QUALITY CONTROL & STANDARD OPERATING PROCEDURES

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OUTLINE

- Introduction
- Quality Control - Meaning
- Types of Quality Control
- Monitoring of Quality Control
- Multi-rule Quality Control
- Quality Control material
- Quality Control Protocol
- Standard Operating Procedures
- Importance of SOP
- Conclusion

INTRODUCTION

Patients' Expectation of Error-free Care Raises the Stakes for Laboratories and Hospitals. However, Laboratory Errors Attract Headlines and Public Concern the most; Hence the need for an effective Quality Control Protocol.

QUALITY CONTROL

Quality Control results are used to validate patient results for proper diagnosis, prognosis or treatment planning.

Quality Control in the medical laboratory is a statistical process used to monitor and evaluate the analytical process which produces patient results.

TYPES OF QUALITY CONTROL.

The ***ISO 15189 Guidelines clause 5.6*** (Technical requirement) elaborates on the importance of ***Assuring Quality of Examination procedures.*** It is sub-divided into two parts;

- **Internal or Daily Quality control (IQC or DQC)** which measures PRECISION.

- **External Quality Control (EQC)** which measures ACCURACY**.**

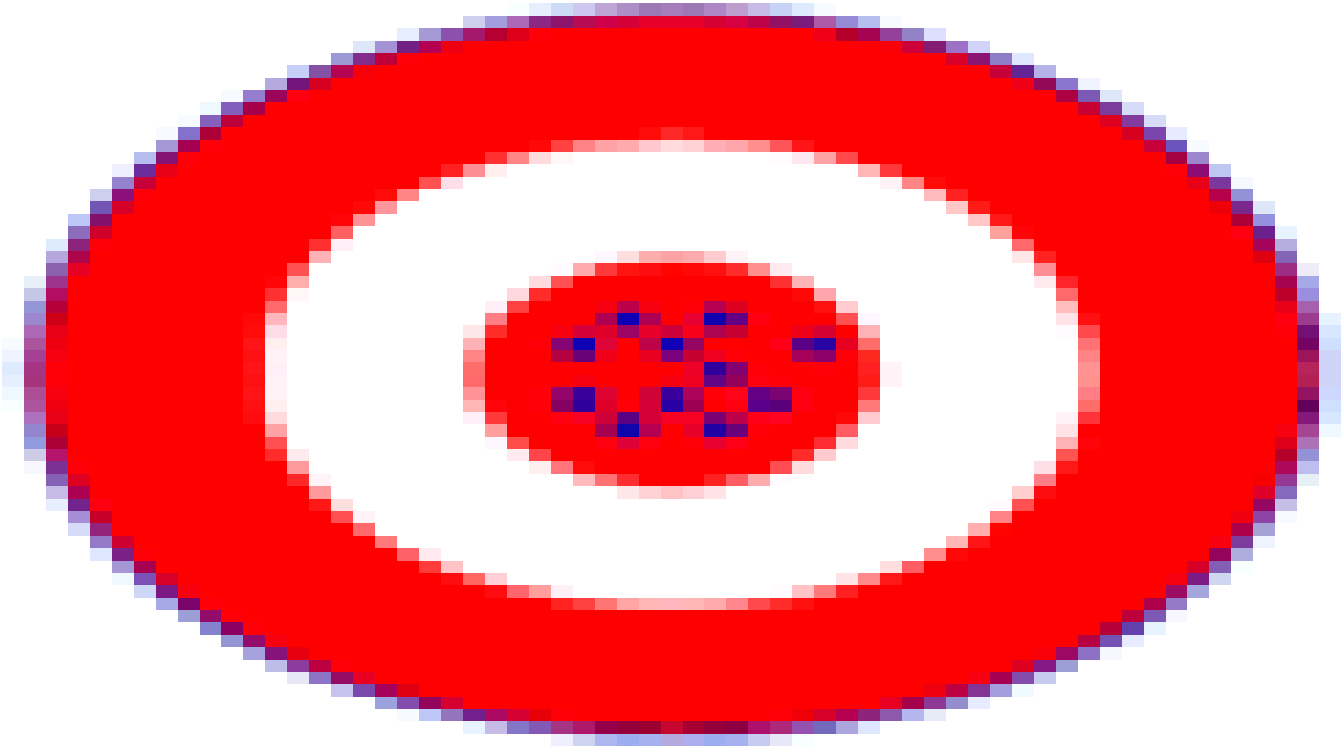
Internal or Daily Quality control (IQC or DQC)

Internal or Daily Quality control (IQC or DQC) which measures PRECISION;

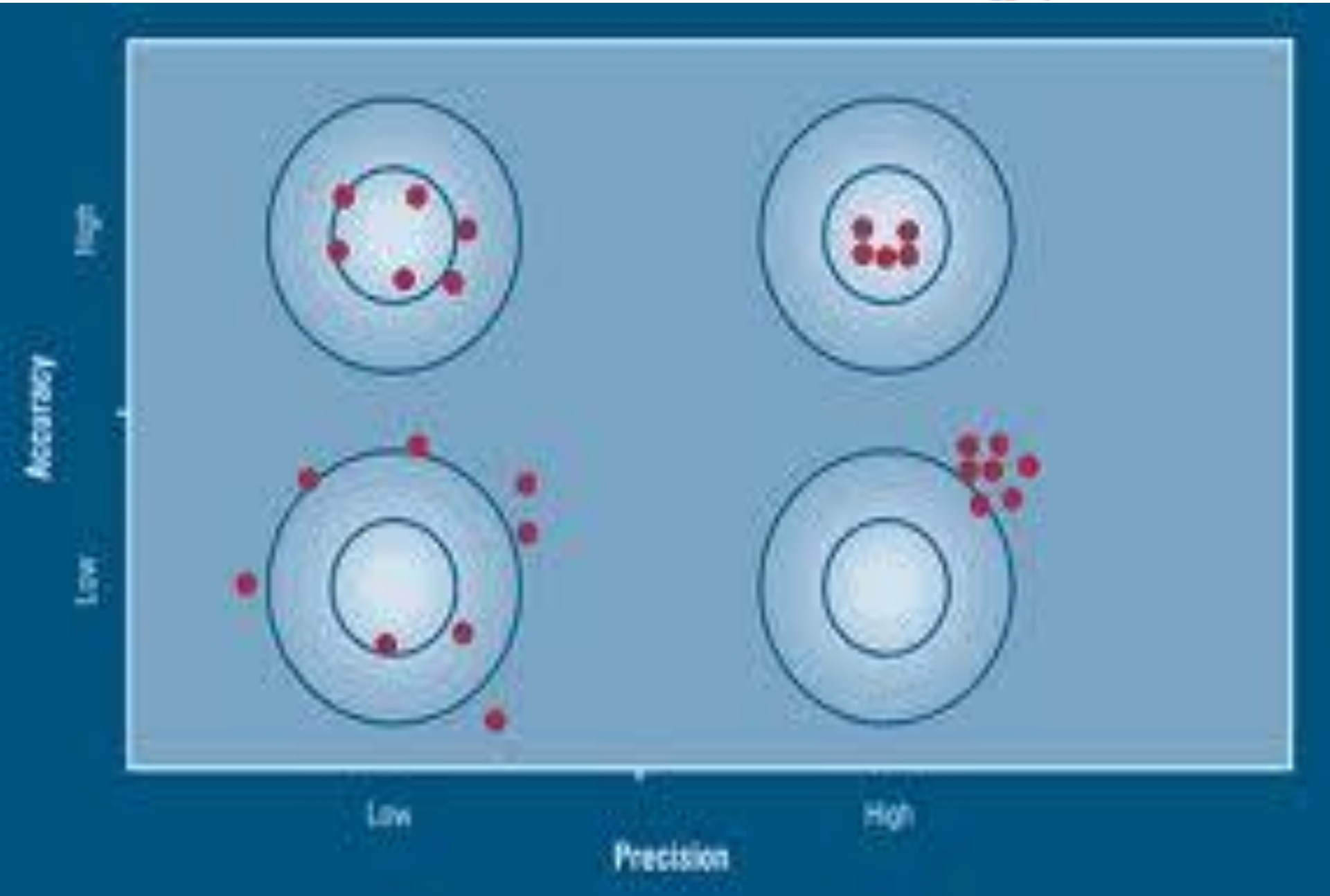
- Evaluates the consistency, repeatability or reproducibility of an equipment performance.
- The acceptability of this performance is measured by the Coefficient of Variation (CV%) as given by the CLIA Act 1988. recently updated in 2012.

External Quality Control (EQC)

- QC testing in which laboratories analyze unknown specimens submitted from an external source or Proficiency Testing body.
- This measures a laboratory's ability to obtain the correct result and is known as ACCURACY testing.



Precision Vs Accuracy



MONITORING OF QUALITY CONTROL

Simply listing the QC results on a sheet of paper or in a book are just not good enough, as it is not sensitive enough to let you see subtle trends in performances.

- The most effective way to display results is graphically, on a Levey - Jennings Chart (LJ) which can be done manually or electronically.

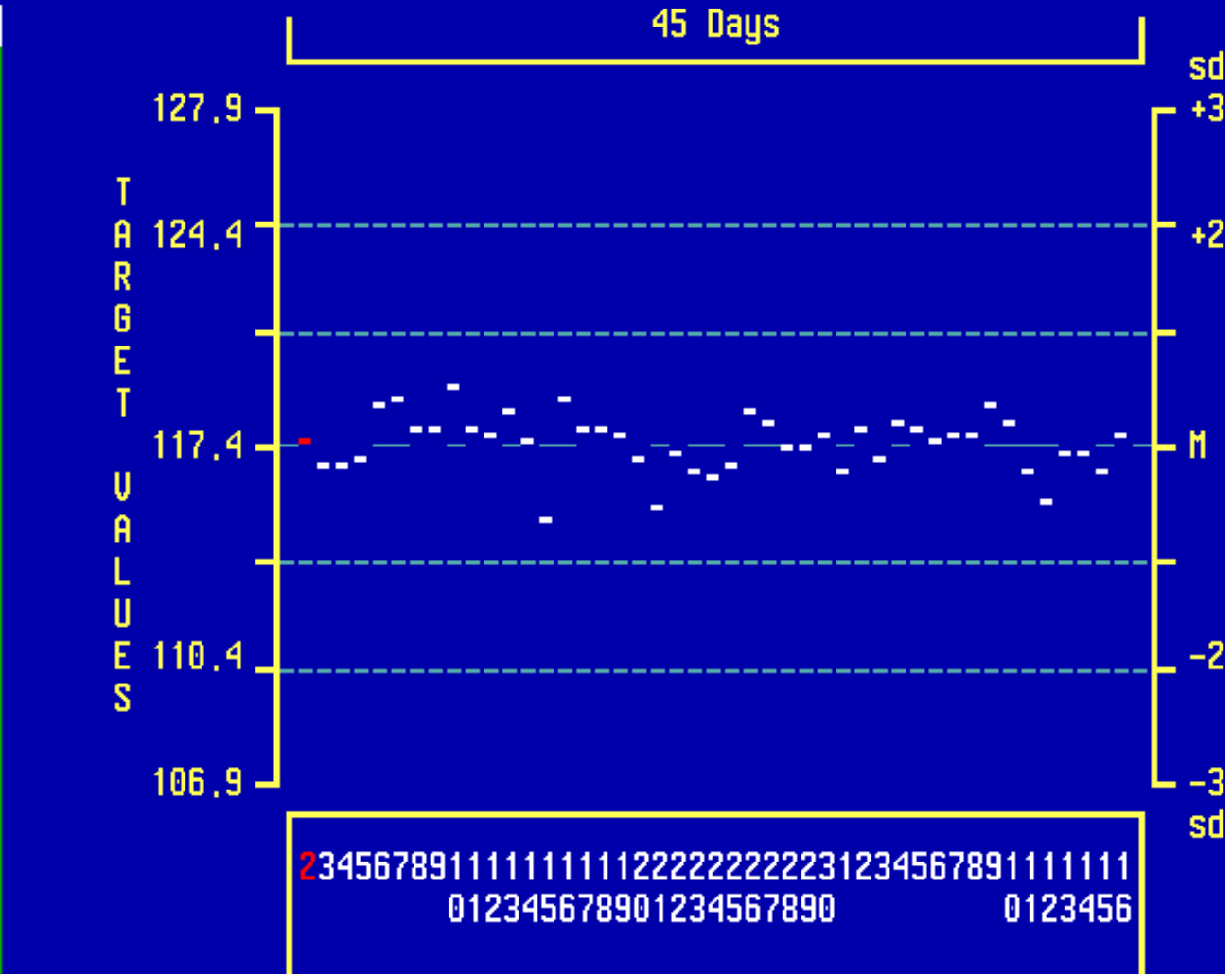
- On an LJ chart, performance of equipment can be monitored to verify on a daily basis by run of QCs to ascertain if it is fit for running patient samples.

QC DISTRIBUTION ON MEDITECH - 1

PathCare

Control	QC SYNCHRON LEVEL 1		NIG	Lot	M210011	Status	ACTIVE	Tech	*ALL*
Test	BNA	From Date	02/09/13	#Observ	45	Min	115.10000	S.D.	0.88
Method	BISE	Thru Date	16/10/13	Mean	117.53	Max	119.30000	Var	0.78
		Shift	*ALL*	Median	117.70	Mode	117.90000	C.V.	0.75

Date	Value	SDI	#Spec
Sep 02	117.50	0.03	1
Sep 03	116.80	0.17	1
Sep 04	116.80	0.17	1
Sep 05	117.10	0.09	1
Sep 06	118.80	0.40	3
Sep 07	118.90	0.43	1
Sep 08	117.90	0.14	1
Sep 09	118.00	0.17	1
Sep 10	119.30	0.54	1
Sep 11	117.90	0.14	1
Sep 12	117.70	0.09	1
Sep 13	118.60	0.34	1
Sep 14	117.50	0.03	1
Sep 15	115.10	0.66	1
Sep 16	118.90	0.43	1
Sep 17	117.90	0.14	1
Sep 18	118.00	0.17	1
Sep 19	117.70	0.09	1
Sep 20	117.00	0.11	1
Sep 21	115.50	0.54	2
Sep 22	117.30	0.03	1
Sep 23	116.70	0.20	1
Sep 24	116.50	0.26	1

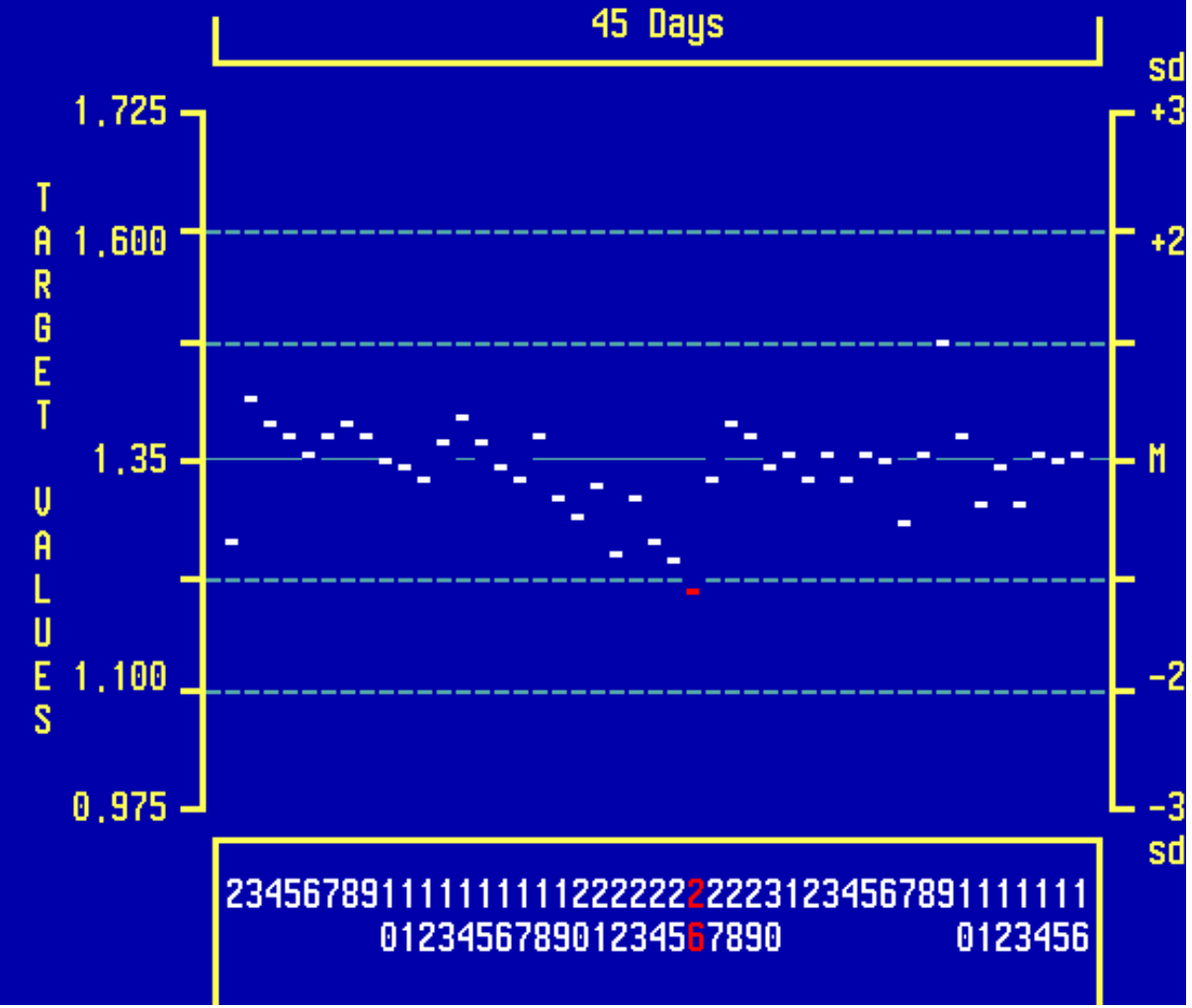


QC DISTRIBUTION ON MEDITECH - 2

PathCare

Control	QC SYNCHRON LEVEL 3		NIG	Lot	M210013		Status	ACTIVE	Tech	*ALL*
Test	BMG	From Date	02/09/13	#Observ	45		Min	1.21000	S.D.	0.050
Method	BCOL	Thru Date	16/10/13	Mean	1.342		Max	1.48000	Var	0.003
		Shift	*ALL*	Median	1.350		Mode	1.36000	C.V.	3.75

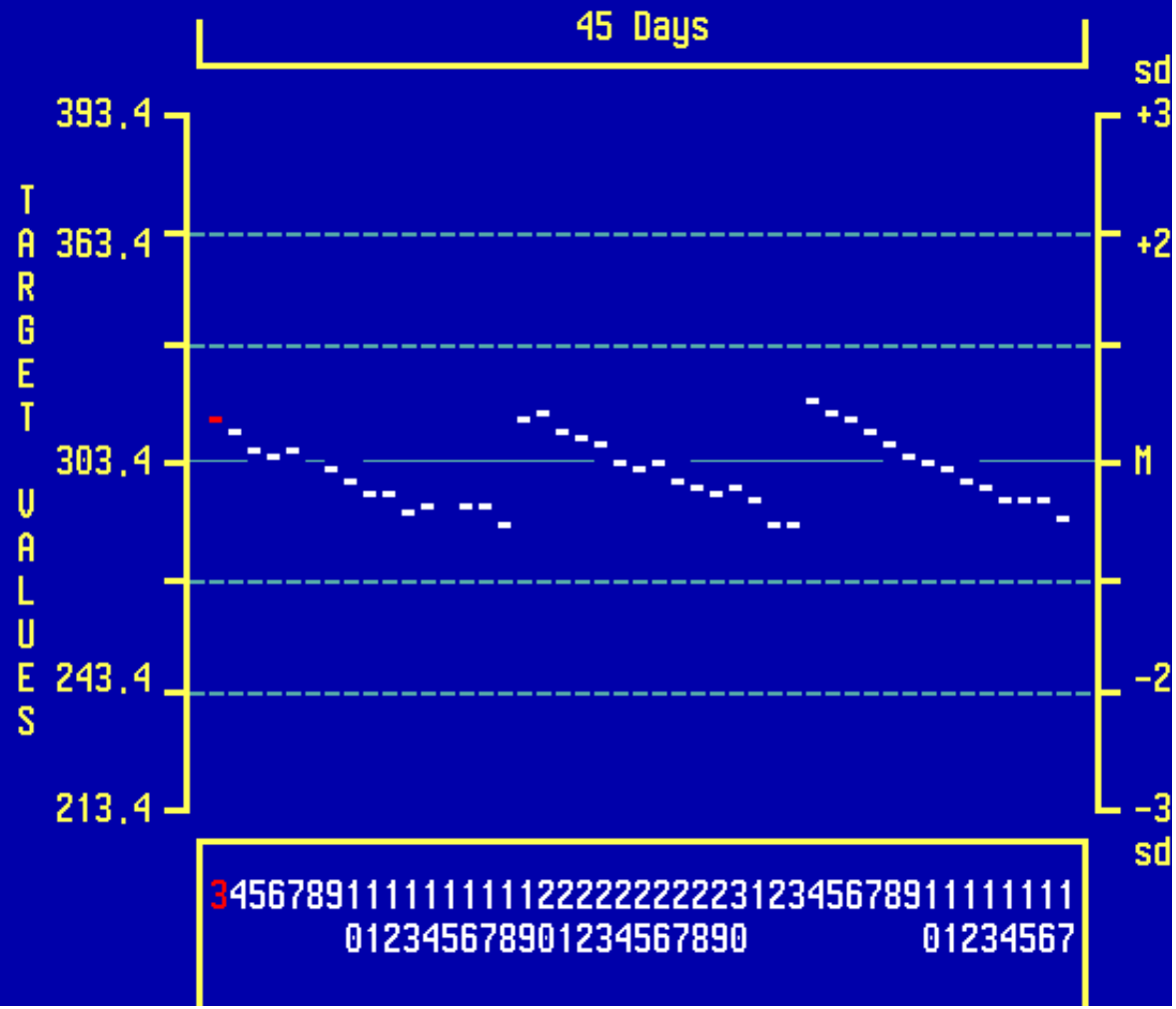
	Date	Value	SDI	#Spec
†	Sep 03	1.420	0.50	1
	Sep 04	1.390	0.30	1
	Sep 05	1.380	0.20	1
	Sep 06	1.360	0.00	1
	Sep 07	1.380	0.20	1
	Sep 08	1.390	0.30	1
	Sep 09	1.380	0.20	1
	Sep 10	1.350	0.00	1
	Sep 11	1.340	0.00	1
	Sep 12	1.330	0.10	1
	Sep 13	1.370	0.10	1
	Sep 14	1.400	0.40	1
	Sep 15	1.370	0.10	1
	Sep 16	1.340	0.00	1
	Sep 17	1.330	0.10	1
	Sep 18	1.380	0.20	1
	Sep 19	1.310	0.30	1
	Sep 20	1.290	0.40	1
	Sep 21	1.320	0.20	1
	Sep 22	1.250	0.80	1
	Sep 23	1.310	0.30	1
	Sep 24	1.260	0.70	1
	Sep 25	1.240	0.80	1



QC DISTRIBUTION ON MEDITECH - 3

Control	QC SYNCHRON LEVEL 3		ABJ	Lot	M210013		Status	ACTIVE	Tech	*ALL*
Test	BGGT	From Date	03/09/13	#Observ	43		Min	287.00000	S.D.	9.07
Method	BENZ	Thru Date	17/10/13	Mean	301.49		Max	320.00000	Var	82.24
		Shift	*ALL*	Median	301.00		Mode	299.00000	C.V.	3.01

Date	Value	SDI	#Spec
Sep 03	315.00	0.39	1
Sep 04	311.00	0.25	1
Sep 05	307.00	0.12	1
Sep 06	305.00	0.05	1
Sep 07	306.00	0.09	1
Sep 09	302.00	0.05	1
Sep 10	299.00	0.15	1
Sep 11	295.00	0.28	1
Sep 12	296.00	0.25	1
Sep 13	291.00	0.41	1
Sep 14	292.00	0.38	1
Sep 16	292.00	0.38	1
Sep 17	292.00	0.38	1
Sep 18	287.00	0.55	1
Sep 19	314.00	0.35	1
Sep 20	316.00	0.42	1
Sep 21	312.00	0.29	1
Sep 22	310.00	0.22	1
Sep 23	309.00	0.19	1
Sep 24	304.00	0.02	1
Sep 25	301.00	0.08	1
Sep 26	304.00	0.02	1
Sep 27	299.00	0.15	1



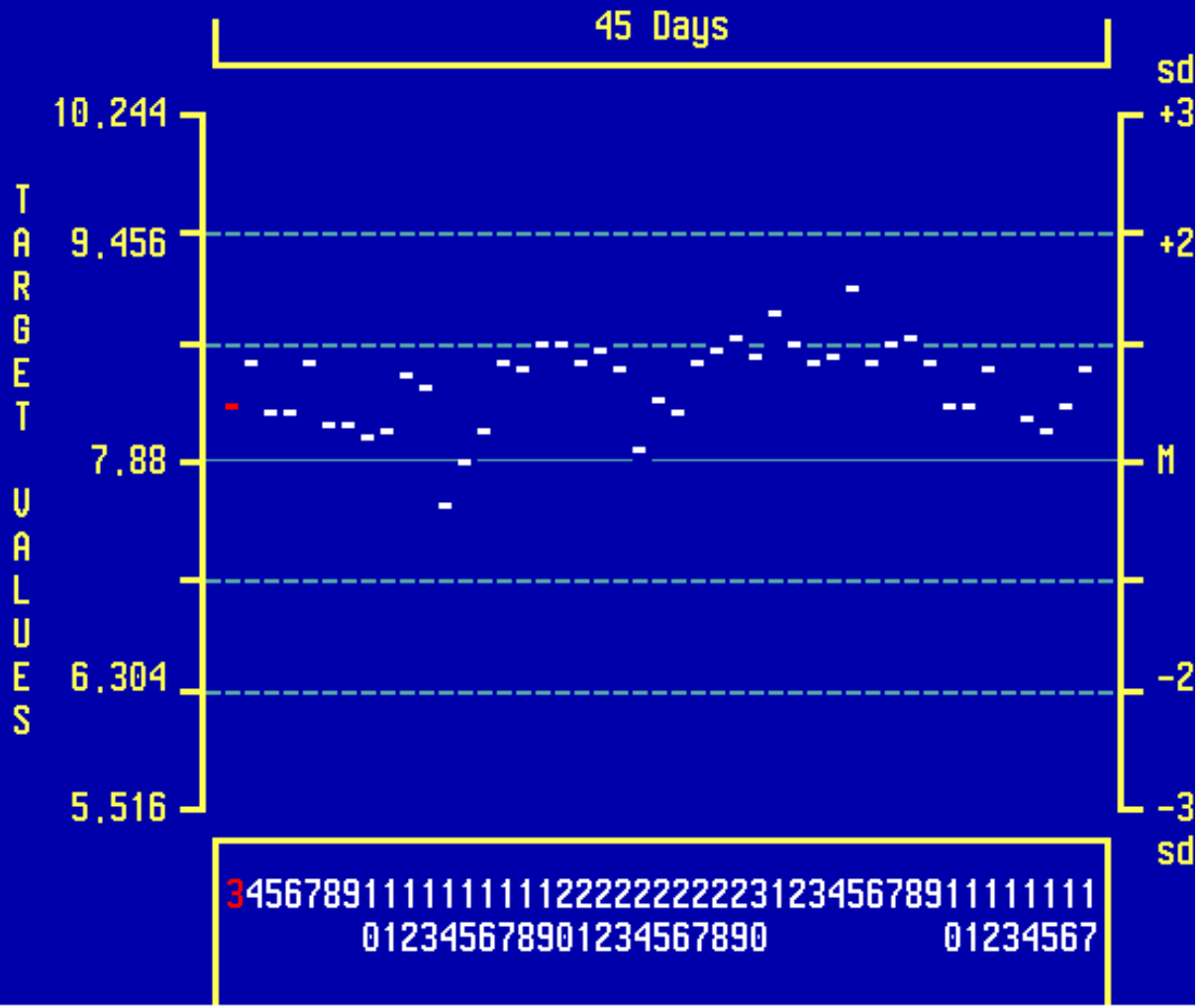
QC DISTRIBUTION ON MEDITECH - 4

PathCare

Control QC BIORAD LEVEL 2 NIG Lot 40812 Status ACTIVE Tech *ALL*

Test	ZEFT3	From Date	03/09/13	#Observ	44	Min	7.58000	S.D.	0.288
Method	ELISA	Thru Date	17/10/13	Mean	8.411	Max	9.08000	Var	0.083
		Shift	*ALL*	Median	8.520	Mode	8.56000	C.V.	3.42

Date	Value	SDI	#Spec
Sep 03	8.240	0.40	1
Sep 04	8.560	0.80	1
Sep 05	8.200	0.40	1
Sep 06	8.200	0.40	1
Sep 07	8.560	0.80	1
Sep 08	8.150	0.30	1
Sep 09	8.140	0.30	1
Sep 10	8.050	0.20	1
Sep 11	8.100	0.20	1
Sep 12	8.460	0.70	1
Sep 13	8.370	0.60	1
Sep 14	7.580	0.30	1
Sep 15	7.900	0.00	1
Sep 16	8.090	0.20	1
Sep 17	8.570	0.80	1
Sep 18	8.510	0.70	1
Sep 19	8.670	1.00	1
Sep 20	8.680	1.00	1
Sep 21	8.560	0.80	1
Sep 22	8.620	0.90	1
Sep 23	8.530	0.80	1
Sep 24	7.950	0.00	1
Sep 25	8.310	0.50	1



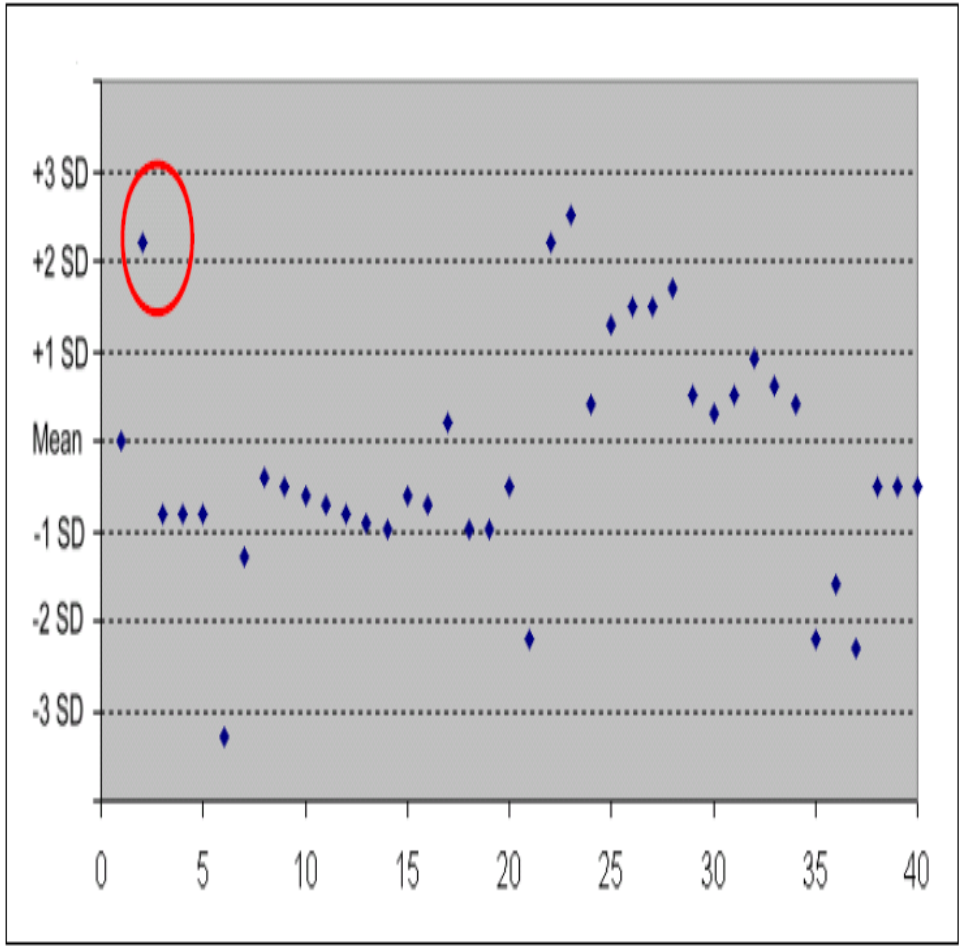
MULTI-RULE QUALITY CONTROL

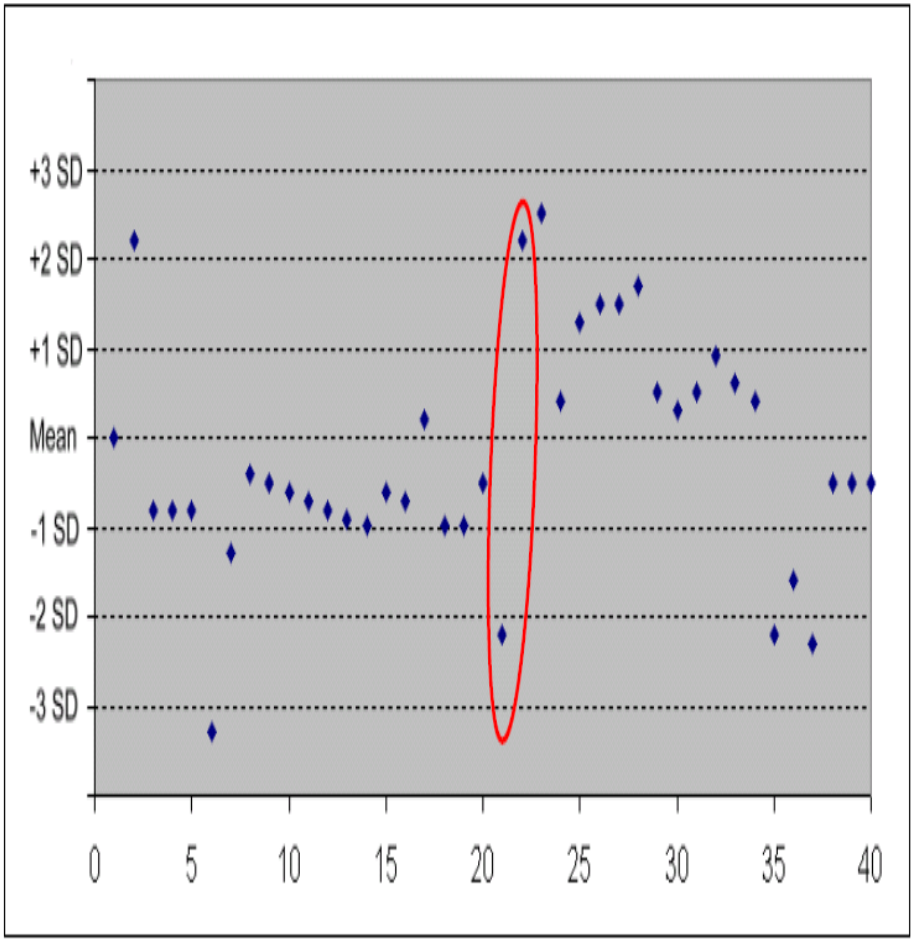
In 1981 Dr James Westgard published an article on QC which set the basis for

- Evaluating the quality for analytical run for medical laboratories.
- A useful tool for identifying random and systematic errors in laboratory test procedures.
- It includes a whole range of rule notable of which are; 1_{2s}, 1_{3s}, 2_{2s}, 2_{3s}, R_{4s}, 4_{1s} & 10_{x}.

TYPES OF ANALYTICAL ERRORS

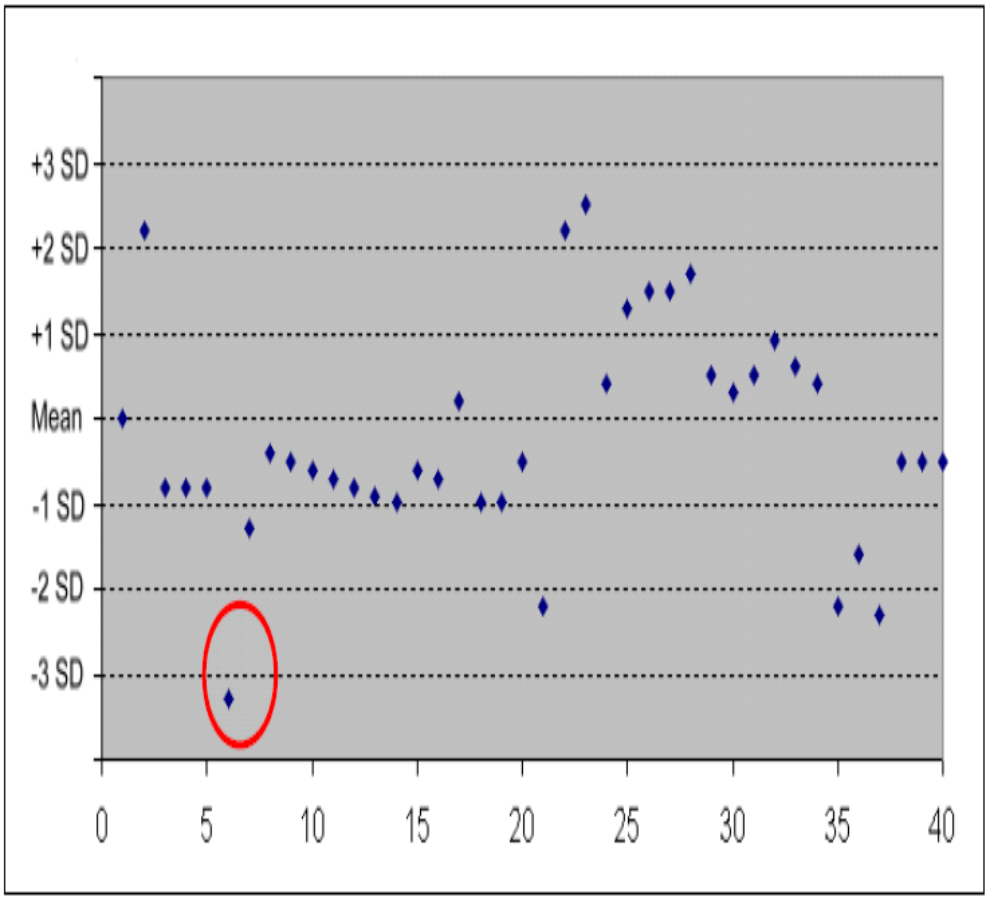
Random error: This is when an occasional result is out of control, either too high or too low, e.g. one result outside +/- 2 SD.

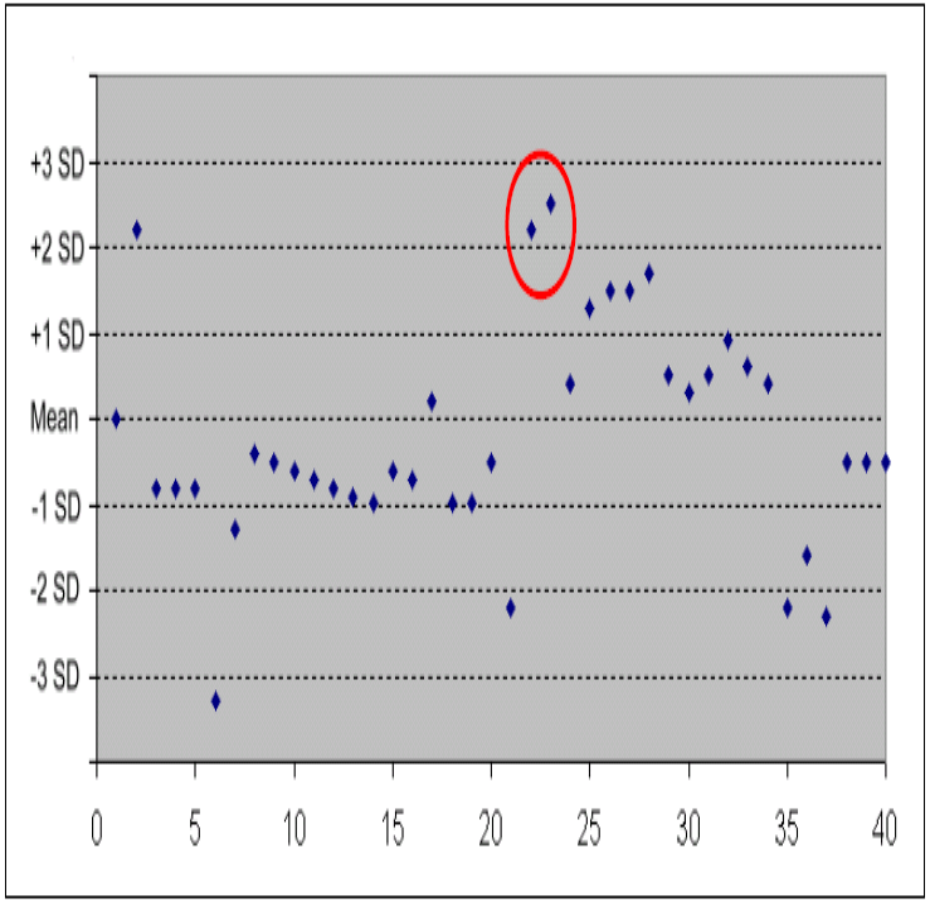




TYPES OF ANALYTICAL ERRORS Cont'd

Systematic error: This is said when the error you are seeing is consistent and always too high or too low, e.g. 3 or more consecutive results outside either +/- 2 SD's.





QUALITY CONTROL MATERIAL

- Quality control material is ideally made from **the same matrix as** patient samples. It can also be animal in origin, aqueous solutions or a commercially prepared organic matrix.
- A control product can be liquid or freeze-dried (lyophilized) material and is composed of one or more constituents (analytes) of known concentration.

QC PROTOCOL

This is an **adopted** and **documented laboratory- specific procedure** intended to minimise the risk of significantly different or aberrant patient examination results being reported in the event of QC rule failure. It entails;

- Establishment of QC frequency – linked to the stability of Instrument and risk to the patient test requested
- Activated QC multi-rule

NOTE: Whatever protocol is adopted, stick to it. Do not change the protocol to suit your needs as QC become "out-of-control".

STANDARD OPERATING PROCEDURES

These are procedures and work instructions that states how a procedure must be carried out. Instrumentation instruction manuals and Package Insert Method Sheets (PIMS) are also regarded as SOP‘s.

STANDARD OPERATING PROCEDURES Cont'd

According to the ***ISO Standard clause 5.5 on Examination procedures***, 'The methods or procedures selected for use shall be evaluated and found to give satisfactory results before being used for medical examination'.

This procedure shall be documented and reviewed periodically.

IMPORTANCE OF THE SOP

The importance of having a documented Standard Operating Procedures are;

- Standardization of processes that yield the same result even by different personnel.
- Provision of an Internal reference guide for laboratory operatives.
- Provision of a platform for continual system improvement.
- Establishment of an Audit trail in a Quality Management System.
- Availability of a documentation as the only proof that a procedure is in practice.

CONCLUSION:

If you think Quality is too expensive, note that; ”Quality will long be remembered after price have been forgotten”.

THANK YOU