divided into:

1. **Repeatability**

   constant conditions (“within run”)

2. **Reproducibility**

   changed conditions:

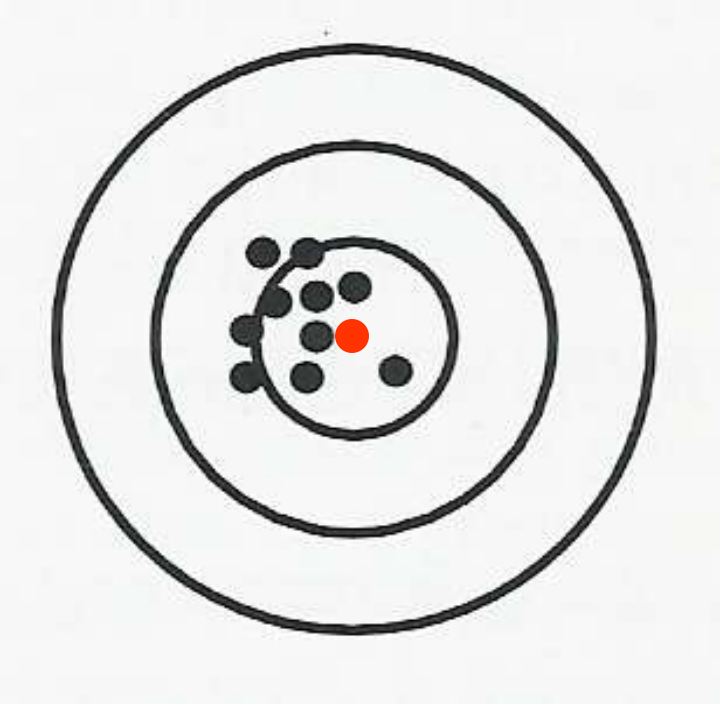
   - Total/”Between run” precision (intermediate precision)
   - Interlaboratory precision (EQAS)

IMPRECISION

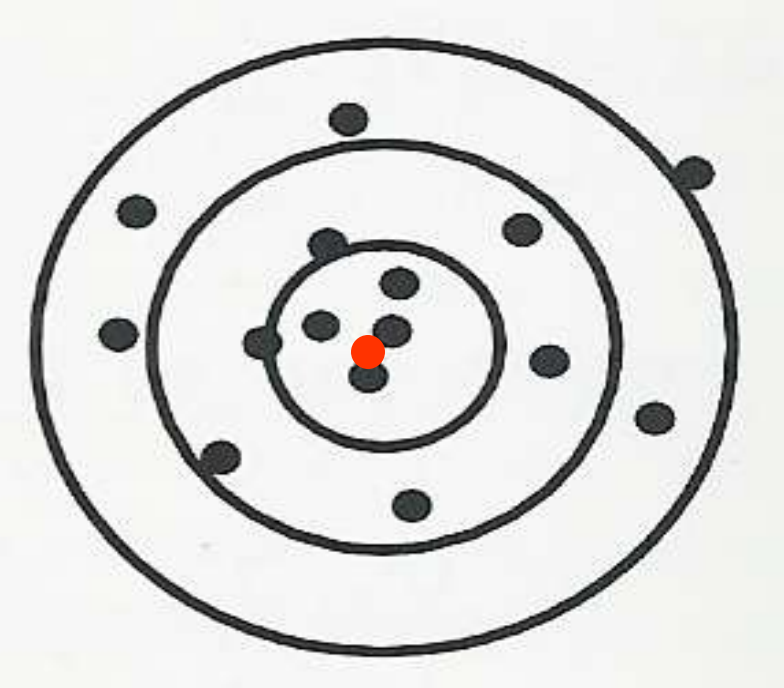
the inverse relationship of precision

is only related to **RANDOM ERRORS**
of measurements
expressed as:
SD and CV

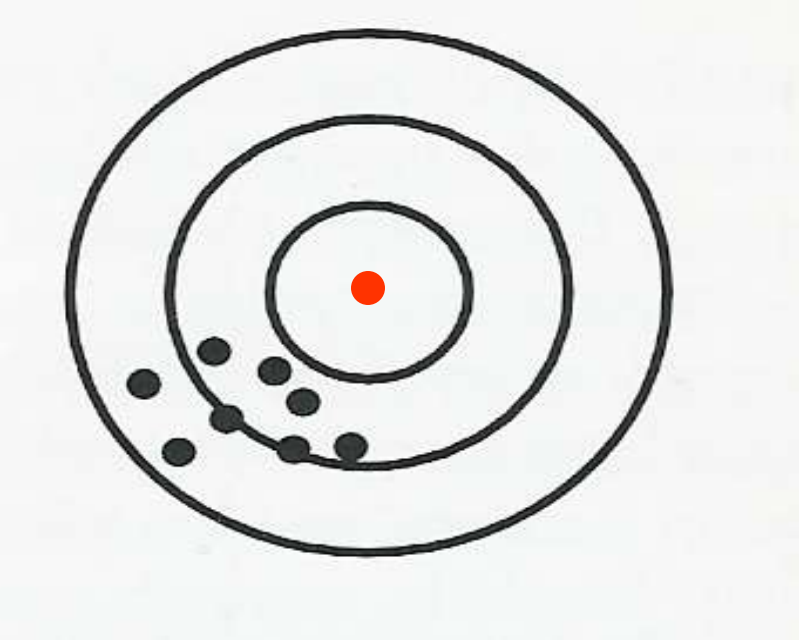
Imprecision LOW



Imprecision **HIGH**

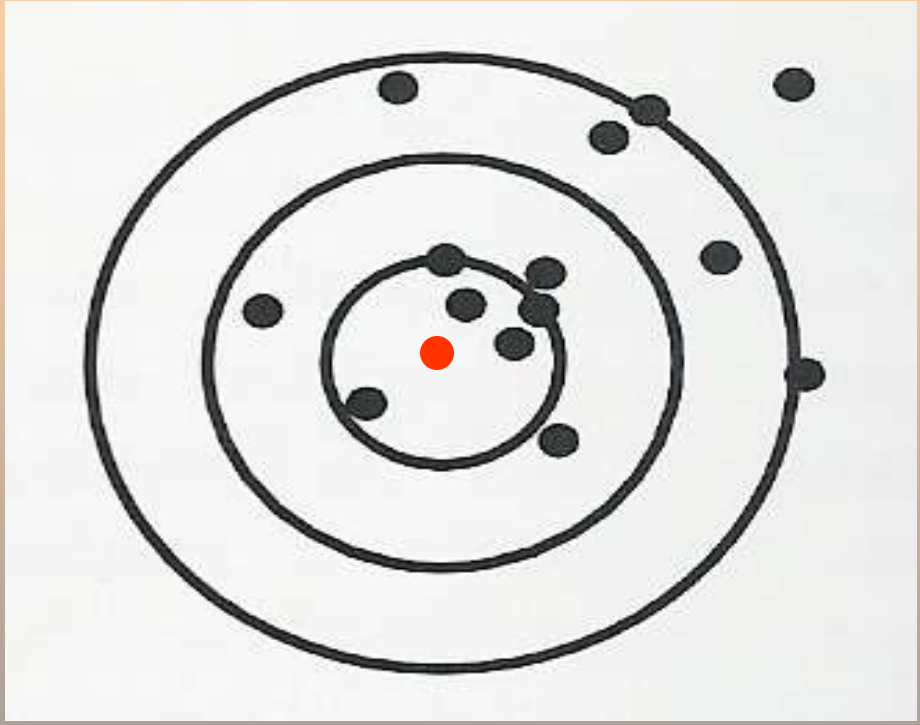


Imprecision LOW



Imprecision **HIGH**

Bias HIGH



Standard Deviation (SD)

SD describes scatter around the mean (expressed in the units being measured)

Standard Deviation (SD)

$$SD = \sqrt{\frac{\sum(X_1 - X)^2}{N - 1}}$$

Mean absolute deviation

Coefficient of Variation (CV)

$$CV(\%) = \frac{SD}{Mean} \times 100$$

The smaller the CV the more reproducible the results

Performance Criteria

Which results are Acceptable?

A simple method of assessing performance
to indicate whether:

- persistent dissatisfactory performance
- deterioration in performance
- any improvement
- casual errors

STATISTICAL METHODS

Statistical Methods are used
to assist in determining whether
performance is acceptable
by analysing, summarising and
reporting on “observations”

In assessing performance using these Statistical methods one should always consider performance at the important **Medical Decision levels** and the clinical impact of unacceptable results

How is Objectivity achieved?

To enable Clinical relevance
of the results obtained the results
should be within a **certain %** of
Assigned central values

ASSESSMENT OF PERFORMANCE

Based on

1. Central Reference value

1. Acceptable Range of performance (Allowable limits of performance)

EQAS Assignment of Analyte dependant

Central Reference Value:

1. overall mean/median of all participating labs are used to indicate the ‘True value”

Or

2. Set Target values

(specified by each EQAS’s program information)

How are TARGET VALUES set?

1. Reference labs using Reference methods

2. Labs using “Higher order” methods
   - precison, trueness and analytical specificity that is > that in routine labs

3. SRM samples by selected Labs

4. Weighed - in values e.g. drugs
   - EQA samples supplemented with known weights of and analyte

ALLOWABLE LIMITS OF PERFORMANCE (ALP)

- is unique for each analyte
- considers unavoidable imprecision of the method
- and normal diurnal variations (BV)
- TAE calculation

ALP

Determines the **level of error** that is required to minimise the risk of adverse outcome when applied to the reporting of patient results

ALP
includes **RANDOM ERRORS** due to:

1. Within and between run variability
2. between calibration variability
3. lot to lot variability of reagent/calibrator
4. between analyser variability

ALP

In addition there may bel
SYSTEMATIC ERRORs due to:

1. Calibration standards used
2. Method / Instrument specific factors
   (Calcium – arsenazo vs cresolphthalein complex)

ALP

Is expressed as :

$\pm\, x$ from the TV

x may be in absolute units

or in %

or in an absolute value up to a certain limit

and a % above a certain limit

Standard Deviation Index (SDI)

$$\text{SDI} = \frac{\text{Lab result} - \text{Group Mean}}{\text{SD of Group}}$$

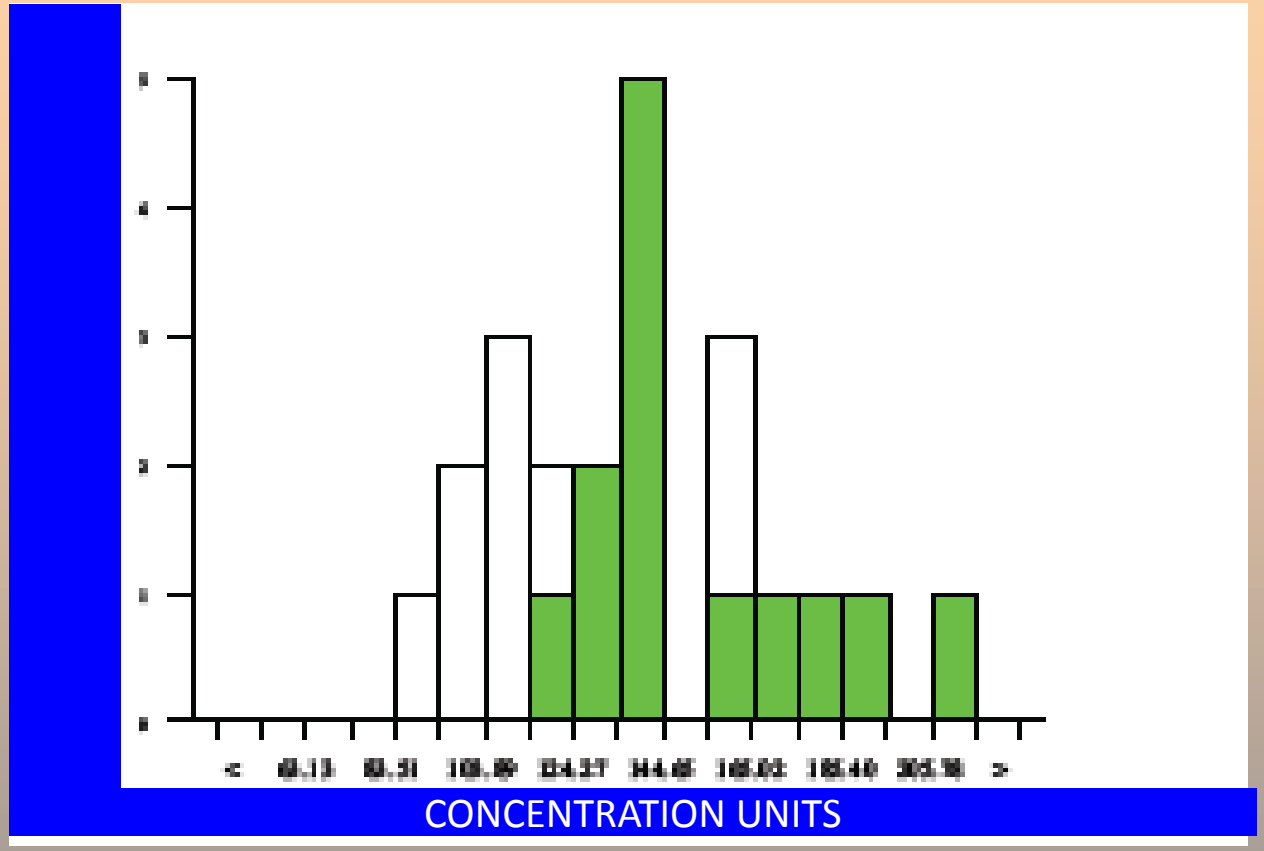
SDI > 2
Lab not in agreement
with labs within the Group

COEFFICIENT of VARIATION INDEX (CVI)

$$= \frac{\text{Lab CV}}{\text{Group CV}}$$

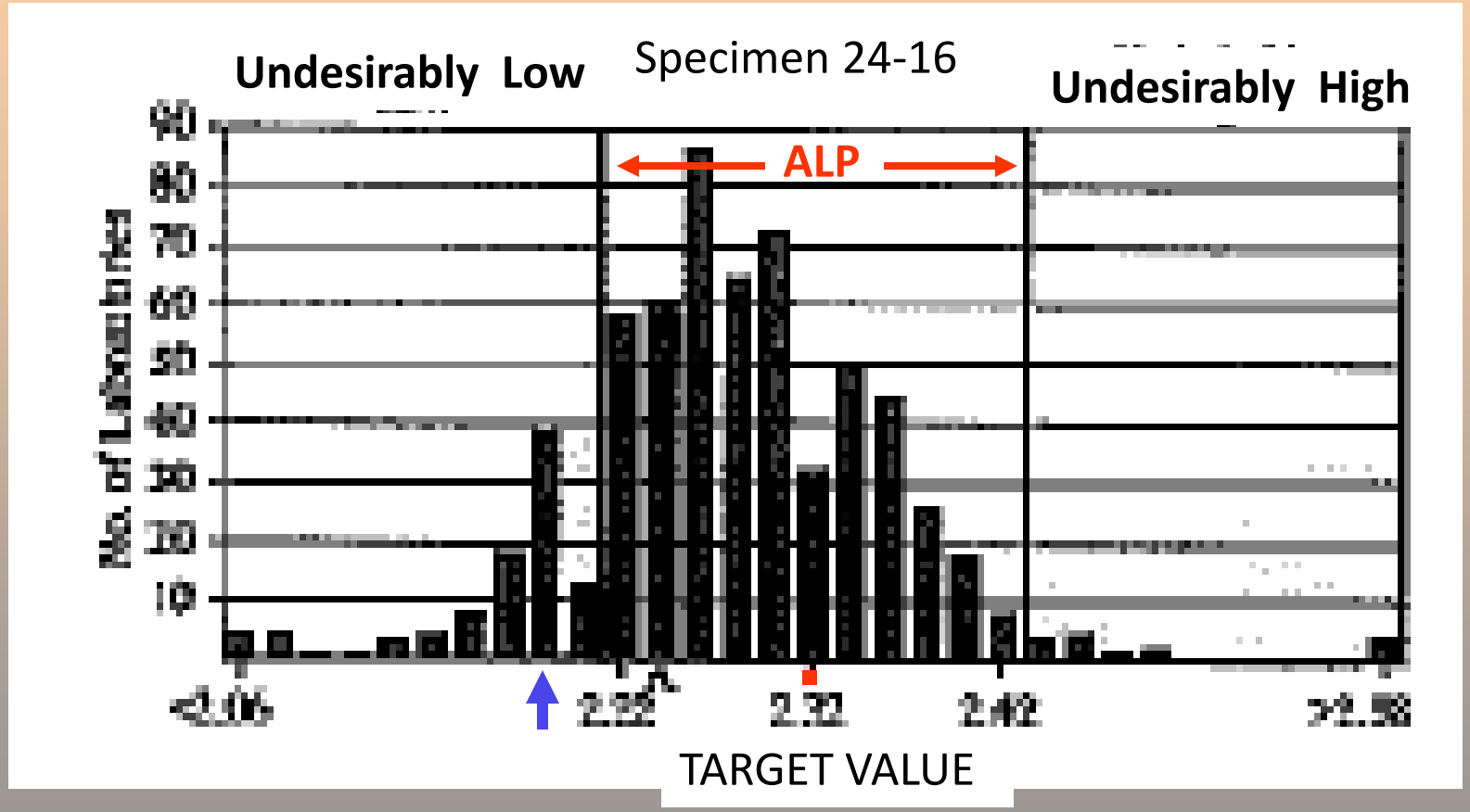
an index of imprecision

BAR GRAPHS/HISTOGRAMS



Qualitative results Histogram allows quick visualisation if your lab's result falls within the overall results for all methods as well as for your method group

HISTOGRAMS

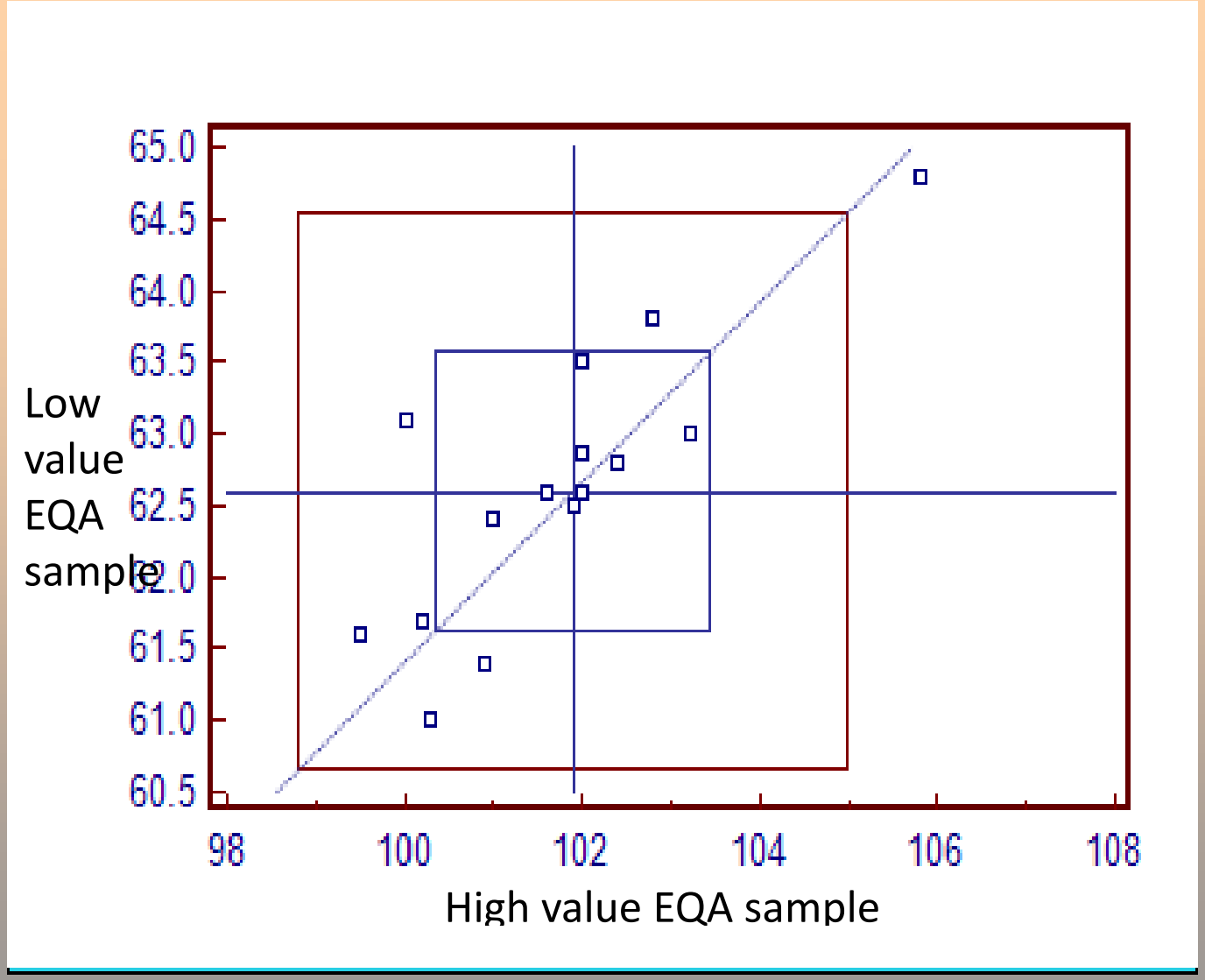

Undesirably Low
Specimen 24-16
Undesirably High
ALP
90
80
70
60
50
40
30
20
10
2.32
2.42
TARGET VALUE

YOUDEN PLOTS

when 2 EQA samples – high and low are analysed by each lab (same method analytical principle, instrument, reagent)

observed results plotted

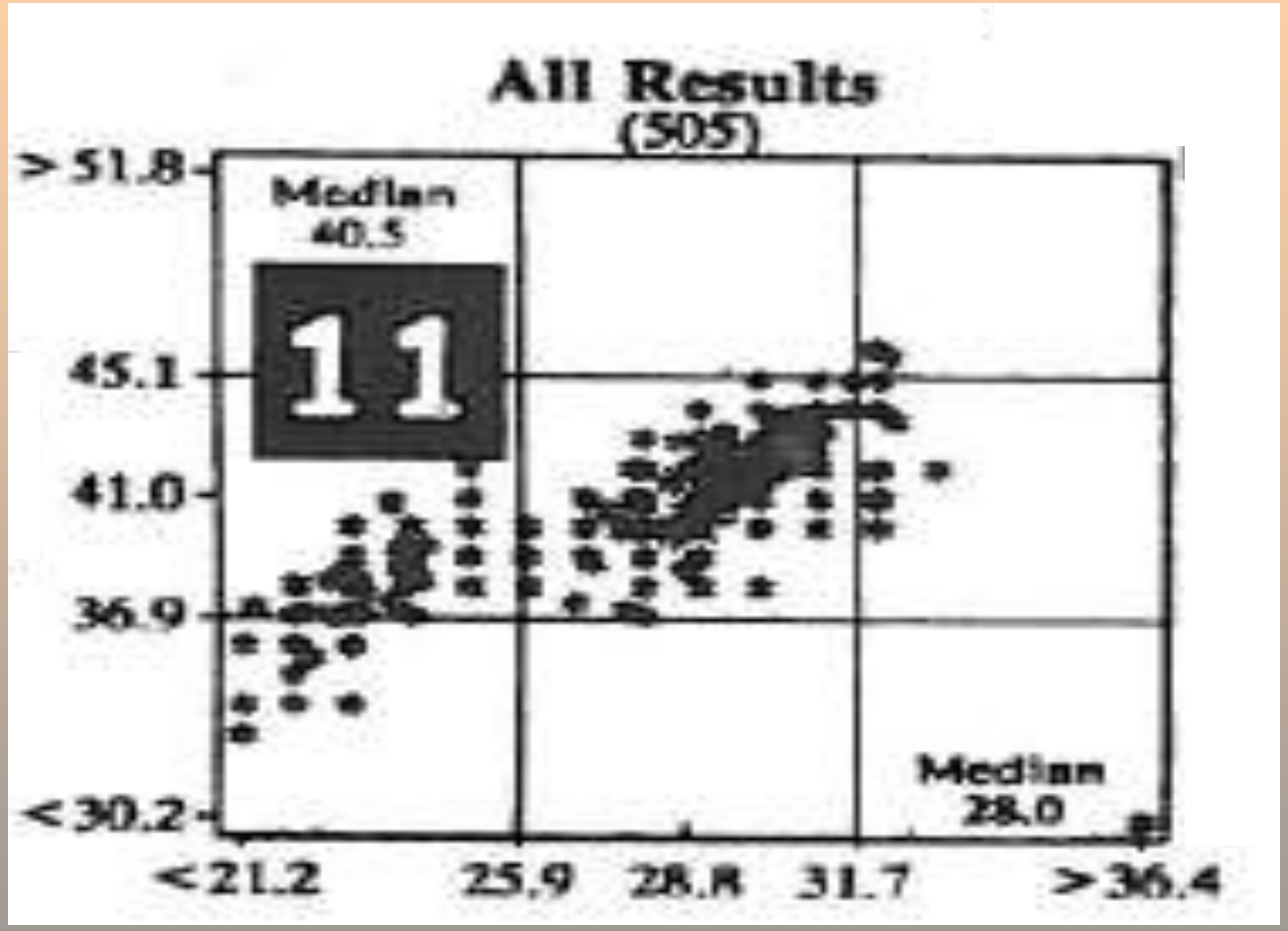
Allows comparison of the relationship of each level's value to the group's performance



Blocks = SDs
Horizontal and vertical median reference lines have equal no. of observations on either side
Central intersection of the median lines = Manhattan median
Far away from MM but close to ref line + Systematic error
Far from reference lines = large random errors

YOUDEN PLOT

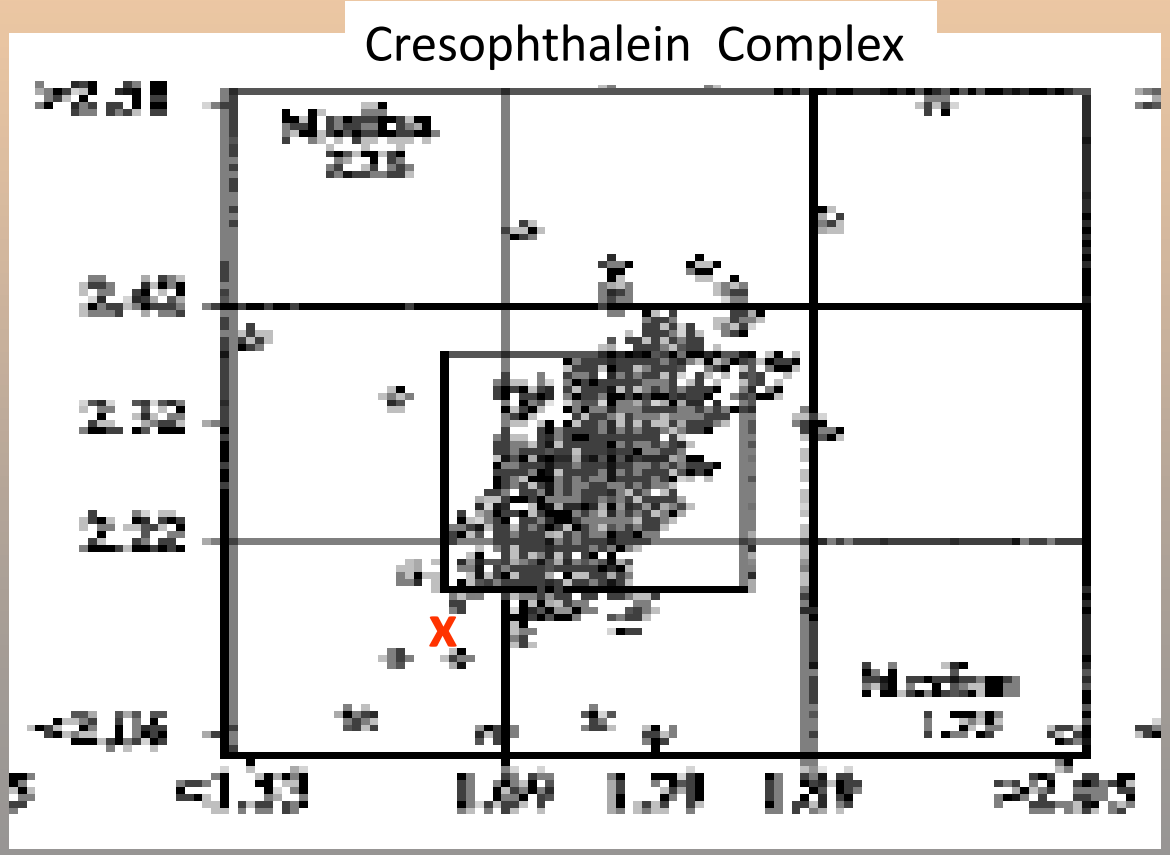
HIGH VALUE EQA

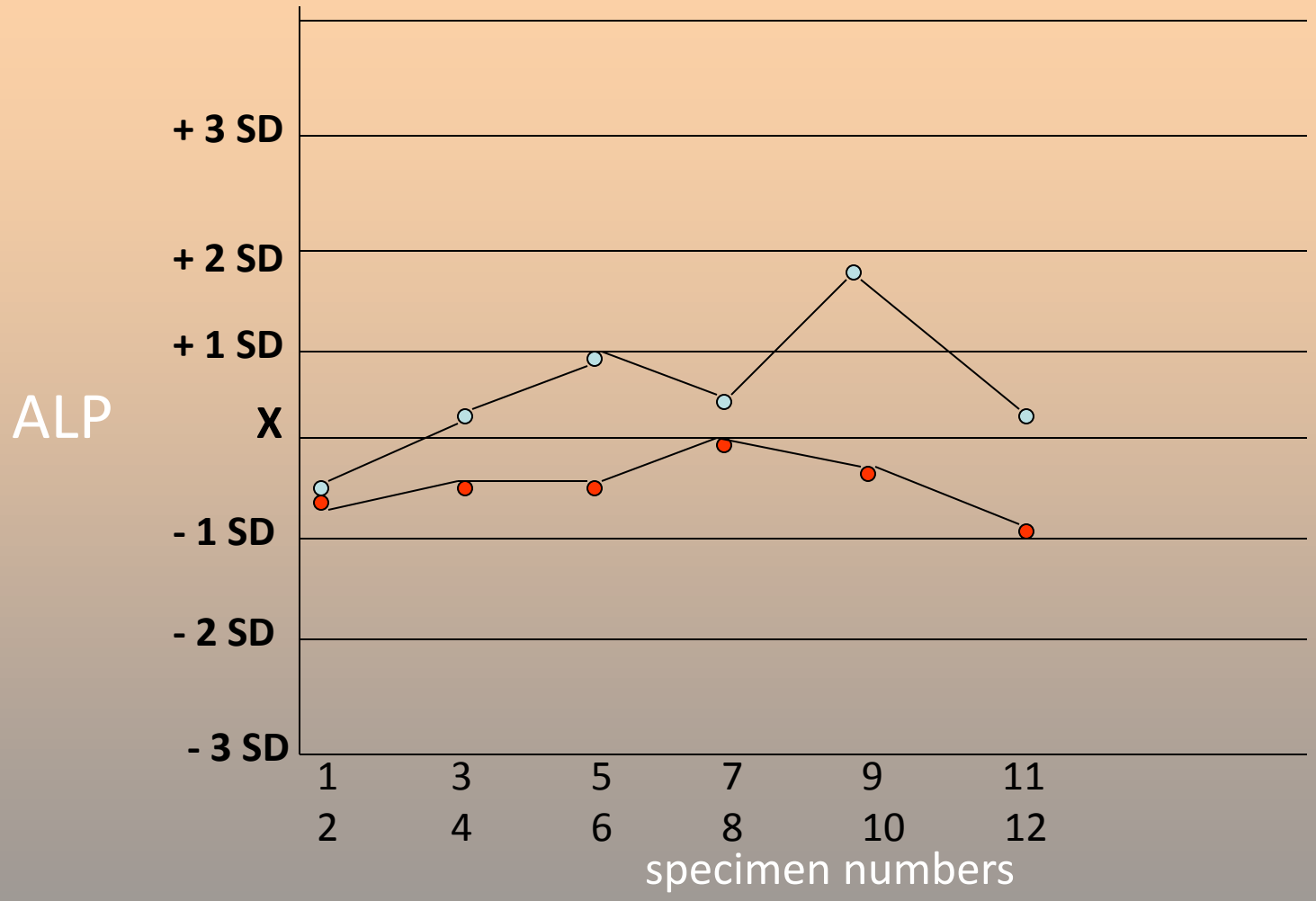


LOW VALUE EQA

Albumin

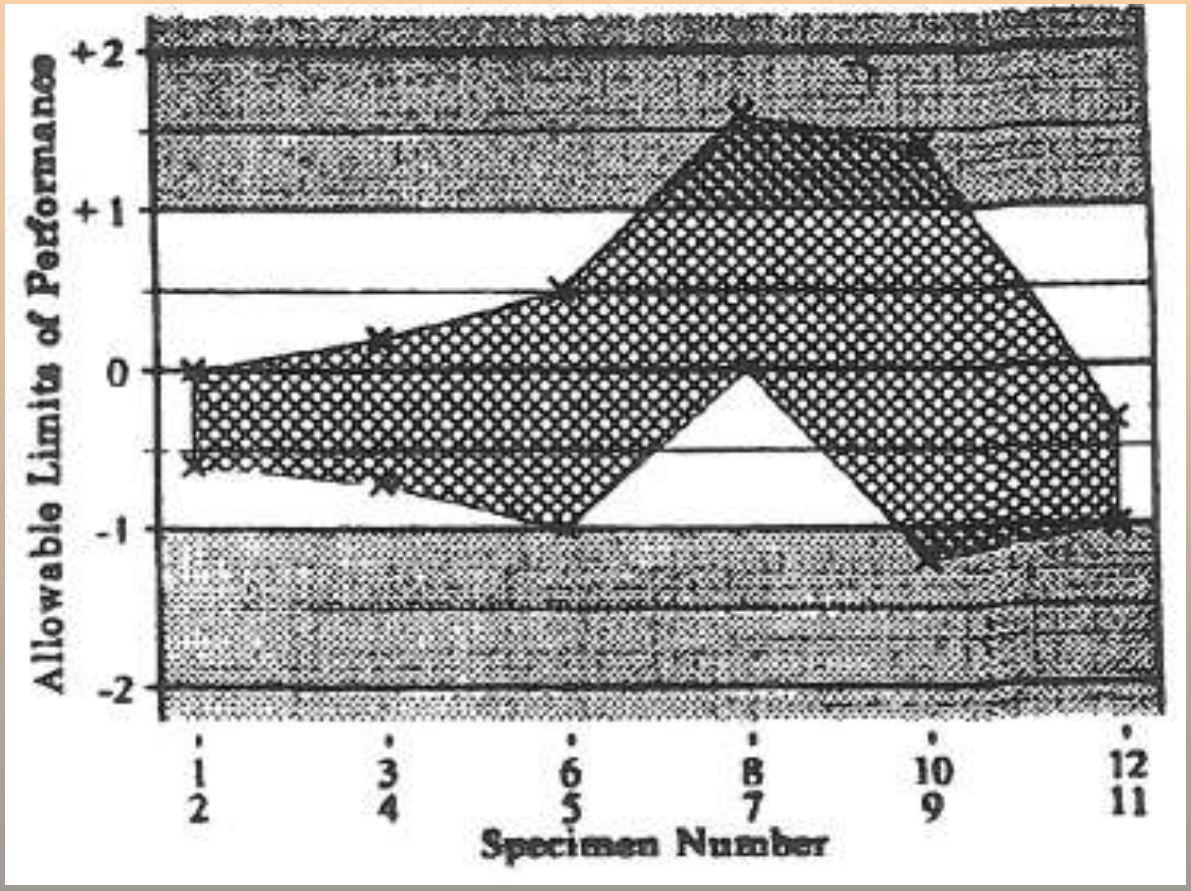
PEER REVIEW BOXES (Subgroups)



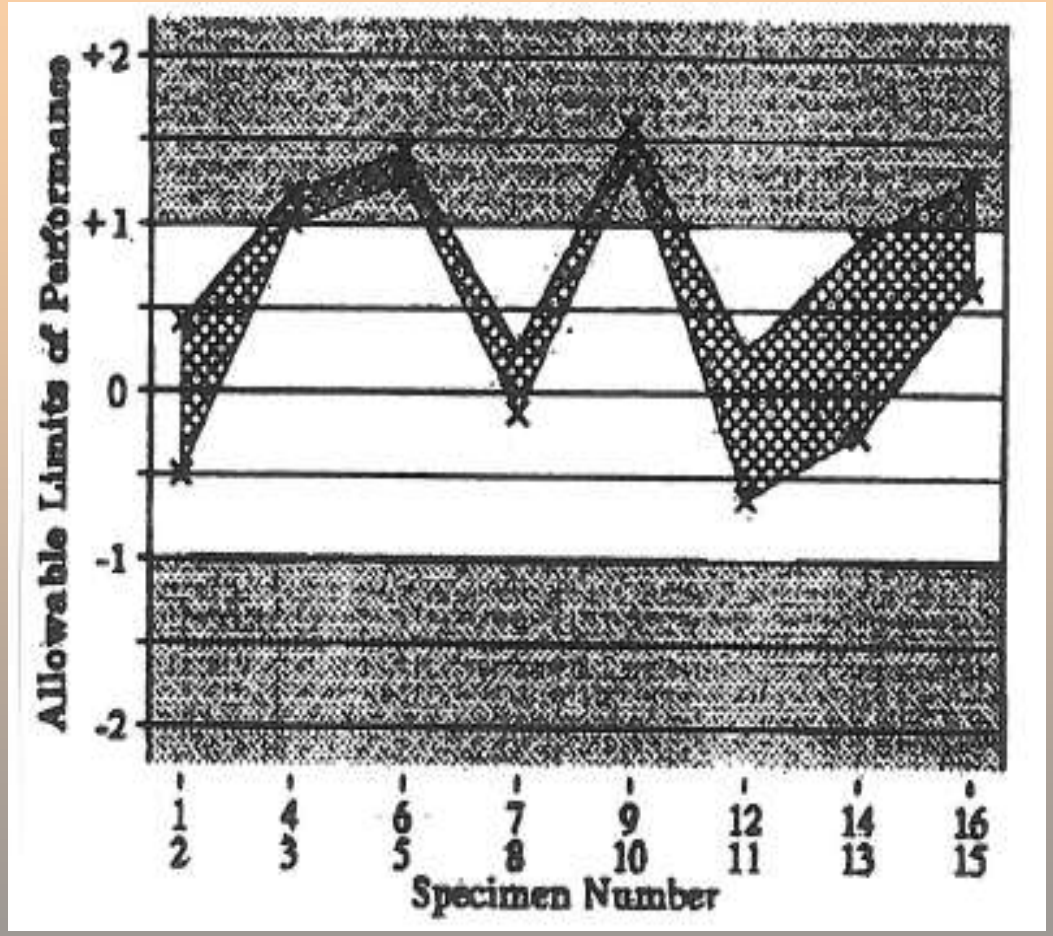


LEVEY – JENNINGS style of reports

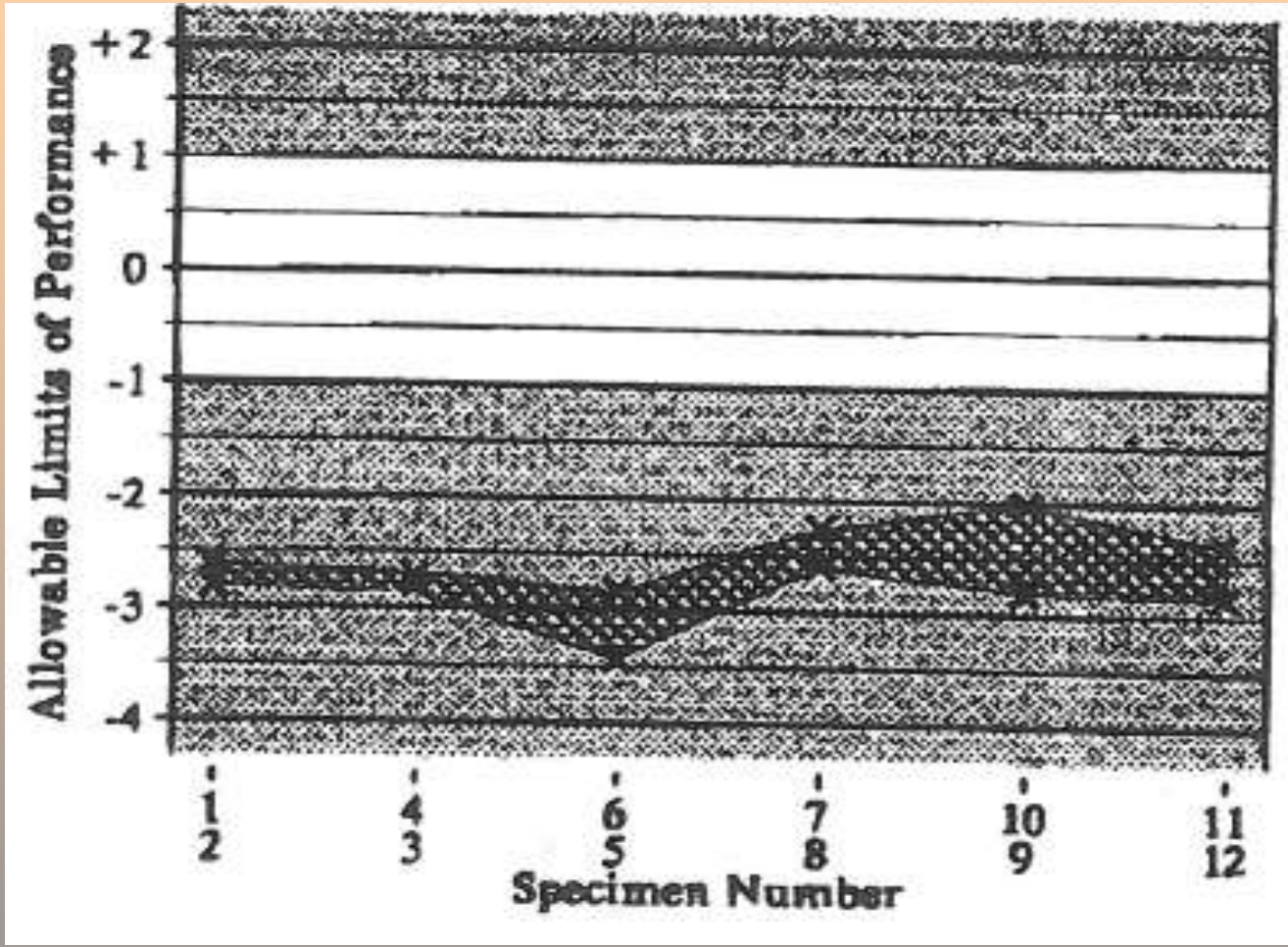
Levey-Jennings-Like Plots



poor precision – within run



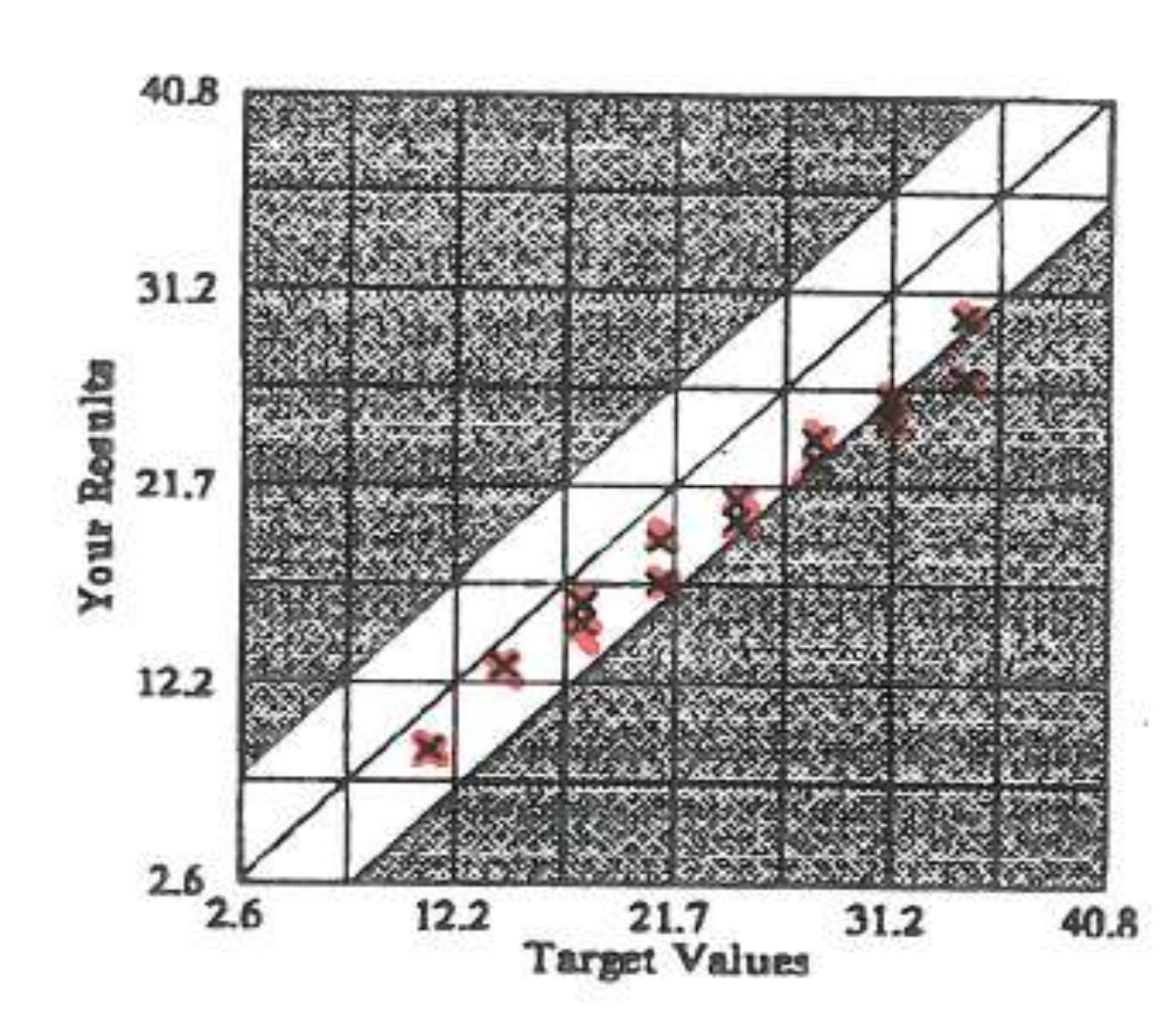
poor precision – between run



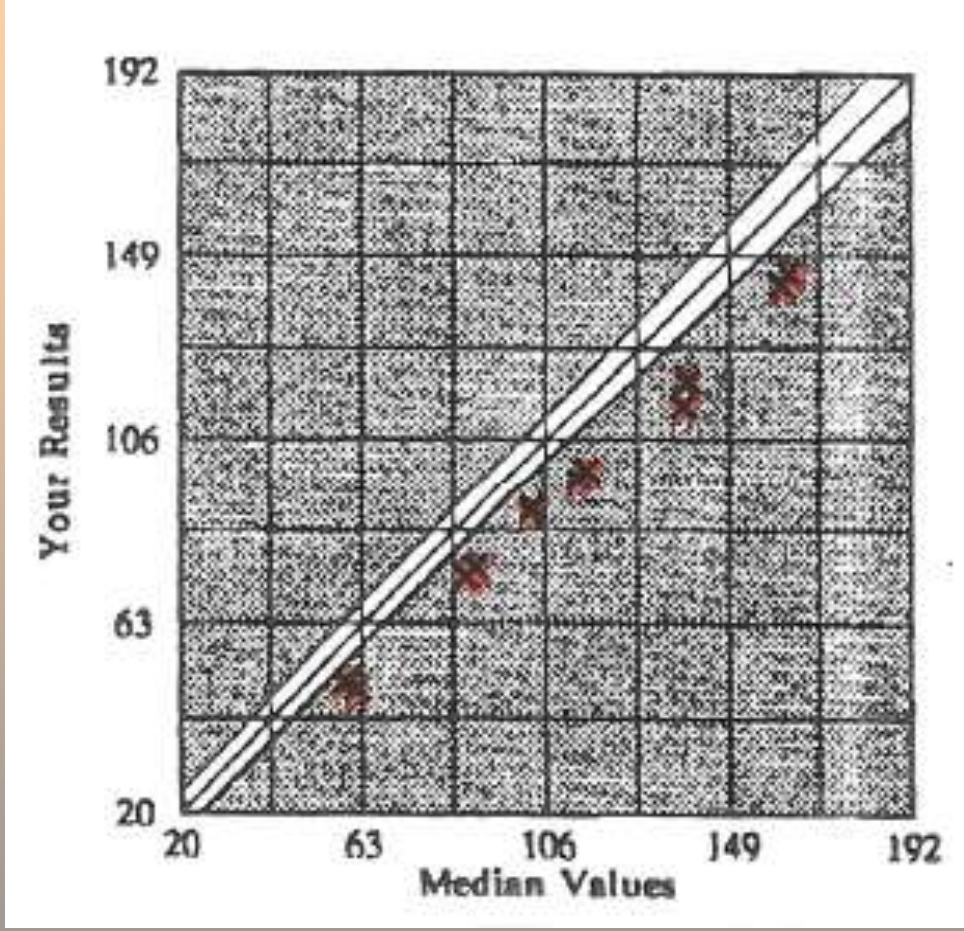
Biased results

LINEARITY GRAPHS

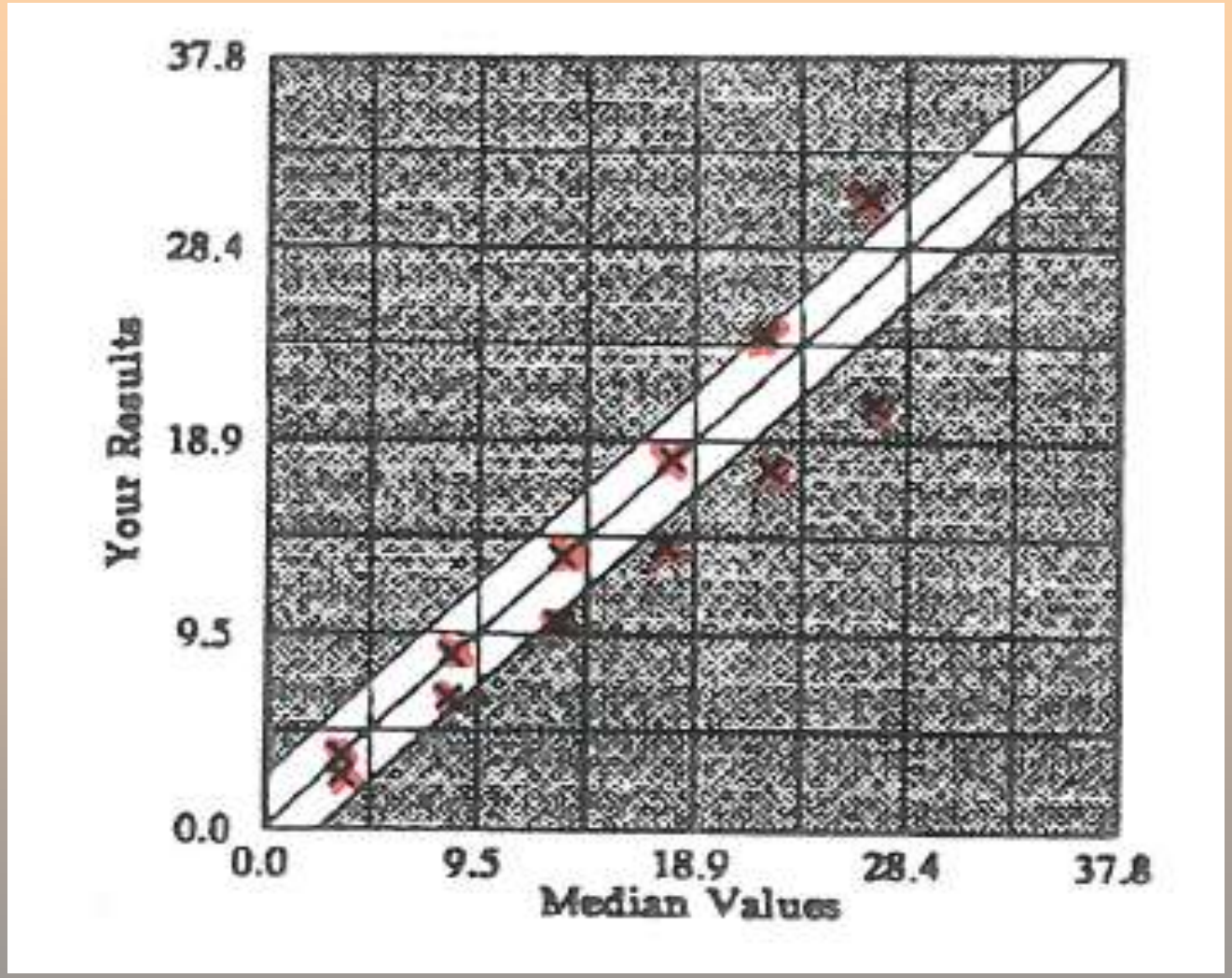
Linearity refers to the relationship between measured and expected values over the analytical range
visualise whether relationship is linear or not


40.8
31.2
21.7
12.2
2.6
Your Results
2.6
12.2
21.7
31.2
40.8
Target Values

Non - Linear



Proportional Bias



Imprecision

BLAND ALTMAN PLOTS

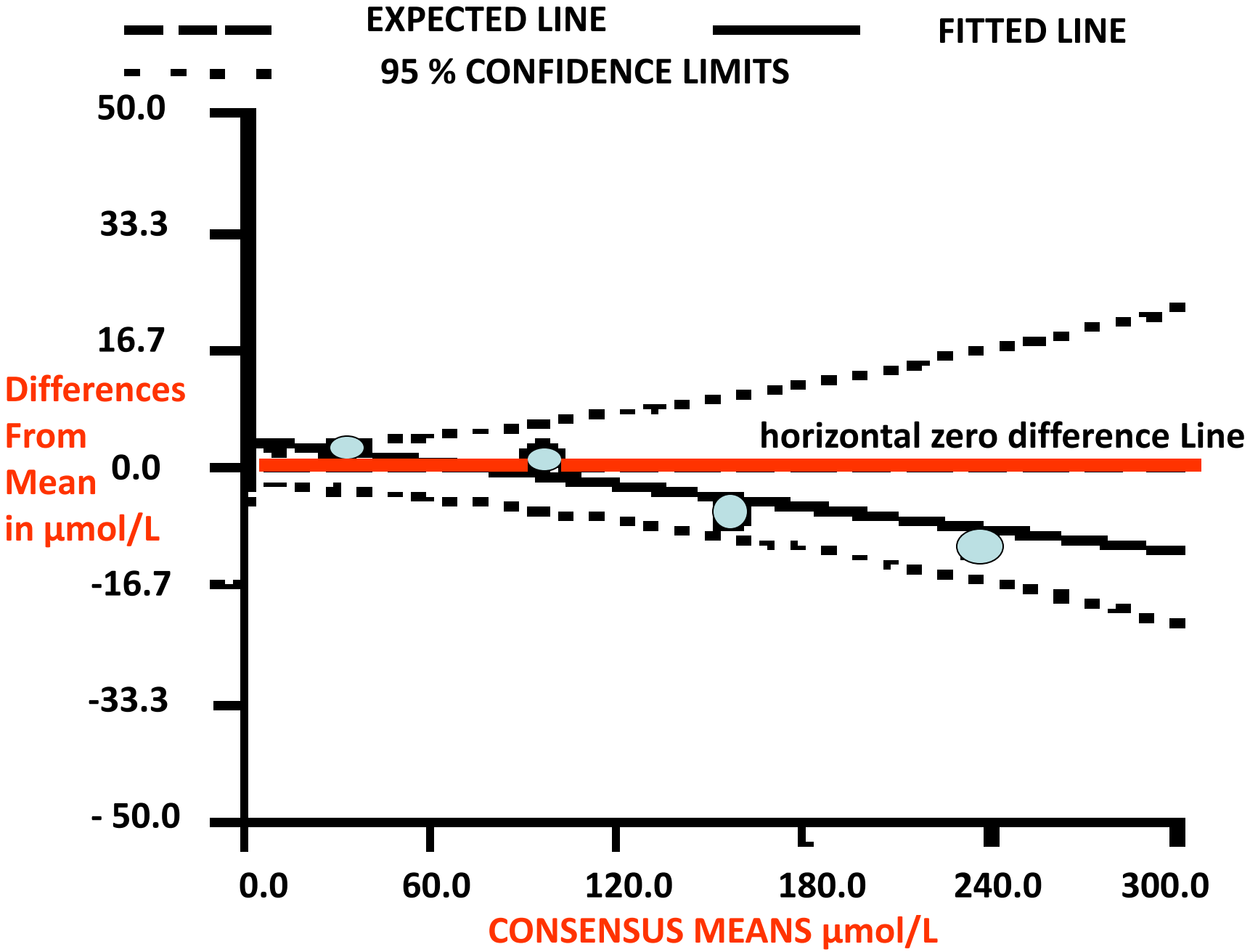
Differences between the lab's results
and the Group (consensus) means (y-axis)

plotted against

Group means (x-axis)

PHENOBARBITAL

UKNEQAS



NHLS PROFICIENCY TESTING PROGRAMME REPORT (ENDOCRINE)

Results of Survey number 1 of 2010/11

Defined Target

Date of Report: 12 May 2010

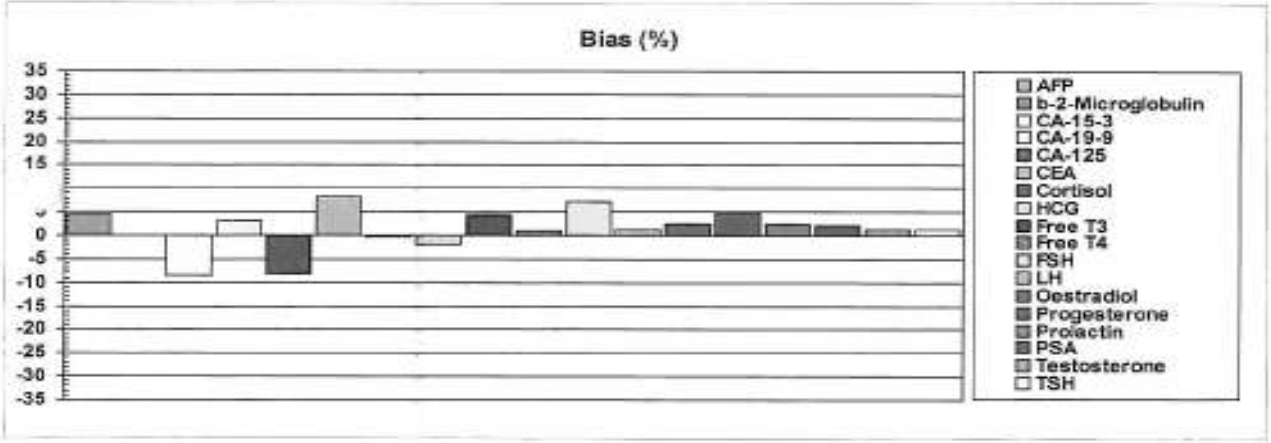
LABORATORY: 003

Hospital x

REGION:

INSTRUMENT: CENTAUR/IMMULITE

TEST	RESULTS	METHOD	FLAG	BIAS %	ACCEPTANCE LIMITS LOW	HIGH	TARGET	ALL LAB MEAN	No.
a-Foetoprotein kU/L	190.00	Centaur		4.40	155.00	209.00	182.00	190.000	4
b-2-Microglobulin mg/L		Pro Spec		NR					
CA-15-3 kU/L	90.60	Centaur		-8.48	84.20	114.00	99.00	97.233	3
CA-19-9 kU/L	199.00	Centaur		3.11	164.00	222.00	193.00	104.155	2
CA-125 kU/L	167.00	Centaur		-8.24	155.00	209.00	182.00	165.000	3
CEA ug/L	52.20	Centaur		8.30	41.00	55.40	48.20	51.575	4
Cortisol nmol/L	1074.00	Centaur		-0.28	897.00	1257.00	1077.00	1113.000	3
HCG U/L	550.00	Immulite		-1.96	469.00	653.00	561.00	550.000	1
Free T3 pmol/L	23.50	Centaur		4.44	19.10	25.90	22.50	23.100	4
[illegible] T4 pmol/L	37.20	Centaur		1.09	31.30	42.30	36.80	36.560	5
[illegible] IU/L	75.30	Centaur		7.11	59.80	80.80	70.30	74.675	4
LH U/L	61.10	Centaur		1.33	50.80	69.80	60.30	58.600	4
Oestradiol pmol/L	1576.00	Centaur		2.54	1153.00	1921.00	1537.00	1633.333	3
Progesterone nmol/L	105.00	Centaur		4.95	79.80	122.00	101.00	102.675	4
Prolactin µg/L	47.00	Centaur		2.40	39.10	52.80	45.90	45.150	4
PSA µg/L	21.90	Centaur		2.34	18.20	24.60	21.40	22.300	5
Testosterone nmol/L	37.30	Immulite		1.36	28.60	45.00	36.80	37.300	1
TSH mIU/L	23.10	Centaur		1.32	19.40	26.20	22.80	24.120	5



Target values are not available for all instruments for all of the analytes. The % Bias cannot be calculated for those results.

21/05/10

* End Of Report *

Analyte : Serum creatinine (umol/L)

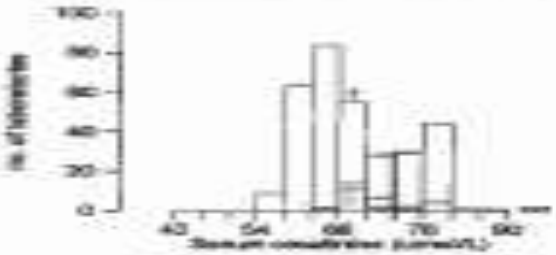
Spec.	Pool	Pool description / Treatments / Additions
48A	120	Pooled human serum (Pool 121) diluted 4:1 with PBS
48B	122	Pool 121 with 10 umol/L added creatinine
48C	149	Pool 148 (48CA) with 50 umol/L added creatinine

- ☐ All methods
- ☐ Dry slide
- ☐ OCD (J&J) Gen 80+ [1UJ2]

Your A score is	
Your B score is	-4.8
Your C score is	2.1

Specimen :

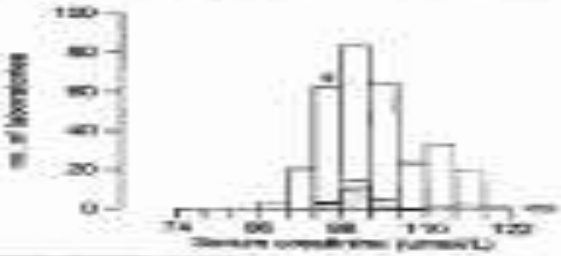
	n	Mean	SD	CV(%)
All methods	313	68.3	7.7	11.3
Dry slide	30	71.4	4.8	6.6
OCD (J&J) Gen 80+ [1UJ2]	15	69.7	1.4	2.0
OCD (J&J) original [1JJ]	15	74.8	5.8	7.8
Compensated Kinetic Jaffe	148	64.3	3.5	5.5
Beckman reagents [1DBK]	32	63.3	4.0	6.3
Roche Modular reagents [1DDC]	74	65.8	2.8	4.2
Traditional Kinetic Jaffe	80	71.9	9.6	13.6
Abbott reagents [1LAB]	27	63.3	5.1	8.1
Olympus reagents [1TOL]	41	78.2	2.3	2.9
O'Leary	19	77.9	3.8	4.9
Enzymatic	38	66.7	2.2	3.3



Your result	67
Target value (ALTM)	68.3
Your specimen:	
Bias	-1.3
transformed bias	-1.9
Accuracy Index	18
'True' value	65
OCD (J&J) Gen 80+ [1UJ2] (reagent)	69.7

Specimen :

	n	Mean	SD	CV(%)
All methods	319	102.9	7.2	7.0
Dry slide	30	103.6	5.5	5.4
OCD (J&J) Gen 80+ [1UJ2]	15	100.5	1.9	1.9
OCD (J&J) original [1JJ]	15	106.8	7.6	7.1
Compensated Kinetic Jaffe	148	102.6	4.6	4.5
Beckman reagents [1DBK]	33	96.3	3.8	3.9
Roche Modular reagents [1DDC]	74	103.0	3.5	3.3
Traditional Kinetic Jaffe	80	108.4	10.0	9.4
Abbott reagents [1LAB]	27	96.8	6.3	6.5
Olympus reagents [1TOL]	41	113.7	2.6	2.2
O'Leary	19	107.0	4.3	4.0
Enzymatic	38	98.6	3.0	3.1



Your result	99
Target value (ALTM)	102.9
Your specimen:	
Bias	-4.7
transformed bias	-4.7
Accuracy Index	47
'True' value	97
OCD (J&J) Gen 80+ [1UJ2] (reagent)	100.0

Specimen :

	n	Mean	SD	CV(%)
All methods	318	57.7	8.5	14.7
Dry slide	30	67.1	7.8	11.6
OCD (J&J) Gen 80+ [1UJ2]	15	60.8	4.1	6.8
OCD (J&J) original [1JJ]	15	72.3	7.8	10.8
Compensated Kinetic Jaffe	148	52.5	3.2	6.1
Beckman reagents [1DBK]	33	53.1	4.4	8.2
Roche Modular reagents [1DDC]	74	52.8	2.5	4.8
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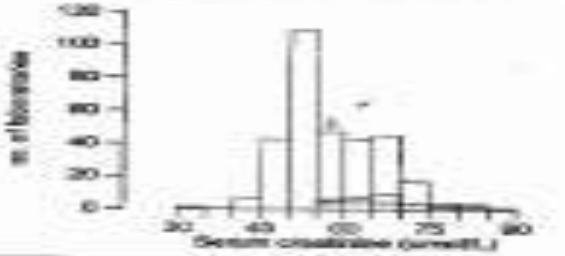
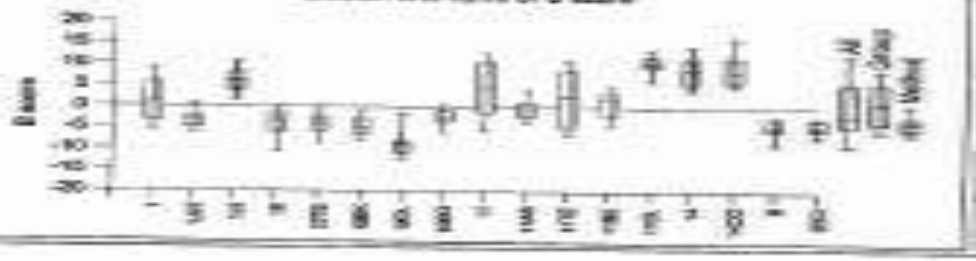
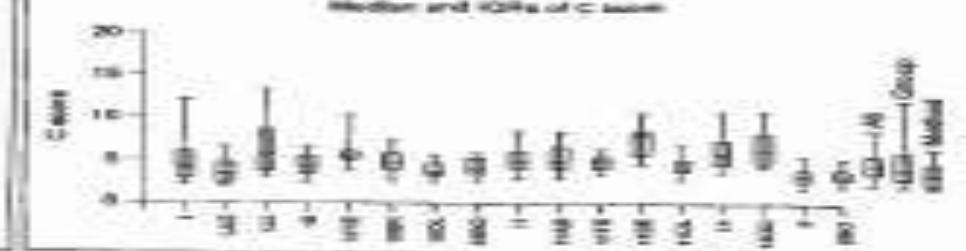


Your result	60
Target value (ALTM)	57.7
Your specimen:	
Bias	+2.3
transformed bias	+3.0
Accuracy Index	30
'True' value	
OCD (J&J) Gen 80+ [1UJ2] (reagent)	62.8

Median and IQRs of B score



Median and IQRs of C score



Mayo Clinic study

Proficiency testing programs are far from ideal monitors of lab performance

50% errors - problems with the survey itself

only 28 % related to specific analytical problems

TROUBLESHOOTING

1. Incorrect classification
2. Incorrect units / conversion
3. Incorrect sample tested
4. Technical errors – reconstitution/dilution inadequate mixing etc
5. Transcription errors
6. Relook at the IQC data
7. Are there trends? High/low bias etc?
8. Change in reagents/calibrants/standardisation?

ROYAL COLLEGE OF PATHOLOGISTS OF AUSTRALASIA (RCPA)

METHOD CLASSIFICATION SYSTEM

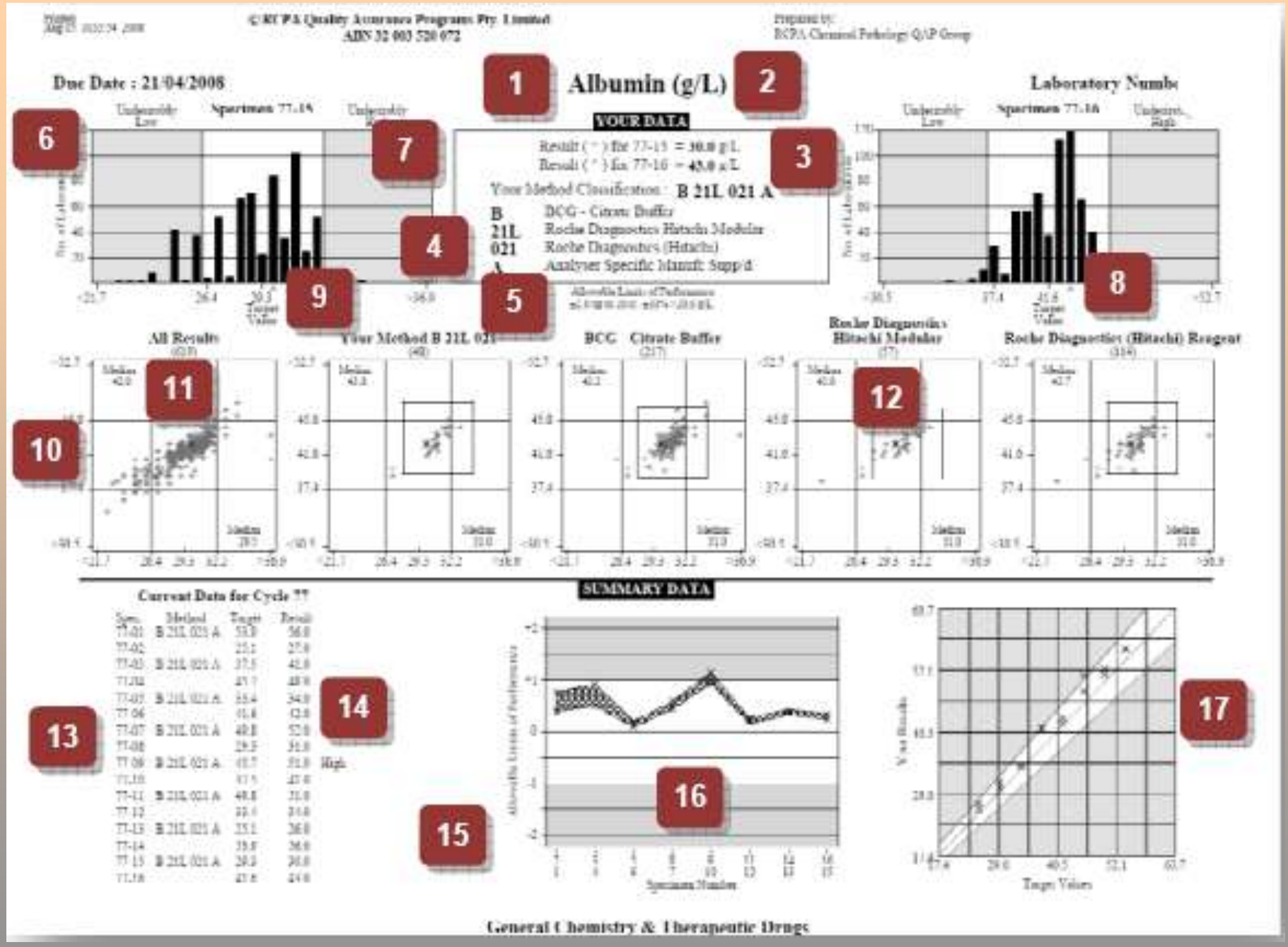
The method classification system is designed to comprehensively describe your analytical system for each analyte. The method classification system is broken down into four categories that describe analytical principle, instrument, reagent manufacturer and calibrator. This breakdown facilitates a high level of peer review, enabling your data to be shown in relation to your immediate peers using the same analytical systems.

RCPA QAP provides all participants with a list of codes for each of the four categories (if applicable) for every analyte. Participants need to review their analytical system and provide a breakdown of their method using these codes. An example of the method classification process is provided below.

General Serum Chemistry Program: Performing albumin on a Roche Hitachi Modular using Roche reagents & calibrator

The list of options for each category for this analyte is consulted:

Category 1 Analytical Principle (Program Specific)	Category 2 Measurement System Examples (See Master List–All Programs)	Category 3 Reagent Source Examples (See Master List-All Programs)	Category 4 Calibrator (Program Specific)
Dye Binding **A** Bromocresol Green Succinate Buffer **B** Bromocresol Green – Citrate Buffer **E** Bromocresol Purple **G** Bromocresol Green – Unspecified Buffer **H** Bromocresol Green – Malate Buffer	**21H** Roche Diagnostics Hitachi 917 **21J** Roche Diagnostics Hitachi 912 **21K** Roche Diagnostics Hitachi 902/904 **21L** Roche Diagnostics Hitachi Modular **21M** Roche Diagnostics Cobas c501/c 311/c 111	**000** Own Preparation **016** Beckman Coulter **019** Biomerieux **020** Bio-Rad **021** Roche Diagnostics (Hitachi) **069** Roche Diagnostics (Integra) **098** Siemens (Bayer) **125** Randox	**A** Analyser Specific Calibrator supplied by your manufacturer. **Other Calibrator** **B** Other Standard not manufacturer supplied. **C** Bovine commercially assayed **D** Human commercially assayed **E** Bovine Material – independently calibrated **F** Human Material – independently calibrated **I** International Protein Standard calibrated vs. BCR CRM 470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ABN 32 003 520 072
Prepared by:
RCPA Chemical Pathology QAP Group
Due Date : 21/04/2008
Albumin (g/L)
Laboratory Numbe
Spartmen 77.15
Spartmen 77.16
YOUR DATA
Result ( ) for 77-15 = 30.0 g/L
Result ( ) for 77-16 = 45.0 g/L
Your Method Classification : B 21L 021 A
B
21L
021
A
BCG - Citrate Buffer
Roche Diagnostics Hitachi Modular
Roche Diagnostics (Hitachi)
Analyser Specific Manuf. Supp'd
All Results
Your Method B 21L 021
BCG Citrate Buffer
Roche Diagnostics Hitachi Modular
Roche Diagnostics (Hitachi) Reagent
SUMMARY DATA
Current Data for Cycle 77
High
Target Values
General Chemistry & Therapeutic Drugs
1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17