QC Challenges and Solutions

- Clinical Biochemistry.

A handful of thoughts

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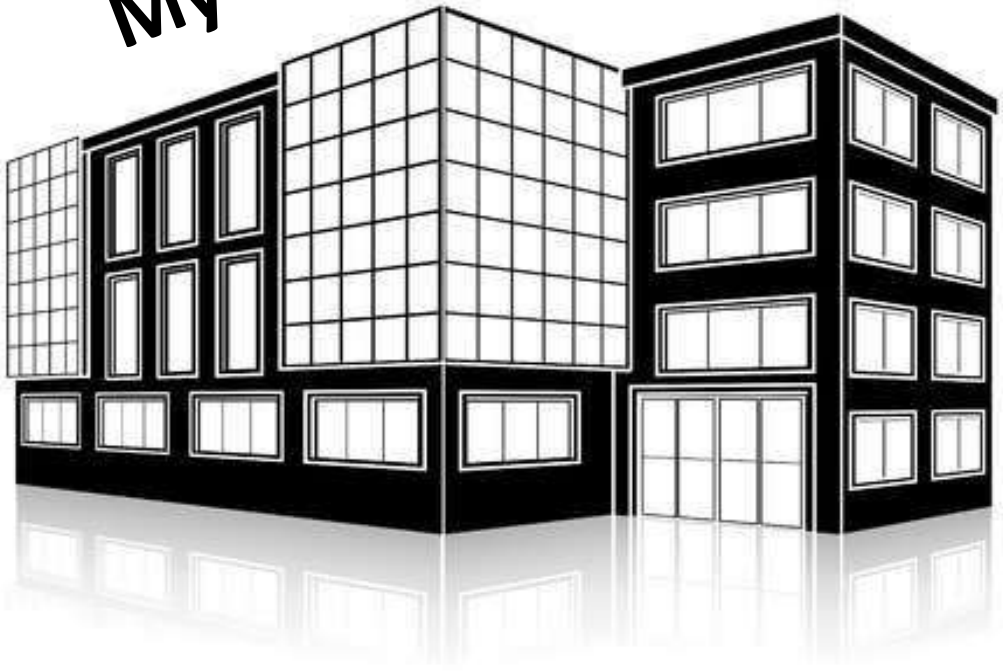
I dreamt..

Director of a laboratory

My Lab

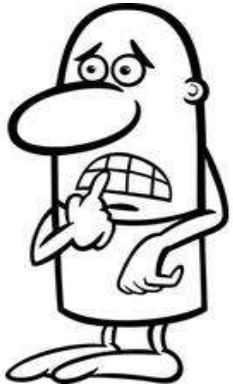


That’s me

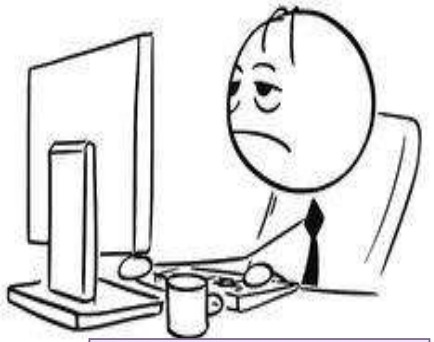
That’s my team..

Head of section

Quality Manager



Technical Manager



Senior Technician

Stores In-charge

STAT Technician

IT Manager

..Lets see what Quality is all about !

That’s my team..

What is Quality?

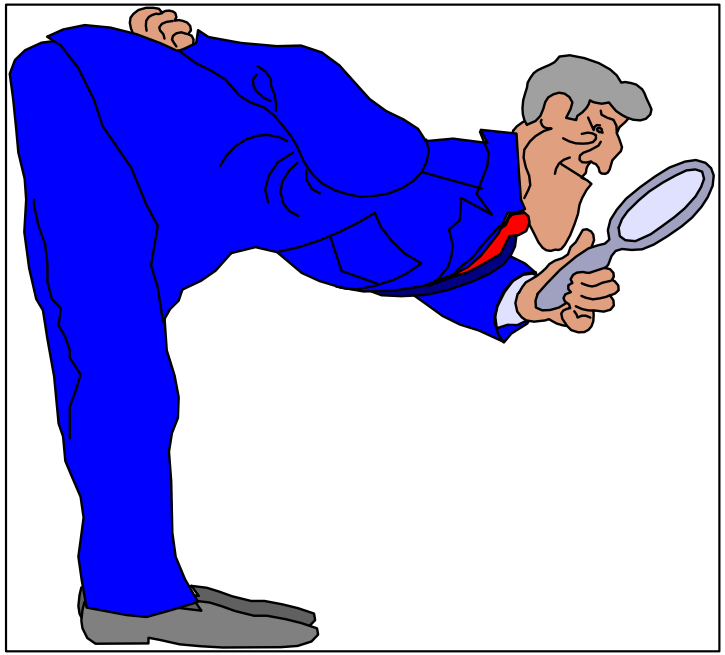
Quality is doing the right things
and doing those things right
Philip Crosby (1970)

Establishing conditions such that the quality of all tests performed in the medical lab assists clinicians in practicing good medicine"

~ Dr. Callum G Fraser

Quality is....

- invisible when GOOD
- impossible to ignore when BAD



Quality

- Sum-total of all the characteristics of a service that has a bearing upon the utilization of the service to the entire satisfaction of the customer.

- Conformance to the requirements of customers.

Clinical Laboratory Quality

1-Accuracy of result

2-Reliability of result

3-Timeliness of result

Quality Assurance

in the biochemistry laboratory is intended to ensure the reliability of the laboratory tests.

Achieved by ⟶

Quality Control

- QC is the study of those errors, which are the responsibility of the laboratory and of the procedures used to recognize and minimize them.

- Statistical process

Quality Control

- Essential element of the QMS
- Component of Quality Assurance
- Monitor the analytic phase

Why Quality Control ?

1.Quality Control gives **reliability** of information about patient's in the form of **correct lab results.**

2 . Reliability or correctness of a lab result depends on **precision**, **accuracy**, **sensitivity**, **specificity** & **appropriateness** of the method used

3.**Reject** results when there is evidence of errors

4.**Monitor** and **evaluate** the **Analytical** process that produces patients results

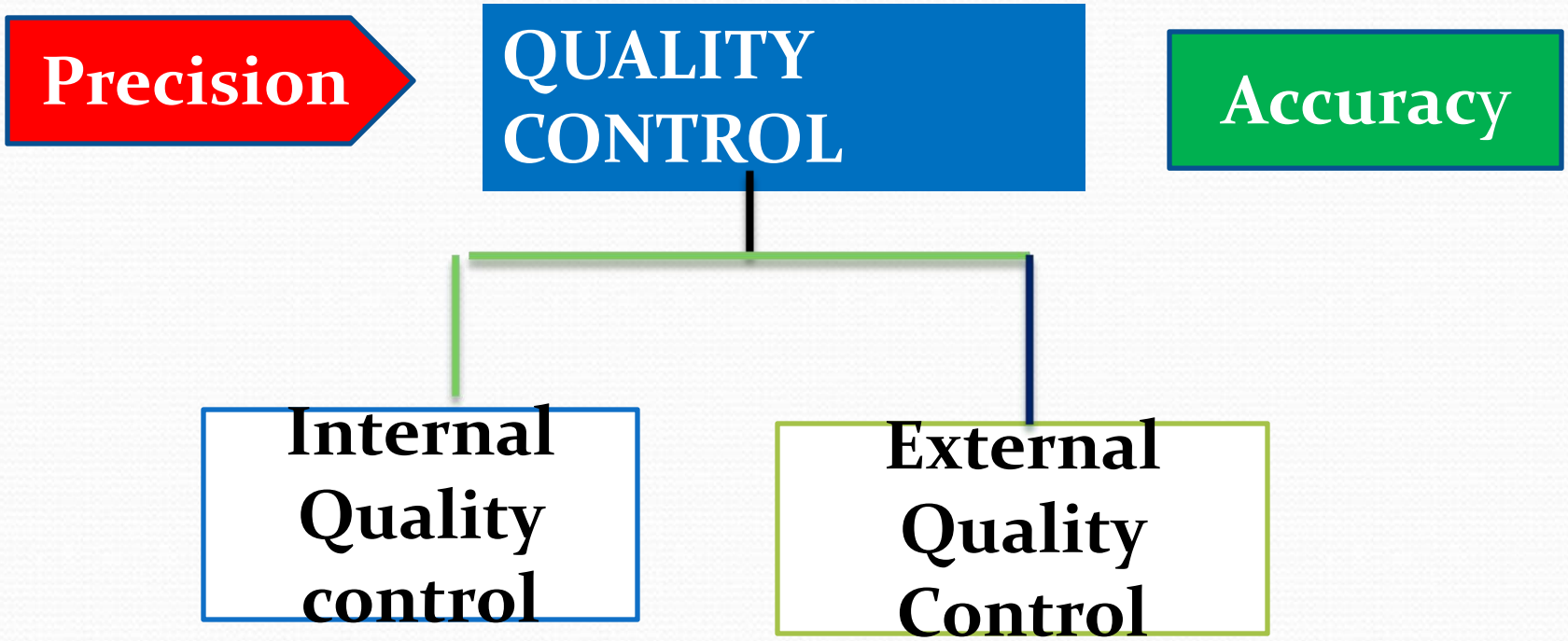
5.It is designed to give clinicians **confidence** in the methods used.

Quality in Laboratory Medicine "Fit For Purpose”

- Right patient
- Right test
- Right specimen
- Right cost
- Right result
- Right reference data

Quality Manager

Two complementary components of Quality procedures are :



IQC and EQA

IQC

- Monitors day-to-day reproducibility-precision, and detects frank errors in any one day's procedures
- personnel, document & reagent control instrumentation, CA

EQA

- Aims at detecting constant differences ("bias") between one laboratory's results and those of others
- International, national

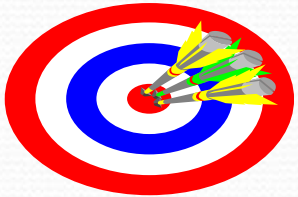
Accuracy vs. Precision

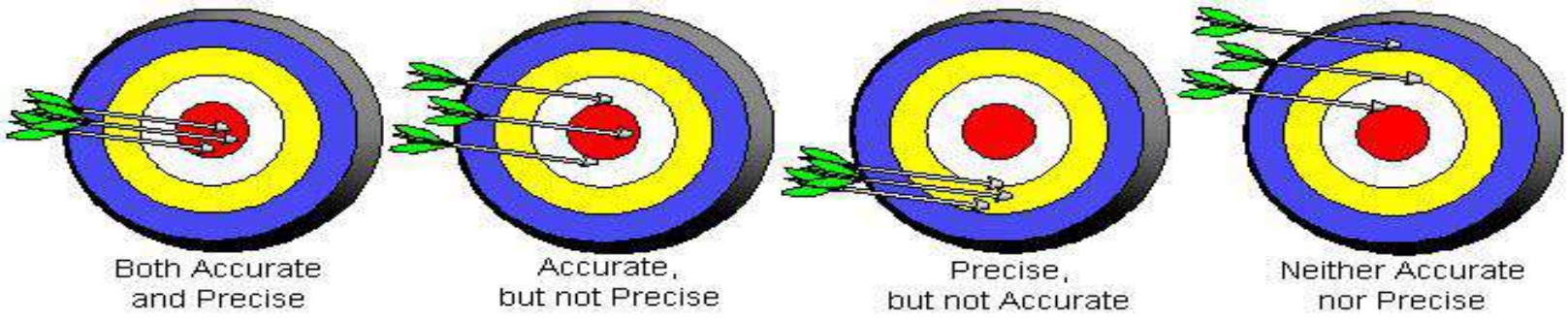
Accuracy

How well a measurement agrees with an accepted value

Precision

How well a series of measurements agree with each other



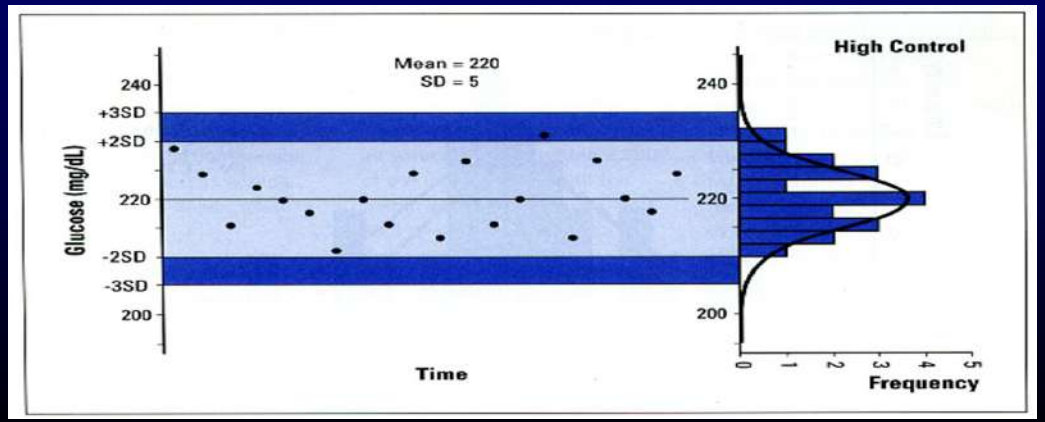


➢ Analytical Errors

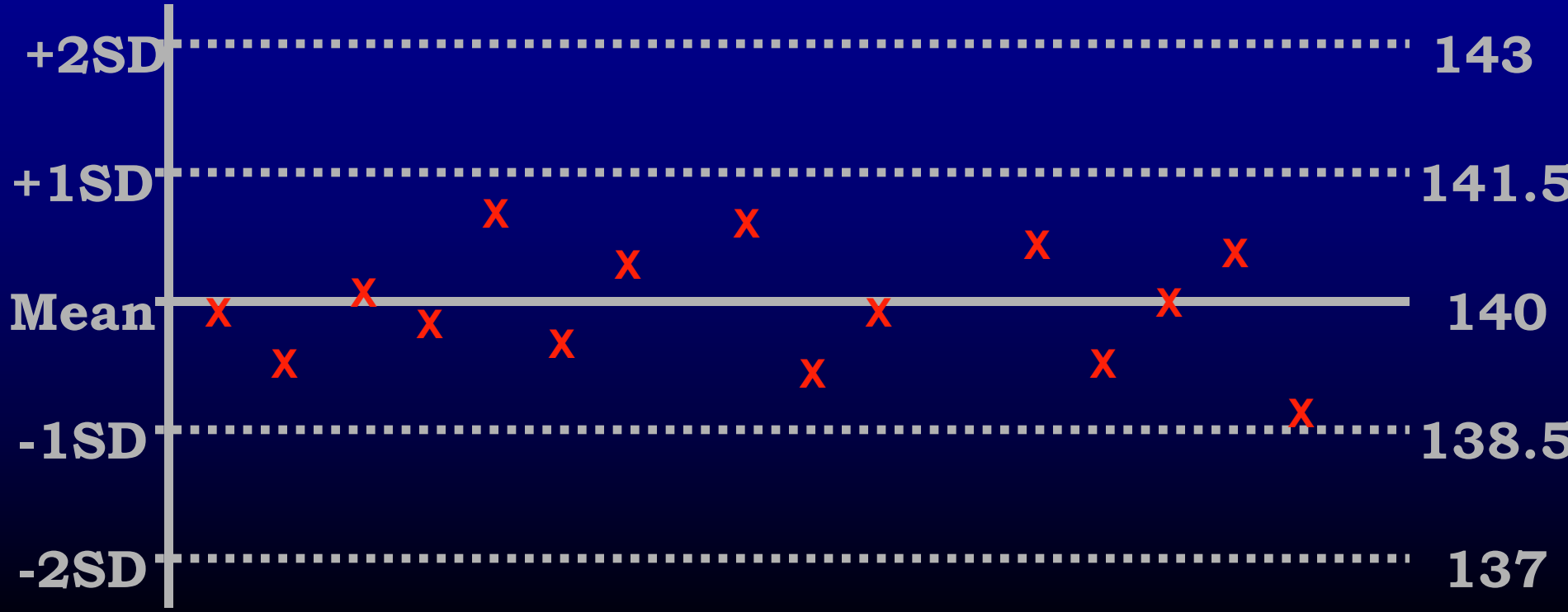
LEVEY

JENNING

(L.J Chart



PERFECT LJ CHART

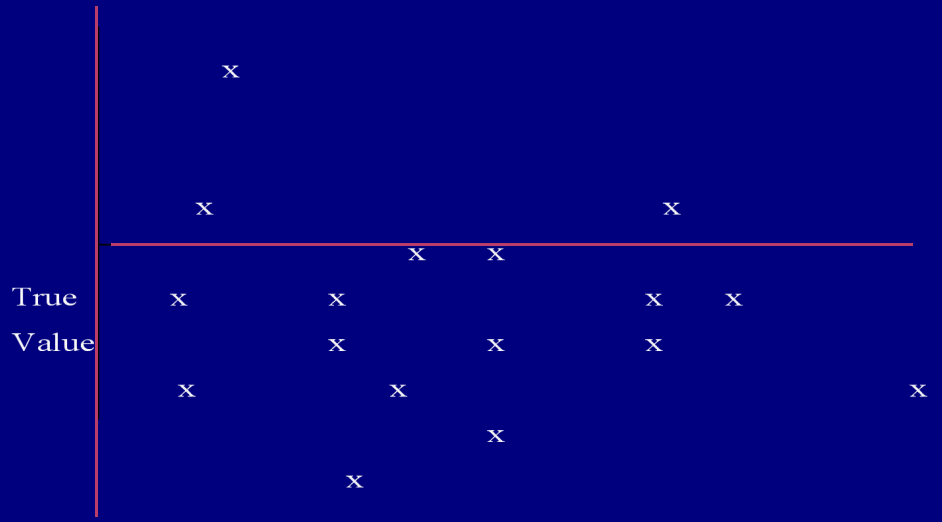


Causes for IQC out-of-control

Types of errors

- **Random errors**
- **Systematic errors**

A- RANDOM ERROR



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Errors that Occur in the Lab :

A- Random errors :

1 - misreading of the colorimeter
Incorrect reading of Std curve/ wrong std curve

2 - Transcriptional error

3- Incorrect placing of decimal point

4- Random Air bubble.

5 - Incorrect reconstitution of QC

6. Calculation error

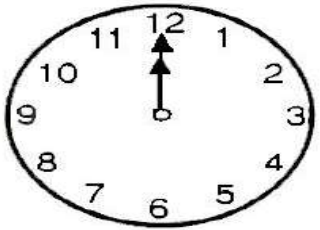
a - incorrect results for dilution , wrong fa

b - calculates results mentally

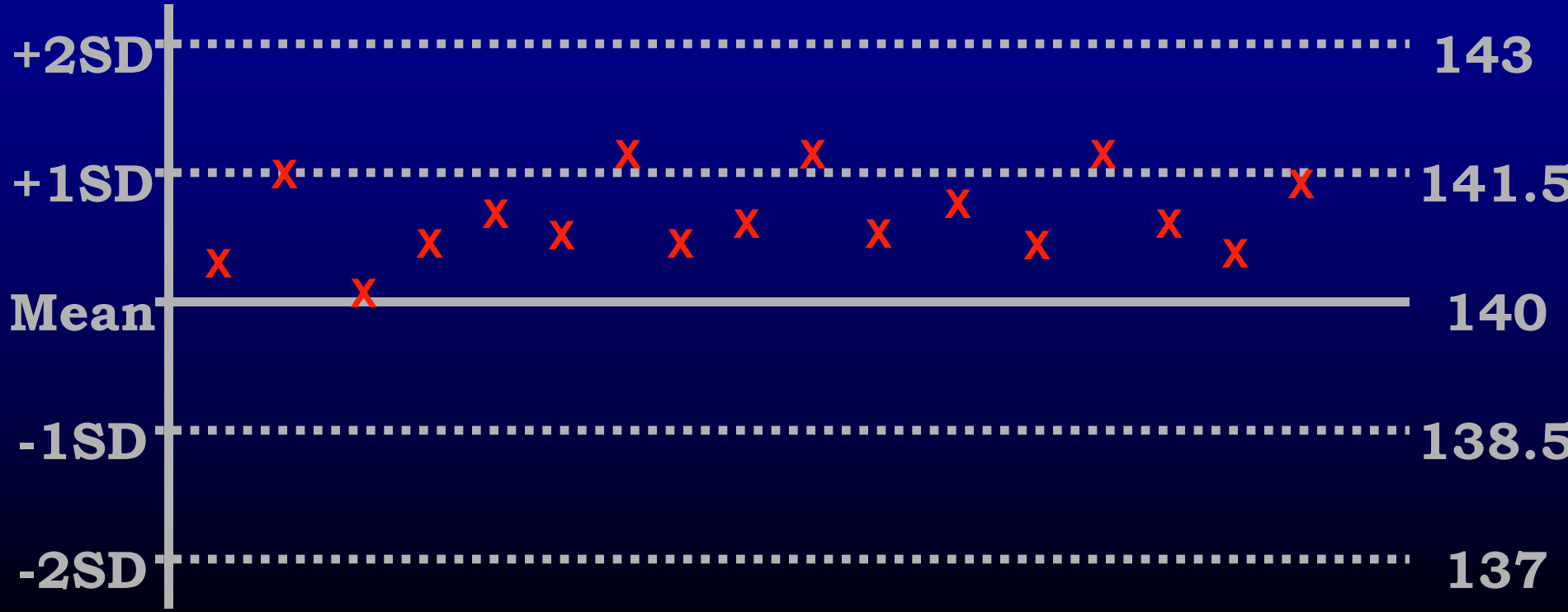
7 -Power supply

8- Operator technique

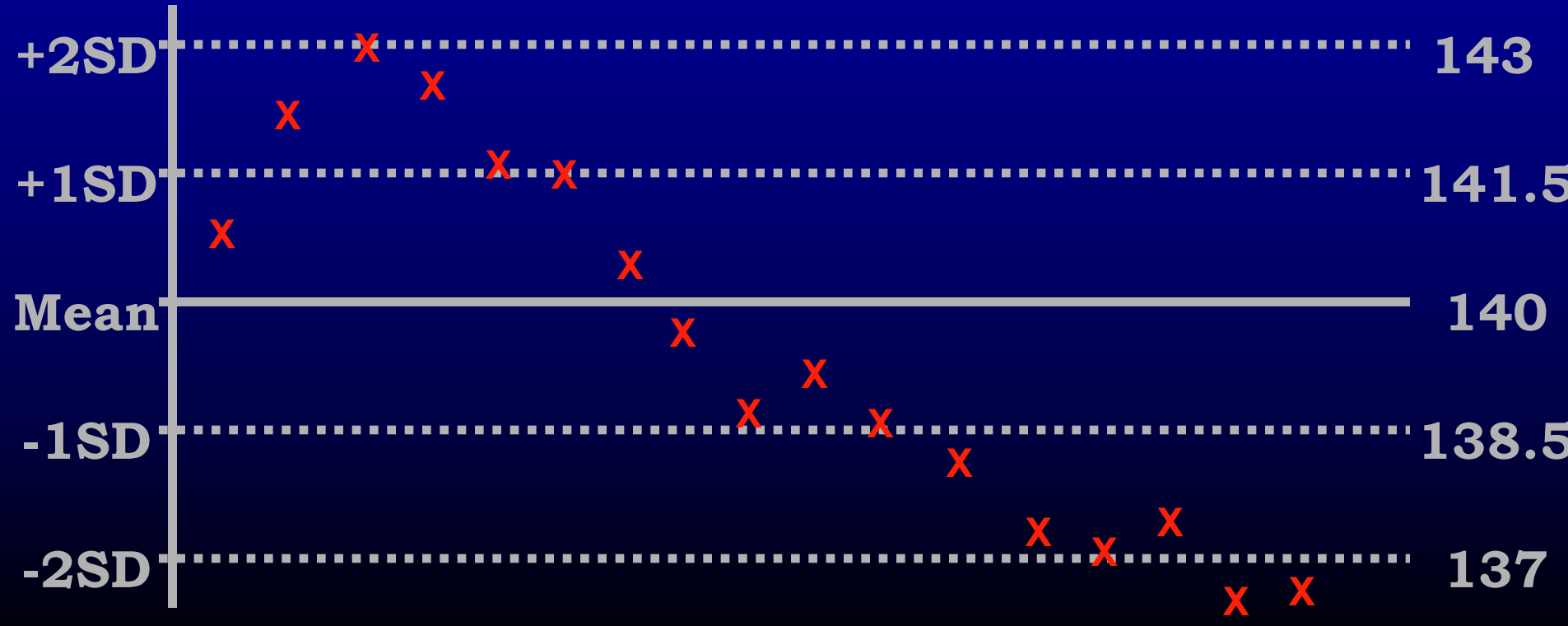
9- Noon / 4 pm clock syndrome



Systematic Error - + ve Bias



Systematic error – trend



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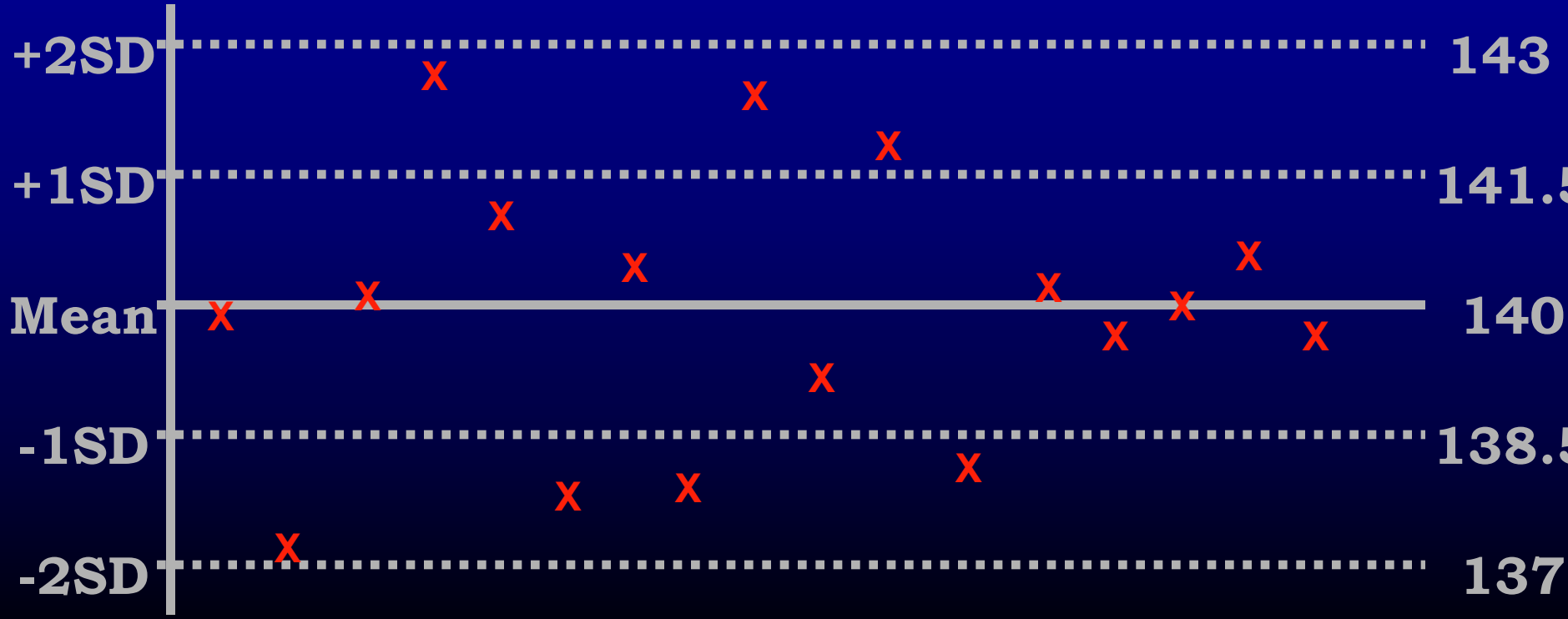
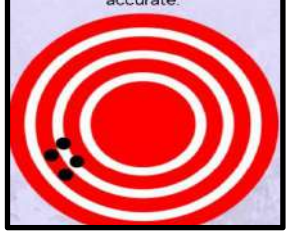

+2SD
+1SD
Mean
-1SD
-2SD
143
141.5
140
138.5
137

2- Consistent or systematic error

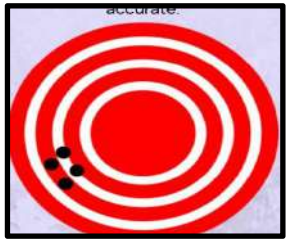


1-Failure to adhere strictly to the recommended procedure

2 - Use of incorrectly prepared standard or reagent.
uncalibrated cuvettes , wrong wavelength, wrong pipette, non- reagent grade water

3-Dirty filter wheel / failing light source
4-Incorrect handling of QC material/ calibrator
5-Improper temperature & humidity in the testing area

2-Consistent or systematic error



8- Dist. Water instead of buffer

9- Ph meter standardized with wrong buffer.

10- Contaminated and outdated reagent / substrate / kits/standard/control

11- Equipment problems .

Remedial Actions

1. Reanalyse the same control immediately / fresh vial of control
2. Repeat the test using new control from different lot
3. Check the reagent system
4. Perform maintenance and rerun the control
5. Recalibrate (only if necessary) and rerun the con

Monitoring accuracy and precision of tests

- Quality of distilled water
- Calibration of testing instruments, balances, centrifuges, semiautomatic pipettes,
- regular servicing and maintaining of equipment
- Use calibrators, QC in each procedure daily.

Two important points that should be considered in selecting the IQC are:

[1] The QC material used must cover the analvtical conc : normal/abnormal controls,

[2] Controls produced by the manufacturer of the test or analyzer should not be used.

WHAT IS EQA

Process that assesses

laboratories analytical and interpretative skills compared to other laboratories by testing the accuracy and quality of their results.

Aim : Educational

a) External verification of quality of service

b) Improve quality of care

Not

To judge centres

The Role of External Quality Assurance

- Confirm assay performance
- Identify poor assay performance
  - Confirm correction of poor performance
- Main Issues
  - Accuracy (precision + bias)
  - Precision

➢A technique to challenge a laboratory's internal QC methods and procedure

4 –A 's

- ✓ 1) Acceptable
- ✓ 2) Accessible
- ✓ 3) Affordable
- ✓ 4) Appropriate

Principles of EQA

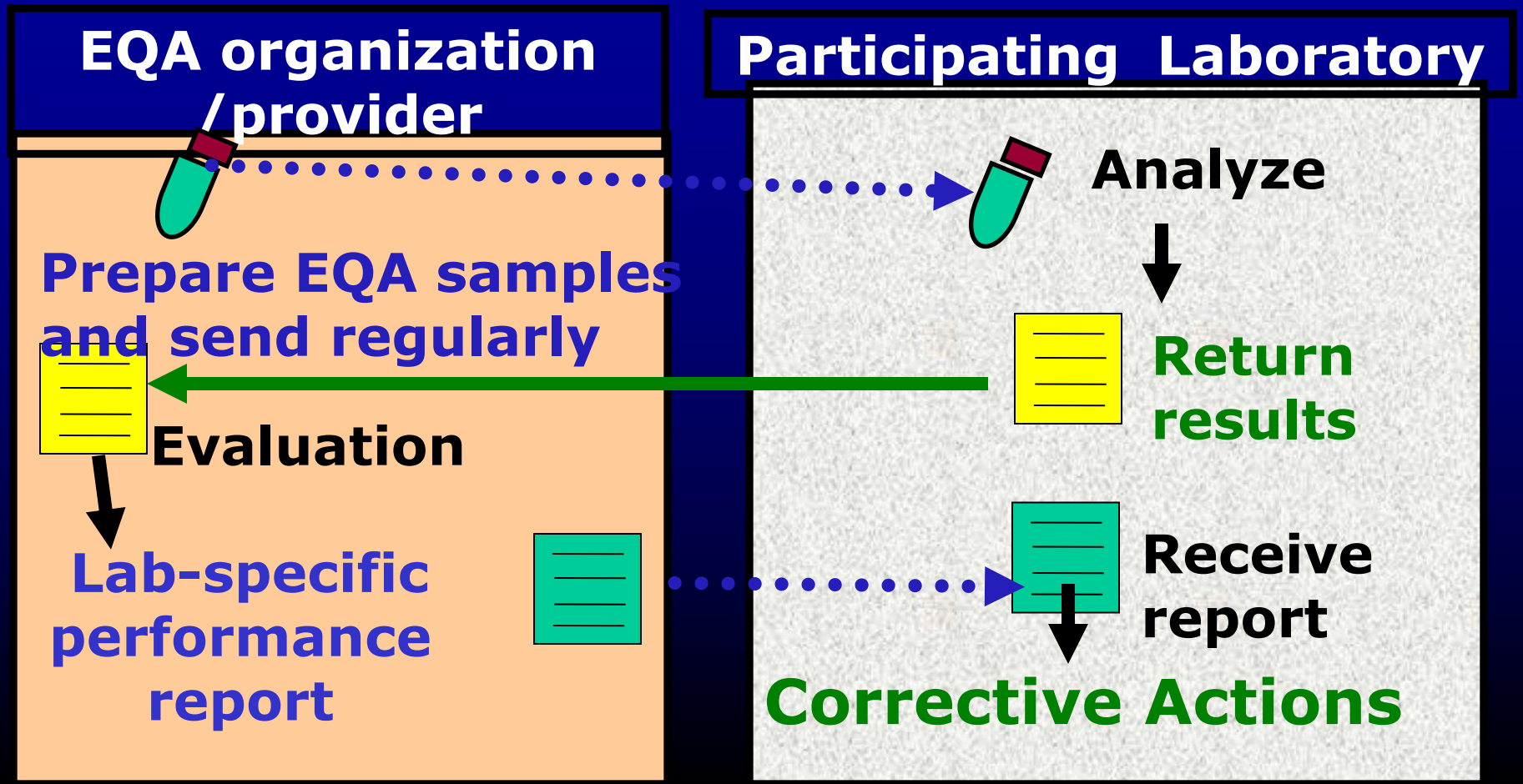
- **Same samples** sent to all participating laboratories

- Assessed for **- analytical accuracy**
  - clerical accuracy of the rep
  - interpretation of the result
- Continual **performance monitoring**
- Provides **feedback** on any potential issues

Principles of EQA

- Identifies imperfect practice and improves Quality
- Investigating factors affecting Quality eg Interferences , Calib errors , etc.
- Allows comparisons , evaluation of methods / Reagents / Instruments

EQAS- Provider & Lab



Lack of consistency between different methods and procedures are due to :

Different

- **Analytical Specificity**
- **Analytical Sensitivity**
- **Calibration**

Causes for failures in EQAS

1.Incorrect Handling of QC Materials

a) Incorrect Reconstitution - 2ml /5ml,

b) Incorrect Storage Conditions

c) Evaporation of Prepared QC Materials

2. Incorrect Procedure

a) Improper Mixing, b) Incorrect Calculation

c) Incorrect Unit (T3- ng/dl / ng/ml)

Causes for failures in EQAS

3.Technical Problem with a Method

a) Calibration Problem

b) Inadequate Maintenance

3) Deterioration of Reagents , expired kit

4. Choosing wrong method /Instrument group
5. Wrong month sample used for analysis.
6. Results not uploaded before due date

VARIABLES THAT MAY CAUSE IMPRECISION

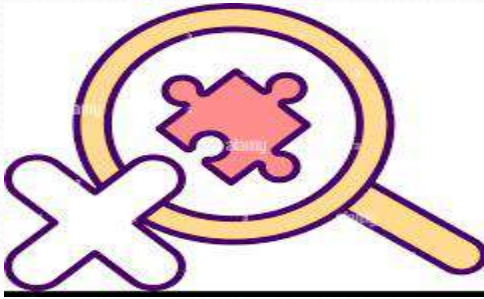
- Un calibrated pipettes

- Quality of deionized water

- SOP not followed properly

- Transcription errors (sodium/ potassium or protein/ albumin result)

TROUBLE SHOOTING IN EQAS



- Check the method selected
- Check the label on the vial
- Check the unit of reporting / conversion
- Check for transcriptional error
- Check the volume – reconstitution error

- **Relook at the IQC data on the day EQAS sample was analysed**

- **Recheck if any calibration , change of reagent was done on that day**

- **Look for trends – bias**

EQA Should Lead to Actions

EQAS BENEFITS

EQA is not for policing, it is a **friendly hand shake**

EQAS is not a substitute to IQC but an **additional support**

Allows **switching** over to better methods.

Allows **comparison** of performance and results

EQA Benefits

- Serves as an early **warning-system** for problem (Identifies systematic kit problems)
- Provides objective **evidence of laboratory quality**
- Identifies **training needs**

Participating lab's responsibility

- chose the right Scheme for your needs
- analyze EQA samples in right time
- monitor and maintain records
- investigate deficiencies
- manage corrective action efforts
- communicate outcomes within lab

Participation in EQAS gives the lab personnel a chance to say with pride that we are a profession willing to examine ourselves and constantly strive for improvement in health care industry.

Major Challenges :

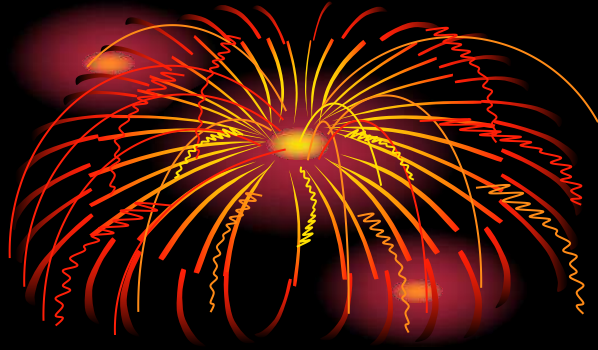
1- Achieving

2- Maintaining

3-Improving Accuracy

4-Timeliness

5-Reliability



THE TWELVE

QUALITY ESSENTIALS

1 ORGANISATION

Vision ,Commitment

Team building

Motivation skills

Good Communication

2 PERSONNEL

Recruitment , Training ,

Competency assessment

Continuing Education

Performance Appraisal

Personal records

3 EQUIPMENT

Right selection,

Performance evaluation

Maintenance , trouble shooting

Frequent service

4 REAGENT INVENTORY

Good quality reagents

Appropriate cost

Proper storage

Expired kits discarded

5 PROCESS CONTROL

Sample management

Lab handbook :
Collection, retention , disposal.

6 DOCUMENTS AND RECORDS

SOP's , Policies : defined by Laboratory

Maintenance of Records

7 Information and Management

- Patient & Sample identifiers (barcode system)
- Computer /electronic based
- Manual / paper based (data entry , legibility,

8 Occurrence Management

Occurrence

- Any event with negative impact

Sources of occurrences

- Unclear responsibilities
- SOP not followed
- Pre and Post examination error

9 ASSESSSMENT

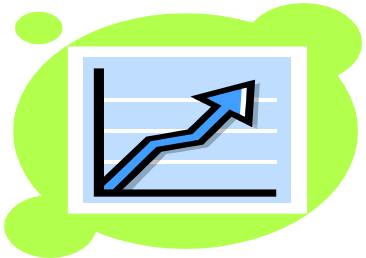
- **Audits** :External /Internal
- Systematic , independent process to determine if required criteria are met.

Types of EQA:

PT/ Retesting

10 Process Improvement

- Constant improvement
- Plan –Do –Check- Act
- Commitment , planning, leadership, Participation



11 Facilities and safety

Identification of risks

PPE

Lab safety program

12 Customer Service

Lab customers :
Physicians , Patient

- Feed back surveys :
- From clinicians

Keys to successful quality control

- Adequately trained, interested and committed staff.
- Common-sense use of practical procedures.
- Willingness to admit and rectify mistakes.
- Effective communication.
- Continuing lab education, Regular Audit

“ It is not because things are difficult that we do not dare, it is because we do not dare that they are difficult”

Lucio Anneo Seneca
Roman philosopher

Team Concept

Together
Everyone
Achieve
More


QUALITY
IT'S
EVERYONE'S
RESPONSIBLITY
THANK YOU!
fppt.com