QUALITY CONTROL IN LABORATORY

WHAT IS QC ?

- QC is a technique that is used to detect & correct errors before they result in a defective product or service.

- It refers to the measures that must be included during each assay run to verify that the test is working properly.

- QC must be practical, achievable & affordable.

TERMINOLOGY

- PRECISION: This indicates how close test measurements to each other when the same test is run on the same sample repeatedly.

- Precision does not imply accuracy.

- ACCURACY: How close to the true value a measurement is.

- The closer to the actual value, the more accurate.

- **STANDARD:** This is a substance of constant composition of sufficient purity to be used for comparison purpose.

- **CONTROL:** This is a sample i.e. chemically & physically similar to the unknown specimen.

- **STANDARD DEVIATION:** This is a statistical expression of scatter or dispersion of values around a central average value.

Calculation of Standard Deviation

$$SD = \sqrt{\frac{\sum(x_n - x)^2}{n-1}}$$

Coefficient of Variation

- The Coefficient of Variation (CV) is the standard Deviation (SD) expressed as a percentage of the mean

  -Also known as Relative Standard deviation (RSD)

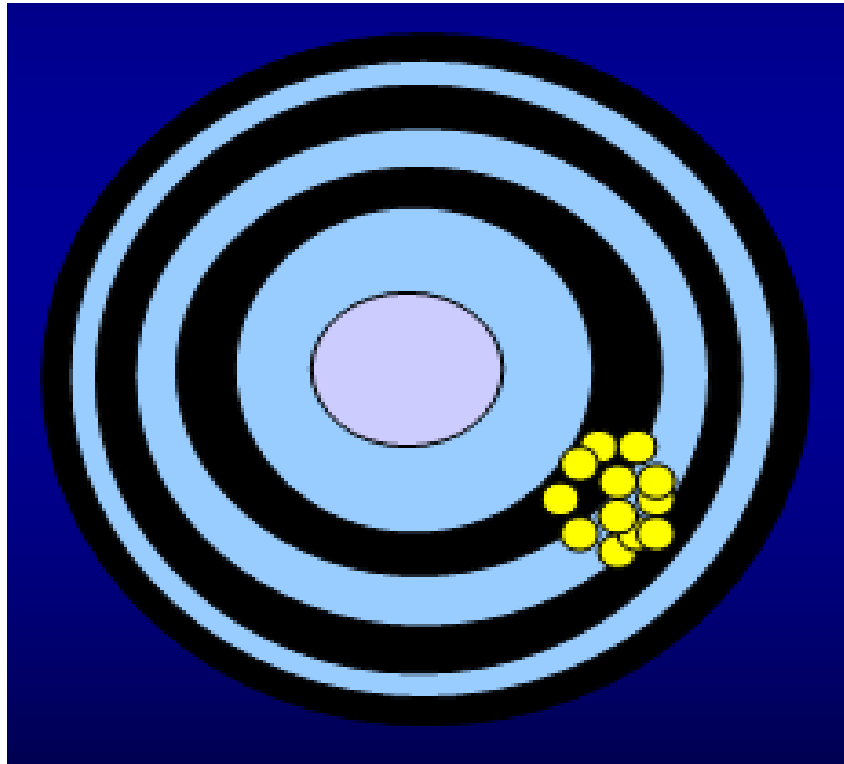- $CV \% = \dfrac{SD}{Mean} \times 100$

CALCULATION OF MEAN

Data set
(30.0, 32.0, 31.5, 33.5, 32.0, 33.0, 29.0, 29.5, 31.0,

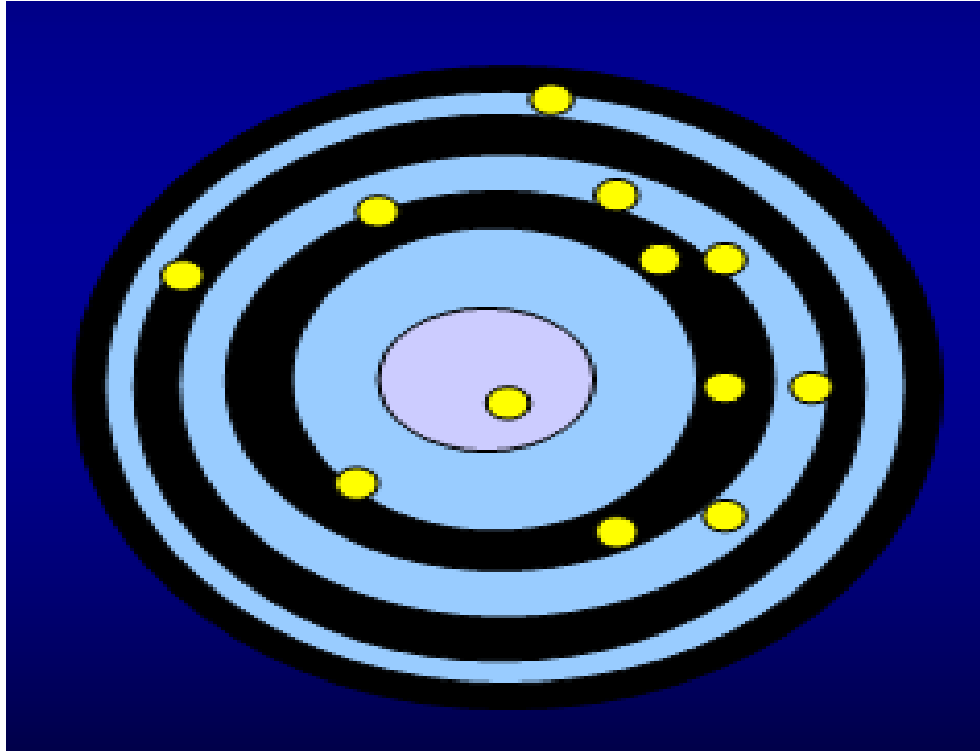32.5, 34.5, 33.5, 31.5, 30.5, 30.0, 34.0, 32.0, 32.0,
35.0, 32.5.) mg/dL

The sum of the values $(X_1 + X_2 + X_3 \dots X_{20})$ divided by the number (n) of observations

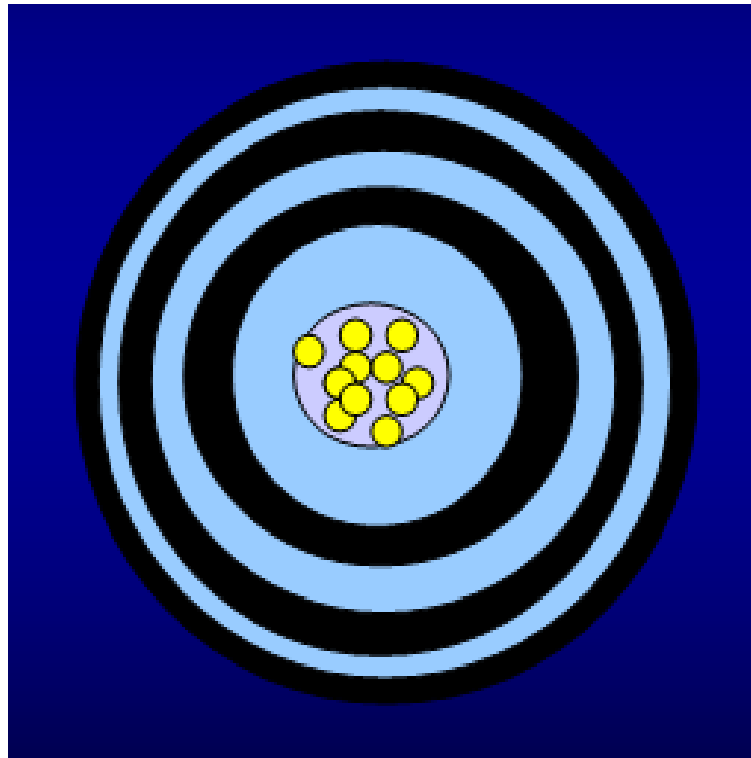The mean of these 20 observations is $(639.5 \div 20)$ = 32.0 mg/dL

PRECISE & INACCURATE

IMPRECISE & INACCURATE

PRECISE & ACCURATE

L. J. CHART

- L-J chart is a graph that quality control data is plotted on to give a visual indication whether a laboratory test is working well.

- It is named after S.LEVEY & E.R.JENNINGS in 1950.

How to create L-J chart?

By using simple statistics

- Mean ⟶ **TARGET**

- Standard Deviation (SD)

- ± 1SD
- ± 2SD
- ± 3SD

⟶ **CONTROL LIMITS**

- Coefficient of Variation (CV %)

CONTROL LIMITS

How to calculate +1 SD, +2 SD, +3 SD & -1 SD, -2 SD, -3 SD

Mean + (1 x SD) =   + 1SD

Mean + (2 x SD) =   + 2SD

Mean + (3 x SD) =   + 3SD

Mean - (1 x SD)   =   - 1SD

Mean - (2 x SD)   =   - 2SD

Mean - (3 x SD)   =   - 3SD

Glucose (Jan 2011) with Manufacturer Mean & Ranges (SD – 21 ; CV- 7.6%)
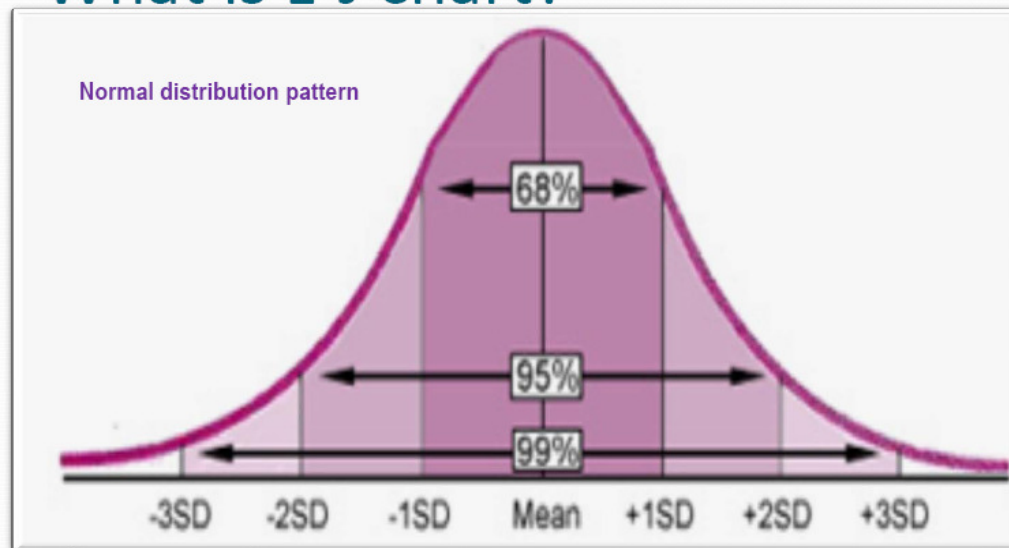
Level 3
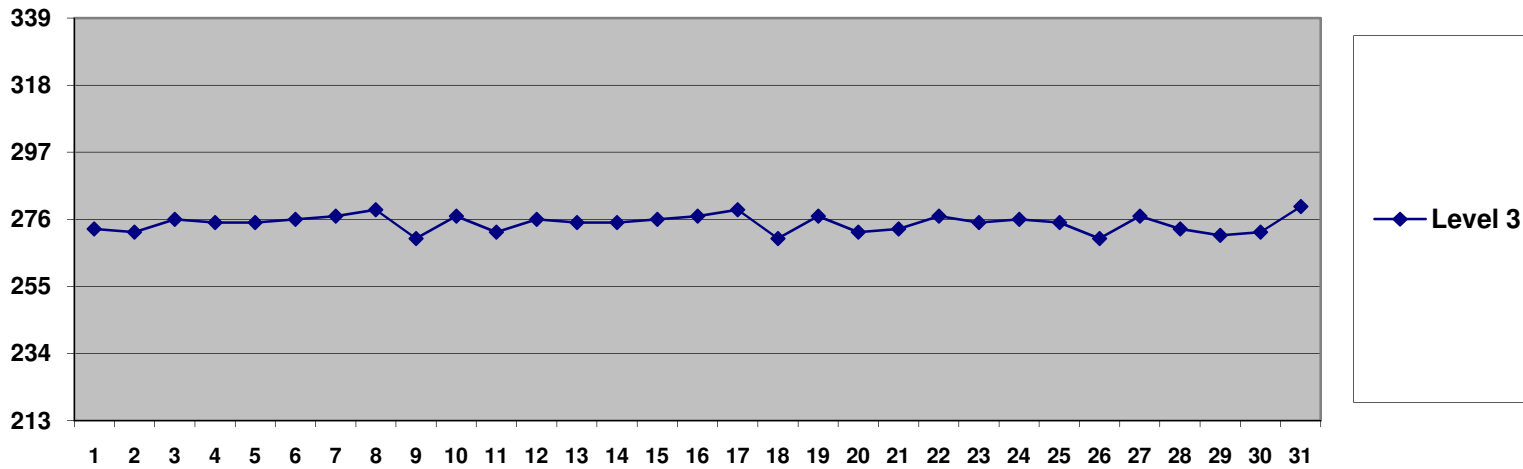
Glucose (Jan 2011) with Lab defined Mean & Ranges(SD – 2.73; CV- 0.99%)

Level 3
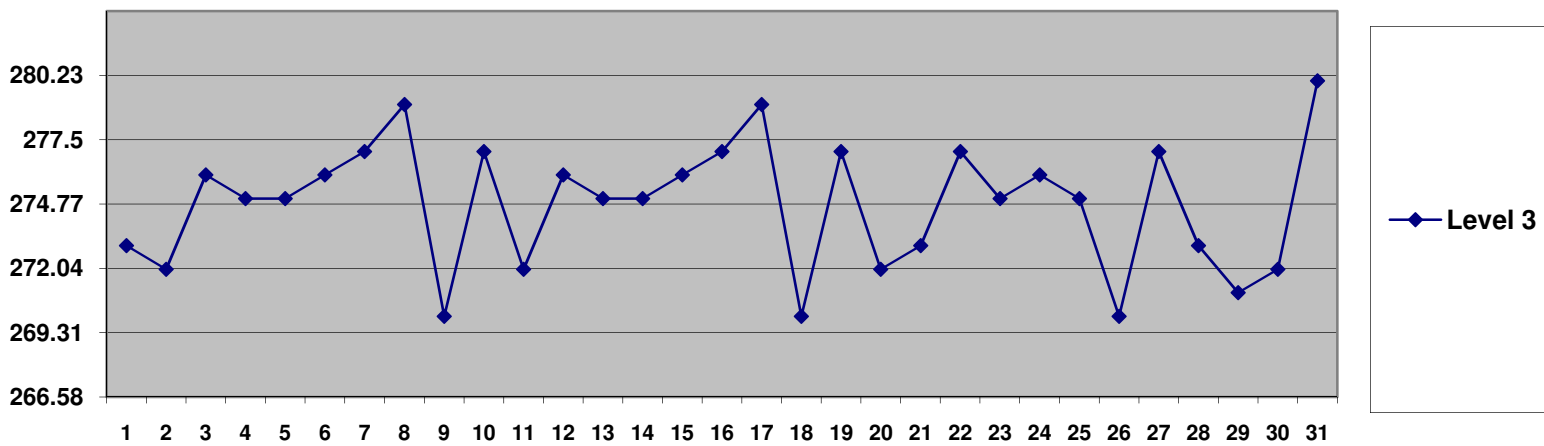
Normal Distribution

- All values are symmetrically distributed around the mean

- Characteristic "bell-shaped" curve

- Assumed for all quality control statistics

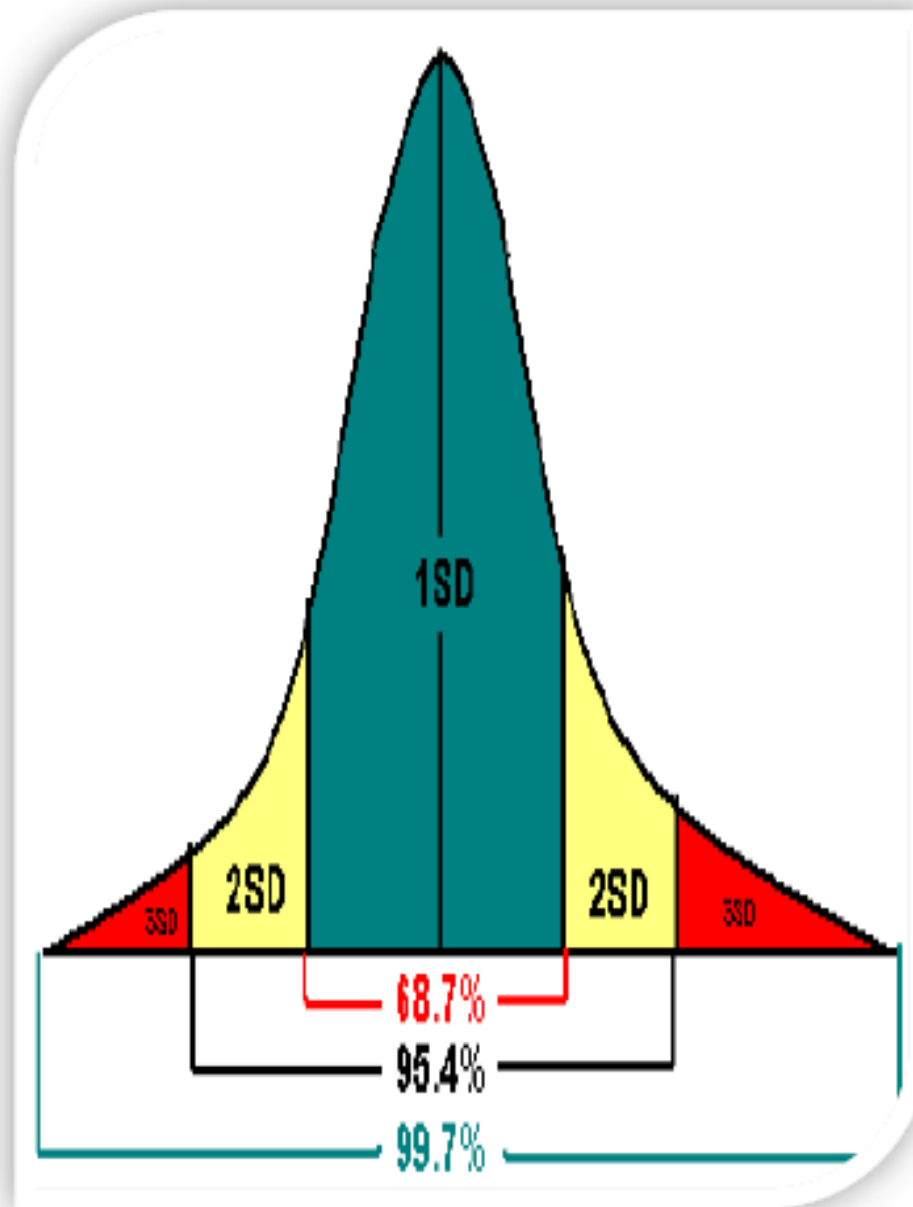# Normal Distribution Curve
or
Gaussian curve

Describes events or data that occur symmetrically about the mean.

Out of 100 events

68.7 will fall within   1 SD

95.4 will fall within   2 SD

99.7 will fall within   3 SD

INTERNAL QUALITY CONTROL

- Use of standard glassware , reagent , equipment

- Well trained staff

- Selection of accurate & precise method.

- At least one primary std. is included with each batch of unknown specimen analysis.

- Occasionally a different primary std . of higher concentration is included to check the reliability of routine primary std.

- The batch result are accepted if the values of control sera are within first SD.

Types of Errors

- <u>Intrinsic</u> : due to an imprecise & inaccurate method.

- <u>Systemic</u> : all high values , all low values.

- <u>Random</u> : technical errors.

- Intrinsic errors can be eliminated by
    A) selecting precise & accurate method.
    B) by using fresh batches of reagents.

- systemic errors can be eliminated by using diff. concentration of primary std. & analyzing control serum.

- Technical with a proper analytical application can be correct random errors.
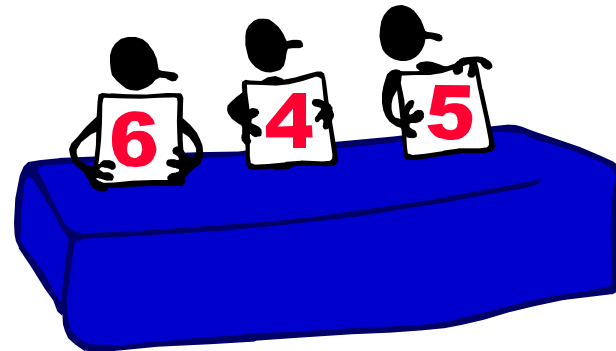
Systematic vs. Random Errors

Systematic Error

Avoidable error due to controllable variables in a measurement.

Random Errors

Unavoidable errors that are always present in any measurement. Impossible to eliminate

PREVENTIVE PHASE

- Collection of specimen

- Separation of serum

- Specimen analysis

- Calculation of test values etc..

RETROSPECTIVE PHASE

- Optimum condition variance

- Routine condition variance

OPTIMUM CONDITION VARIANCE

- Refers to the results obtained under optimum conditions i.e. by using

   i)freshly prepared reagents

   ii)by using standardized glassware

ROUTINE CONDITIONS VARIANCE

- Refers to the results obtained by using routine requirements i.e. by using routinely stored reagents and glassware in regular use.

WESTGARD RULES

- 1-2S

- 1-3S

- 2-2S

- R-4S

- 4-1S

- 10X

- Multi control QC rules (WESTGARD RULES) given by Dr. James Westgard of the University of Wisconsin in an article in 1981 on laboratory quality control that set the basis for evaluating analytical run quality for medical laboratories.

- The Westgard system -based on the principles of statistical process control used in manufacturing nationwide since the 1950s

- Six basic rules in the Westgard scheme: 1-3s, 2-2s, R-4s, 1-2s, 4-1s, and 10x. These rules are used individually or in combination (multi-rule) to evaluate the quality of analytical runs.

- Detect random or systematic errors

- **Warning 1$_{2SD}$ or 1-2s:**
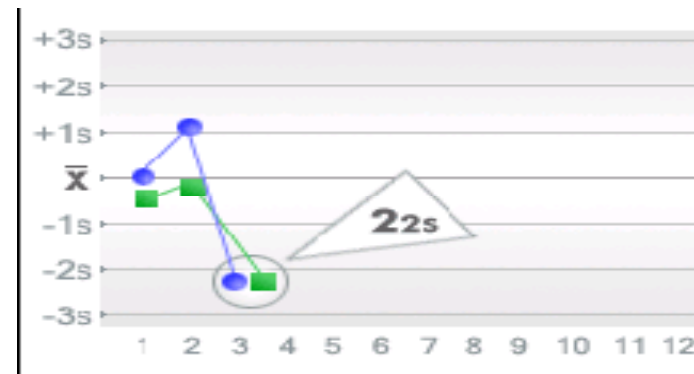It is violated if the single IQC
value exceeds the mean by ± 2SD.
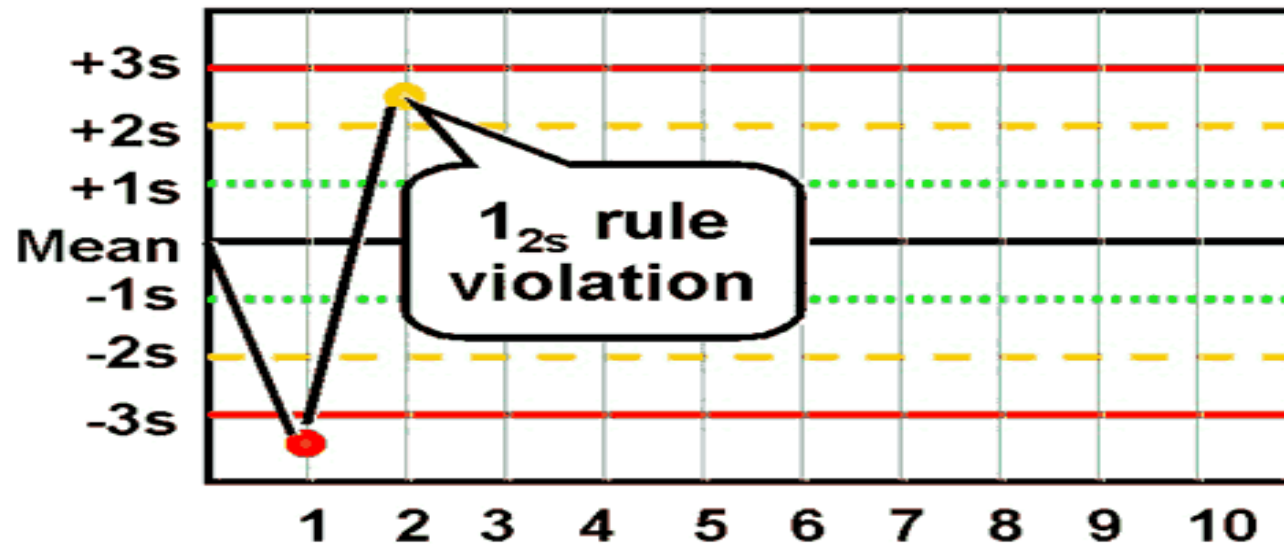
- **Rejection 2_{2SD} or 2-2s:**

- This rule detects systematic error and is applied within and across runs.
- It is violated within the run when two consecutive control values exceed the "same" (mean + 2s or mean - 2s) limit.
- The rule is violated across runs when the previous value for a particular control level exceeds the "same"
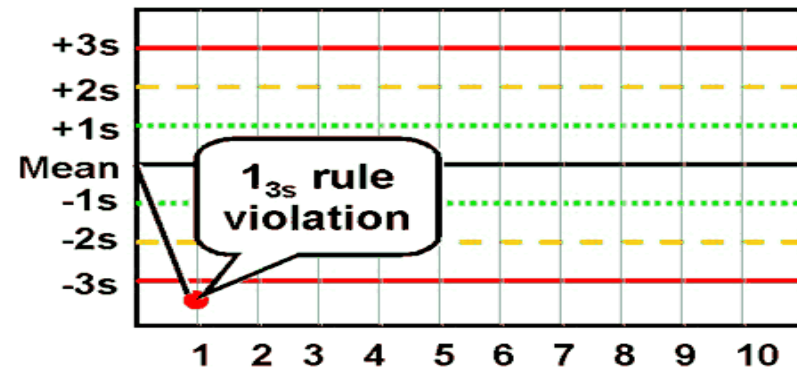 (mean + 2s or mean - 2s) limit.
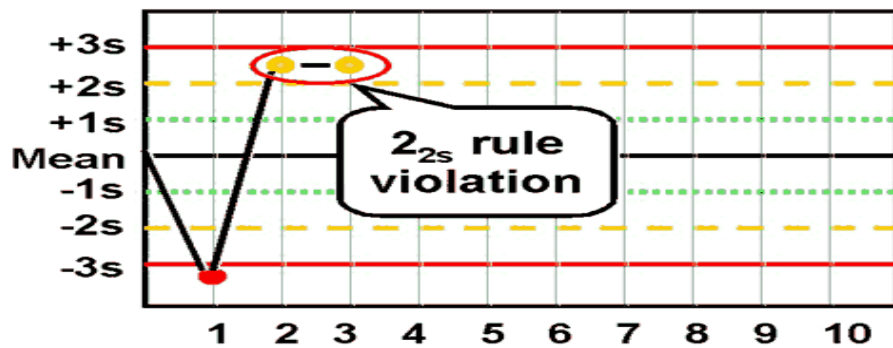

Within run violation

Across run violation

• Rejection 1_{3SD} or 1-3s:

- • It is violated when the single IQC value exceeds the mean by ±3SD.
- • This rule is applied within control material only.
- • The 1-3s rule identifies unacceptable random error or possibly the beginning of a large systematic error.


• Rejection 4_{1SD} or 4-1s:

It is violated if four consecutive IQC values exceed the same mean plus 1s or the same mean minus 1s control limit.
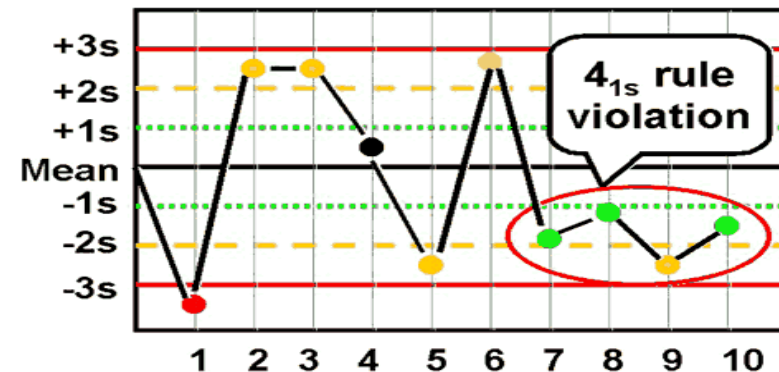
• Rejection 10x:

- This rule detects systematic bias and is applied both within and across control materials.
- It is violated across control materials if the last 10 consecutive values, regardless of control level, are on the same side of the mean.
- The rule is violated within the control materials if the last 10 values for the same control level are on the same side of the mean.
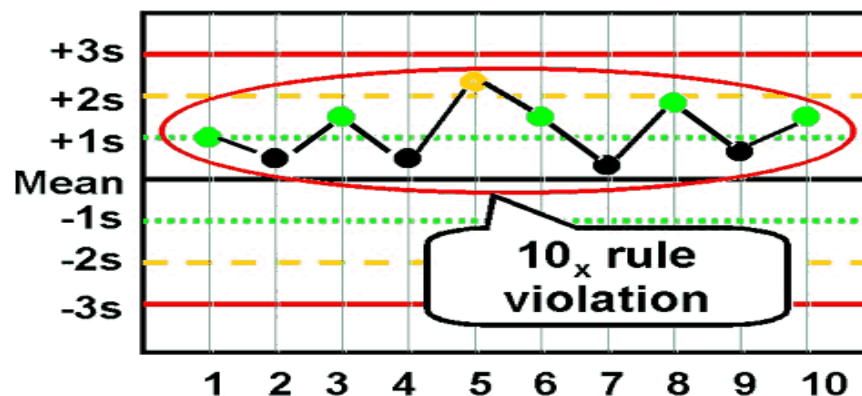
Westgard Procedure Flowchart
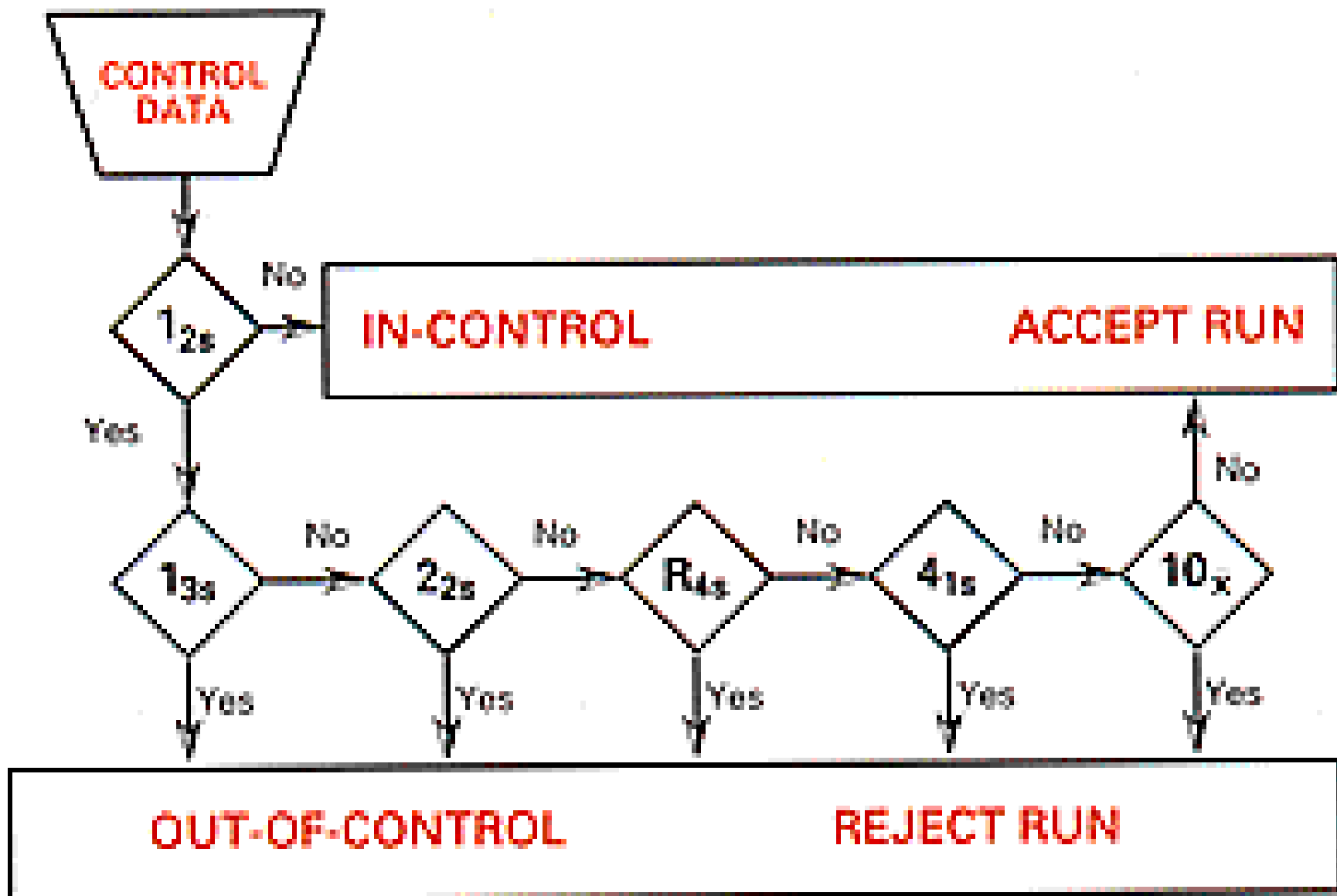
EXTERNAL QUALITY CONTROL

- All the participating laboratories daily analyze the same lot of control material.

- The results are tabulated monthly & sent the sponsoring groups for the data analysis.

- Summary reports are prepared by the program sponsor & are distributed to all participating laboratories .

- The mean of values of all reference laboratories is taken as the " true " or correct value & is used for comparison with the individual laboratory reported values.

- If the difference between the reported value & the true value is statistically significant then the reporting lab is alerted.

THANK YOU