Internal Quality Control

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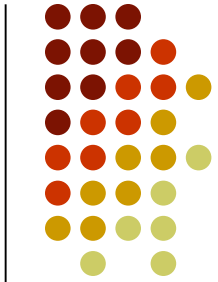
Aim of Quality control

- **“The aim of quality control is simply to ensure that the results generated by the laboratory are correct.”**
- **Quality assurance is mainly concerned that the right test is carried out from the right specimen and gives the right result and right interpretation, which must be delivered to the right person at the right time”**

Factors Affecting The Quality of Results



- The educational background and training of the laboratory personnel
- The condition of the specimens
- Environment (temp & humidity) of laboratory
- The controls used in the test runs
- Reagents
- Equipment
- The transcription of results
- The reporting of results

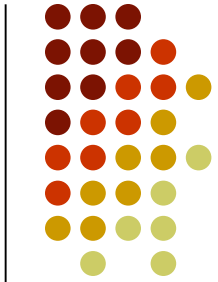
How to choose a QC pool

- A q.c. material must be closely matches the specimens.
- Mainly three type of QC material available
  1. Commercial lyophilized pool material
  2. Commercial stabilized liquid pools
  3. Frozen patient pool specimens

Commercial lyophilized pool material

- Less turbidity
- More stability than all other type
- Smaller imprecision
- Costly than all others
- In our laboratory we use randox lyophilized pool meterial

Commercial stabilized liquid pools



- In Stability=
  - Lypholized >Liquid pool > patient pool

Frozen patient pool specimens

- Patient serum is more frequently used than plasma because it does not contain any preservative or precipitating material.
- Dangerous to use
- Pre-tested for HIV,HBsAg
- Less stable
- Ethyle glycol and yeast tuted

Care taken during preparing QC

- During reconstitution, do not mix too quickly or too vigorously
  - It may interfere with the solubilization of the lyophilized material
  - Denature its protein constituents
- If frozen liquid – mix the sample six times by inversion
  - Because protein & other compounds became concentrated at bottom of vial during freezing

This are main two type of Quality control

1. **External Quality Control**
2. **Internal Quality Control**

Internal Quality Control Specimens

IQC specimens comprises values within each clinically significant ranges

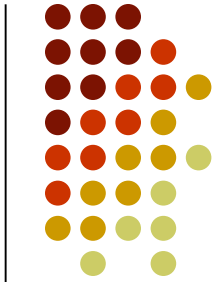
1. **Higher value**
2. **Normal value**
3. **Lower value**

In our laboratory we use QC5 as lower value and QC8 as higher value

Standard deviation [SD]

- Standard deviation may also be used to monitor on-going day-to-day performance.
- Standard deviation is a statistic that quantifies how close numerical values (i.e., QC values) are in relation to each other.
- Imprecision, is used to express how far apart numerical values are from each other.
- Standard deviation is calculated for control products from the same data used to calculate the mean. It provides the laboratory an estimate of test consistency at specific concentrations.

Coefficient of variation (CV)



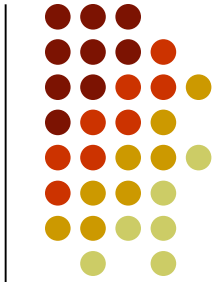
- The coefficient of variation(CV) is the ratio of the standard deviation to the mean and is expressed as a percentage.

CV=mean/SD*100

Coefficient of variation ratio(CVR)

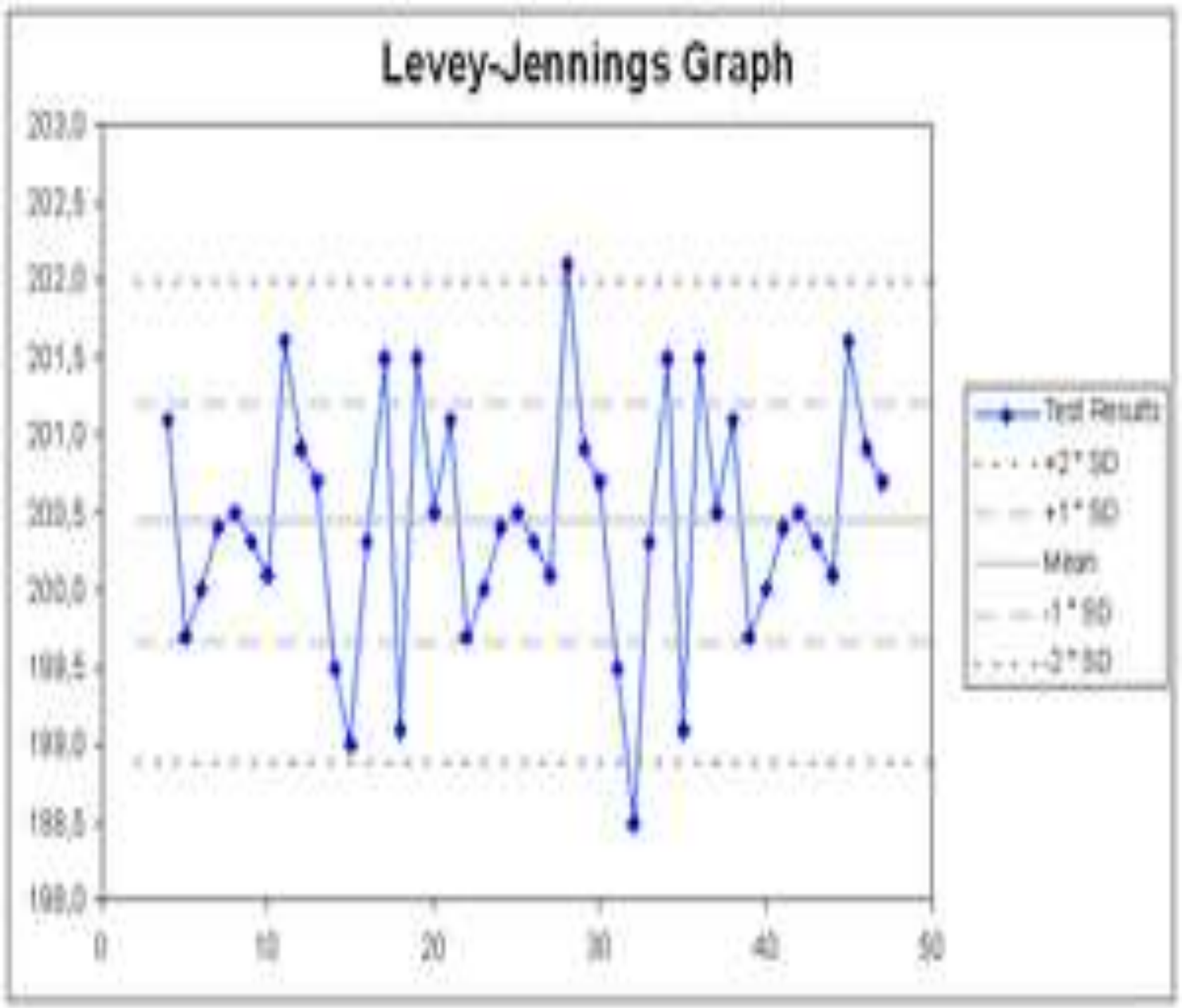
- A laboratory can determine whether the precision of a specific test is acceptable is to compare its precision to that of another laboratory performing the same test on the same instrument using the same reagents.

LEVEY-JENNING CHART

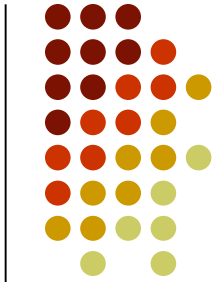


- A **Levey-Jennings chart** is a graph that Quality control data is plotted on to give a visual indication whether a laboratory test is working well.

- On the x-axis the date and time, or more usually the number of the control run, are plotted. A mark indicate how far off the actual result from the mean (which is the expected value for the control).


Levey-Jennings Graph
203,0
202,5
202,0
201,5
201,0
200,5
200,0
199,5
199,0
198,5
198,0
0
10
20
30
40
50
Test Results
+2* SD
+1* SD
Mean
-1* SD
-2* SD

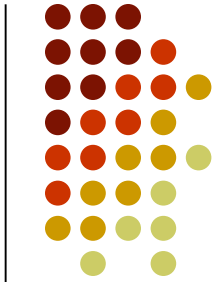
Levey-Jenning Control



A leavey - Jenning Control Chart depend on the use of IQC specimens and is developed in the following manner:-

- **Put up the IQC specimen for at least 20 or more assay runs and record down the value / O.D.**
- **Calculate the mean and standard deviations (S.D.)**
- **Make a plot with the assay run on the x-axis, and value / O.D. on the y axis.**
- **Draw the following lines across the y-axis: mean, -3, -2, -1, mean,1, 2, and 3 S.D.**
- **Plot the value / O.D. obtained for the IQC specimen for subsequent assay runs**
- **Major events such as changes in the batch no. of the IQC sera and instruments used should be recorded on the chart.**

Systemic error



- Systemic error is evidenced by a change in the mean of the control values.

- The change in the mean may be gradual and demonstrated as a trend in control values or it may be abrupt and demonstrated as a shift in control values.

Trend	Shift
A trend indicates a gradual loss of reliability in the test system	Shift in QC data represent a sudden and dramatic +VE or –VE change in test system performance.

Random error

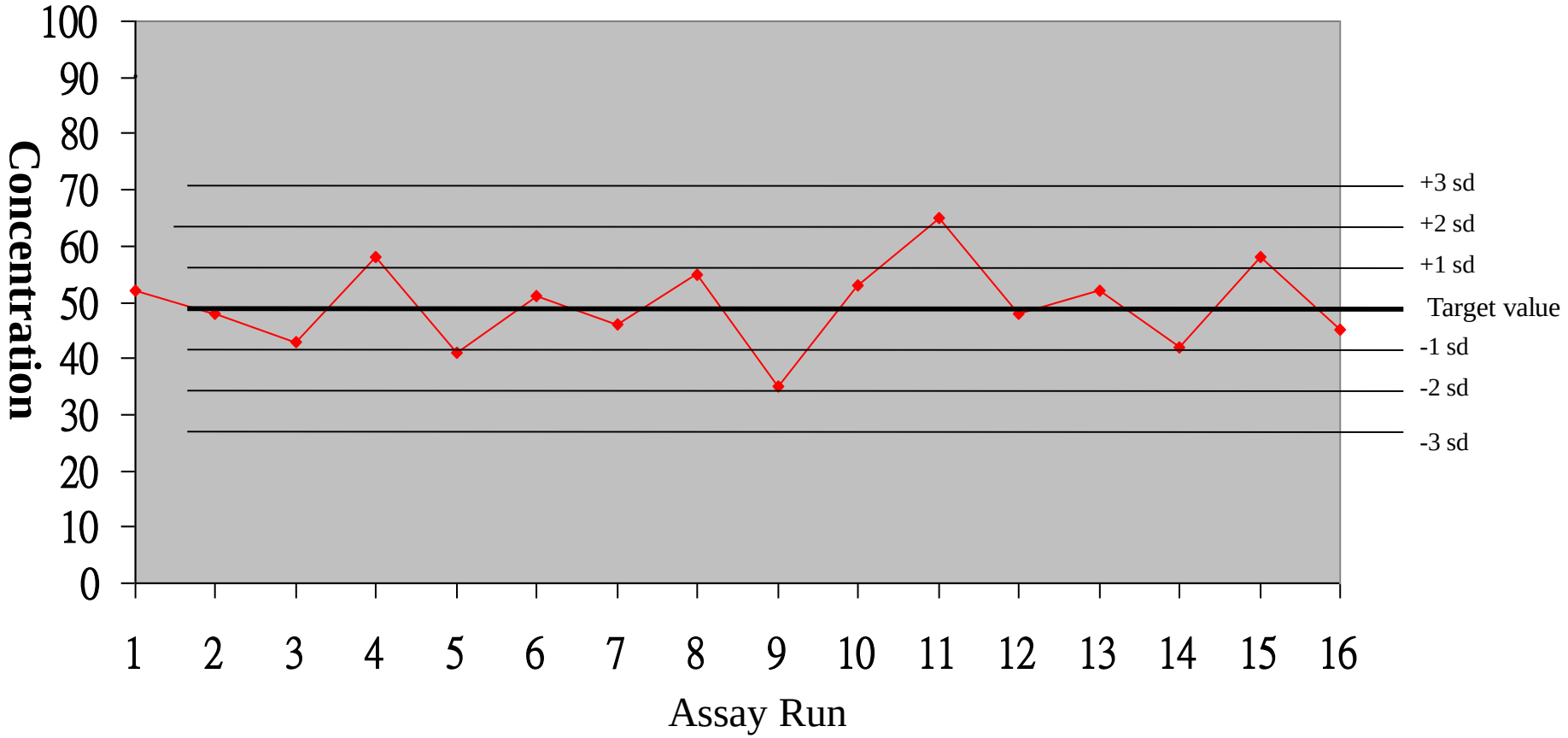
- Random error is any deviation away from an expected result.

- For QC results, any +VE or –VE deviation away from the calculated mean is defined as random error.

Westgard rules

- **Can be use to detect both random and systematic errors.**
- **There are six commonly used Westgard rules**
  - **three are warning rules**
  - **the other three mandatory rules.**

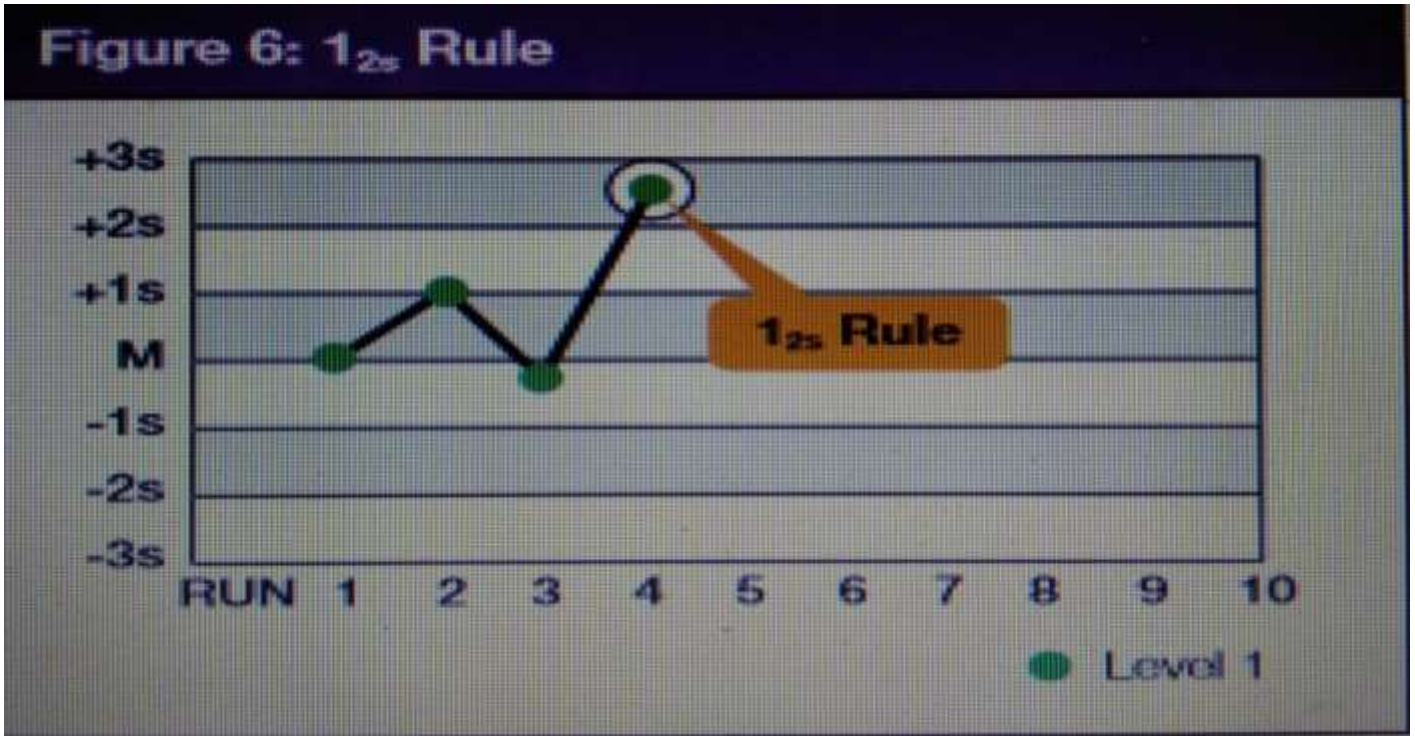
Levey-Jenning Chart



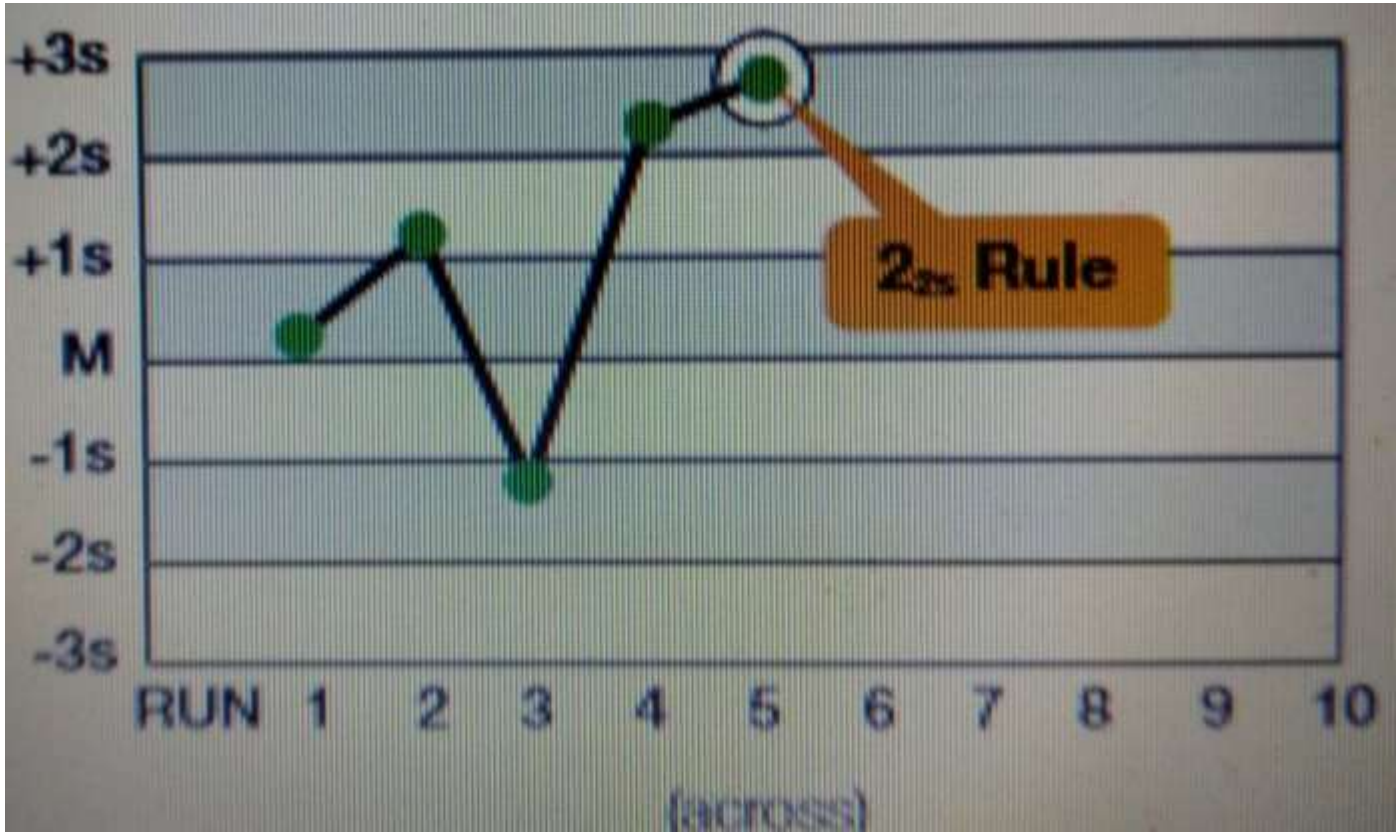
Target Value = 50 U/ml & S.D. = 10 U/ml

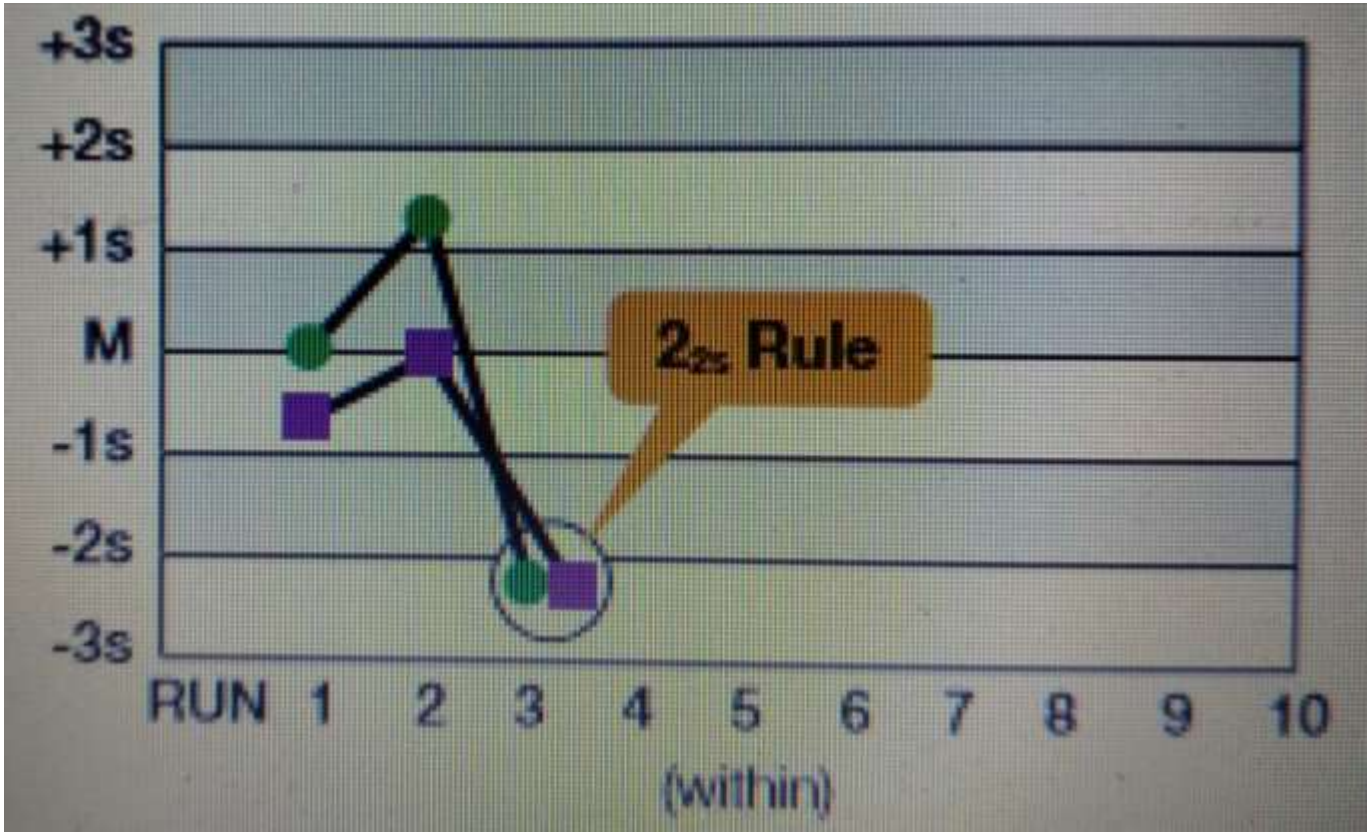
Warning rules

- **Warning 1_{2SD} : It is violated if the IQC value exceeds the mean by □2SD. It is an event likely to occur normally in less than 5% of cases.**

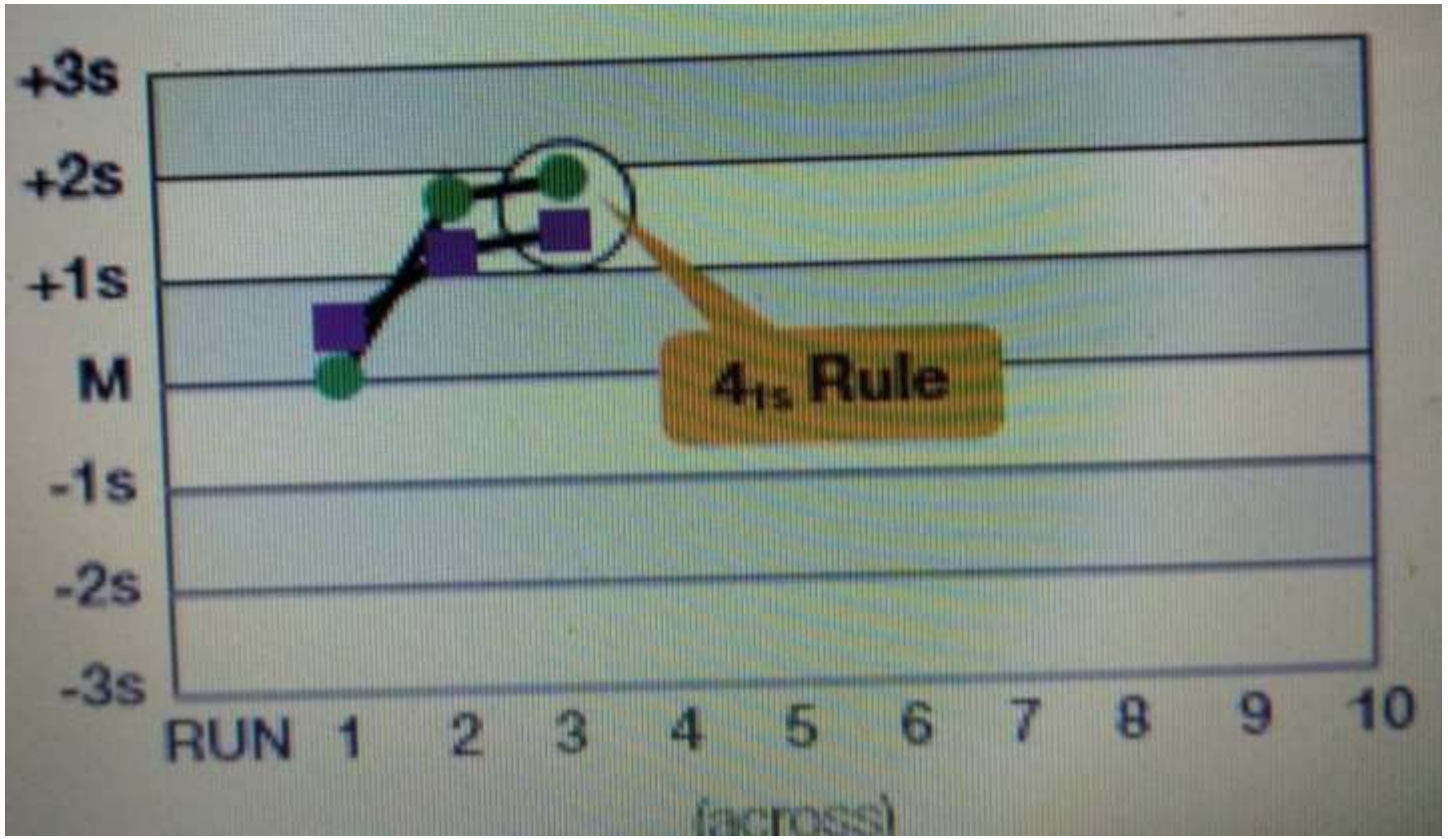


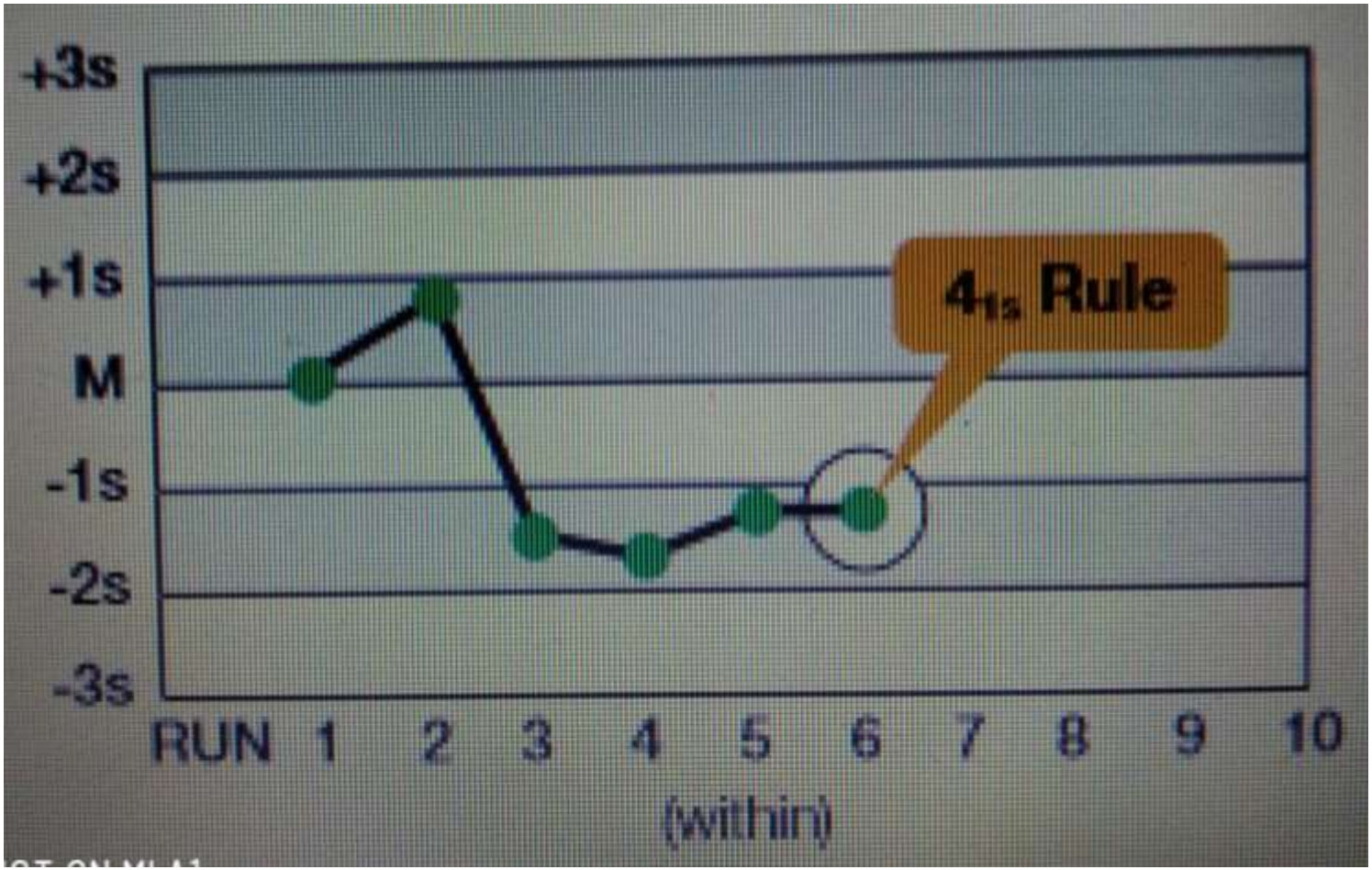
- **Warning 2_{2SD} : It detects systematic errors and is violated when two consecutive IQC values exceed the mean on the same side of the mean by □2SD.**




+3s
+2s
+1s
M
-1s
-2s
-3s
2zs Rule
RUN 1 2 3 4 5 6 7 8 9 10
(within)

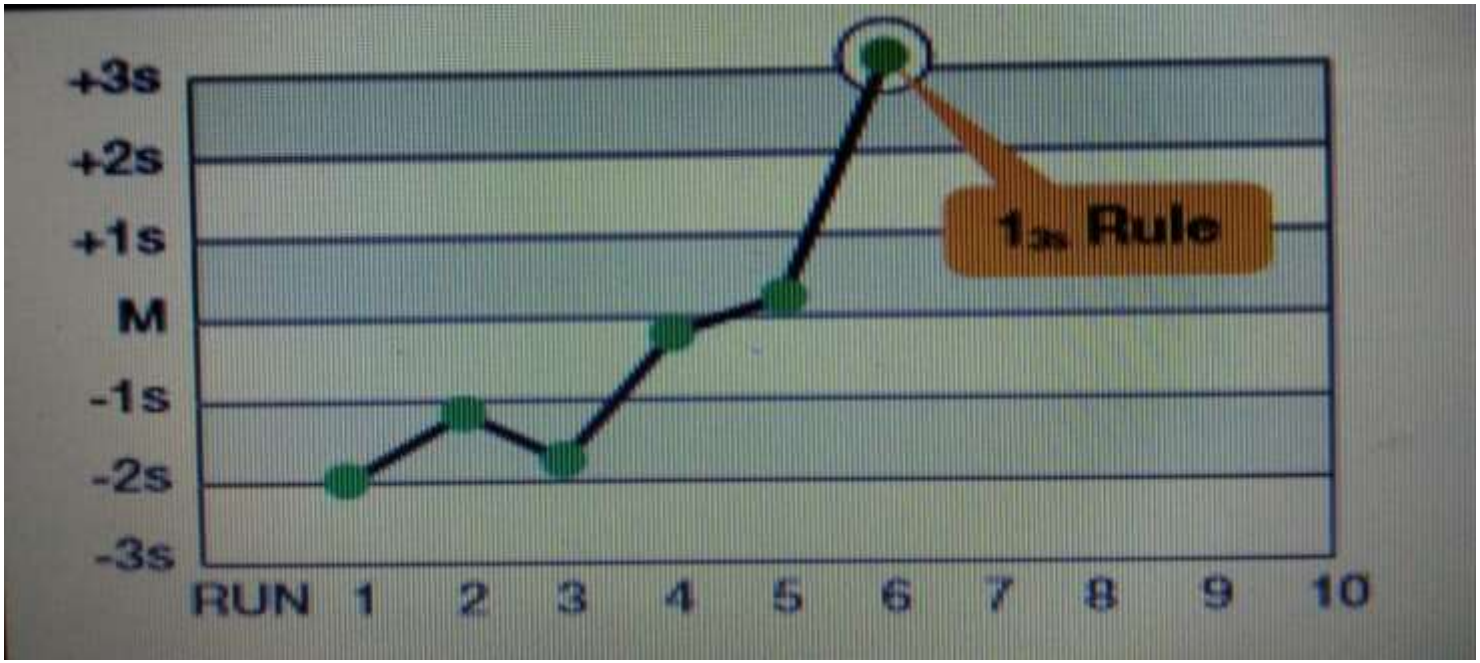
- **Warning 4_{1SD} : It is violated if four consecutive IQC values exceed the same limit (mean □ 1SD) and this may indicate the need to perform instrument maintenance or reagent calibration.**



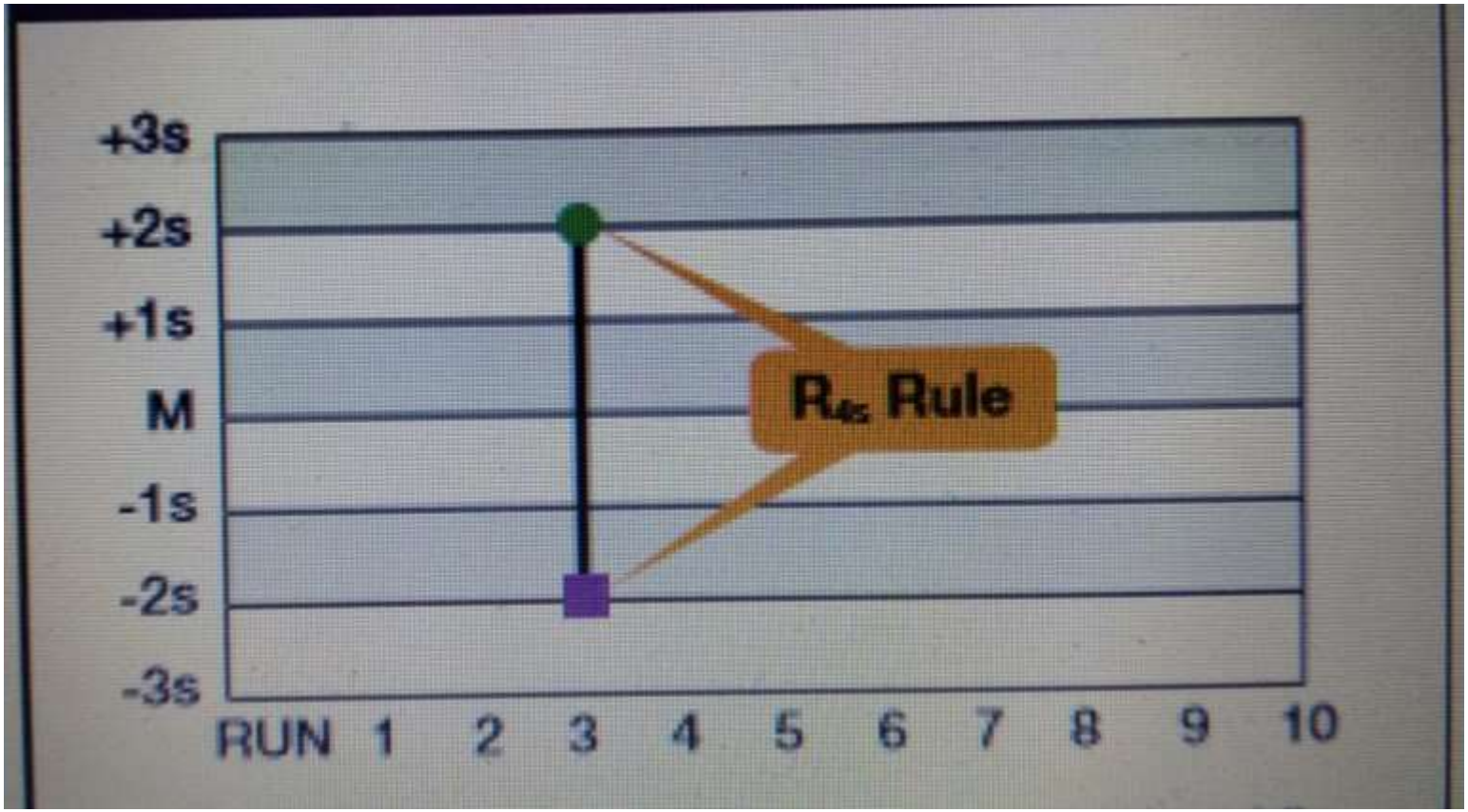

+3s
+2s
+1s
M
-1s
-2s
-3s
4₁s Rule
RUN 1 2 3 4 5 6 7 8 9 10
(within)

Mandatory rules

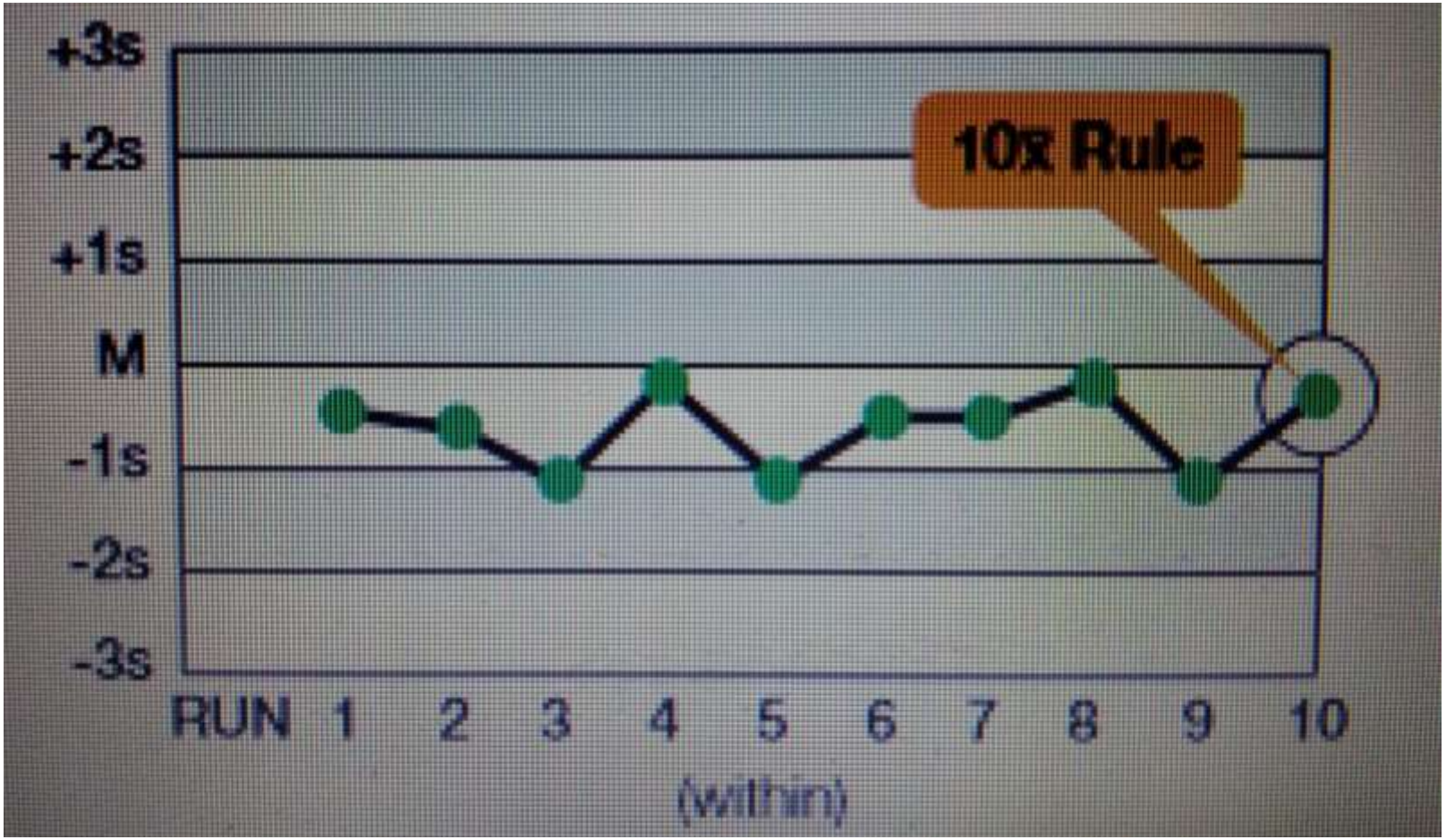
- **Mandatory 1_{3SD} : It is violated when the IQC value exceeds the mean by □3SD. The assay run is regarded as out of control.**



- **Mandatory R_{4SD} : It is only applied when the IQC is tested in duplicate. This rule is violated when the difference in SD between the duplicates exceeds 4SD.**



- **Mandatory 10x : This rule is violated when the last 10 consecutive IQC values are on the same side of the mean or target value.**



Another way to QC

- Using patient data in decision making
  - Most of the patient results fall on reference interval & few results are abnormal.
  - Deviation from usual pattern of result gives worning sign to testing person.

Action to resolve the analytic problem

- Repeat QC pool from fresh aliquots
- Reconstitute set of QC & repeat assay from it.
  - QC can be mishandled, resulting change in analyte concentrations because of enzyme denaturation or evaporation

Serum sample

- Look for clots, reagent levels , mechanical fault.
- Check Test parameter of analyte.
- Recalibrate the instrument for “out of control” analyte, then reassay all the controls.
- Install a new bottle or new lot number for the reagents, recalibrate and reassay QC.
- Perform periodic maintenance, recalibrate and reassay QC.

What is calibration?

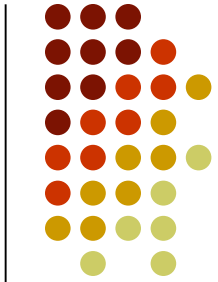
- Calibration is the comparison of a measurement device (an unknown) against an equal or better standard.
- A standard in a measurement is considered the reference; it is the one in the comparison taken to be the more correct of the two.
- Calibration finds out how far the unknown is from the standard.

Why calibrate?

- Calibration can be an insurance policy because out-of-tolerance (OOT) instruments may give false information leading to unreliable products.

- In addition, OOT conditions may cause good products to fail tests, which ultimately results in unnecessary rework costs and production delays.

Calibration quality management system



- ✓ Accredited calibration lab
- ✓ Comprehensive equipment list
- ✓ Calibrated and no calibration required items properly identified
- ✓ Documented calibration procedures
- ✓ Equipment custodianship
- ✓ Traceable assets
- ✓ Trained technicians

THANK YOU...