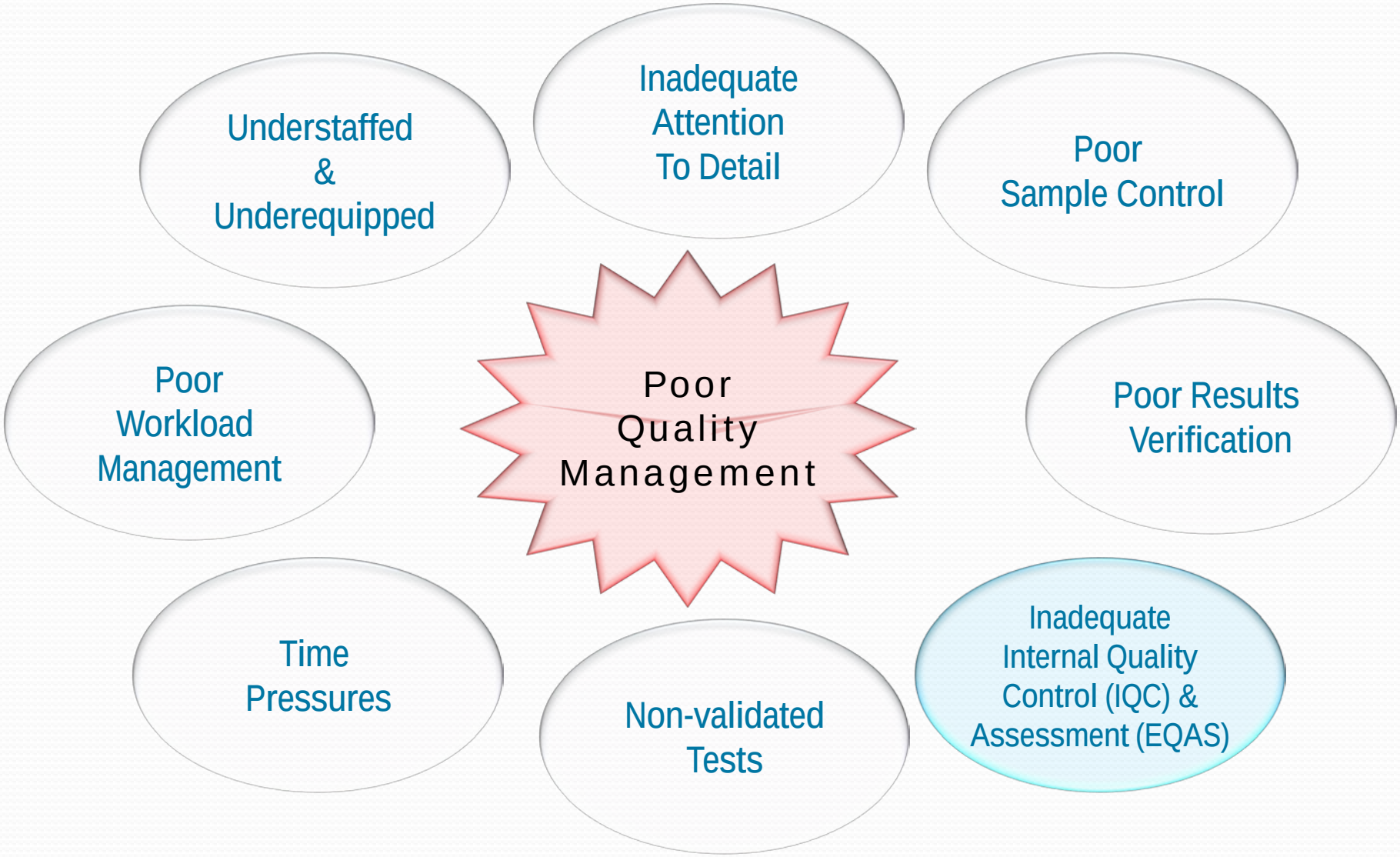
Statistical Quality Control - Hematology

M R Tiwari
M Sc (TQM)
Hematopathology, TMH, Mumbai

Why do laboratory errors occur?



ISO 15189

INTERNATIONAL STANDARD

ISO 15189

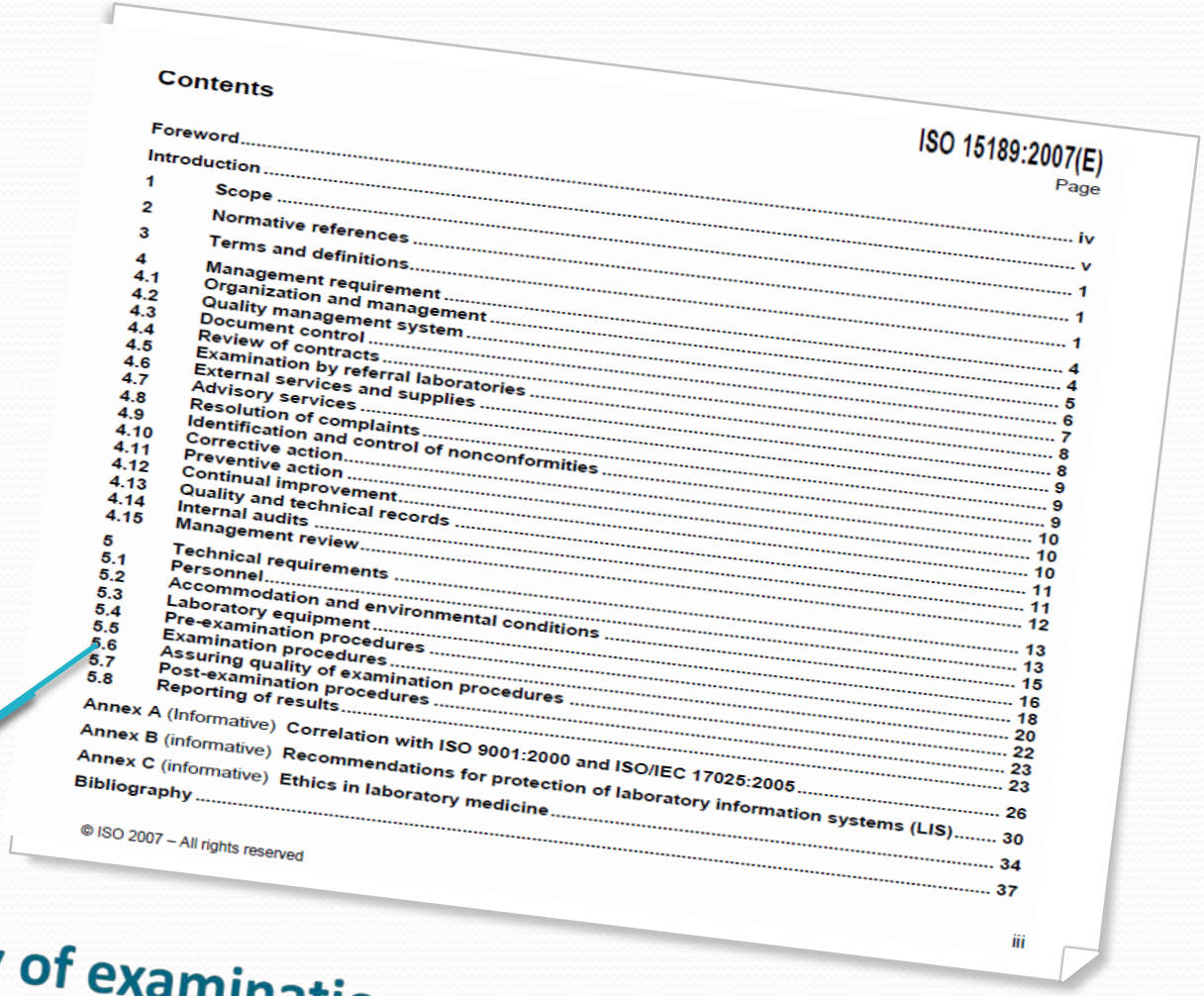
Second edition
2007-04-15

Medical laboratories — Particular requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences particulières concernant la qualité et la compétence

Reference number
ISO 15189:2007(E)

ISO 15189



ISO 15189:2007(E)

Contents

5.6 Assuring quality of examination procedures

Terminologies – IQC & EQAS

- Precision
- Accuracy
- Calibration
- Carryover
- Control
- Calibrator
- Standardization
- Validation

- Levey-Jennings chart
- Mean
- Standard Deviation
- Control Limits
- Coefficient of Variation
- Westgard Rules
- Z-Score

STATISTICS

The Levey-Jennings Chart's Inventors

In 1931, Dr. Walter Shewhart, a scientist at the Bell Telephone Laboratories, proposed applying statistical based control charts to interpret industrial manufacturing processes.

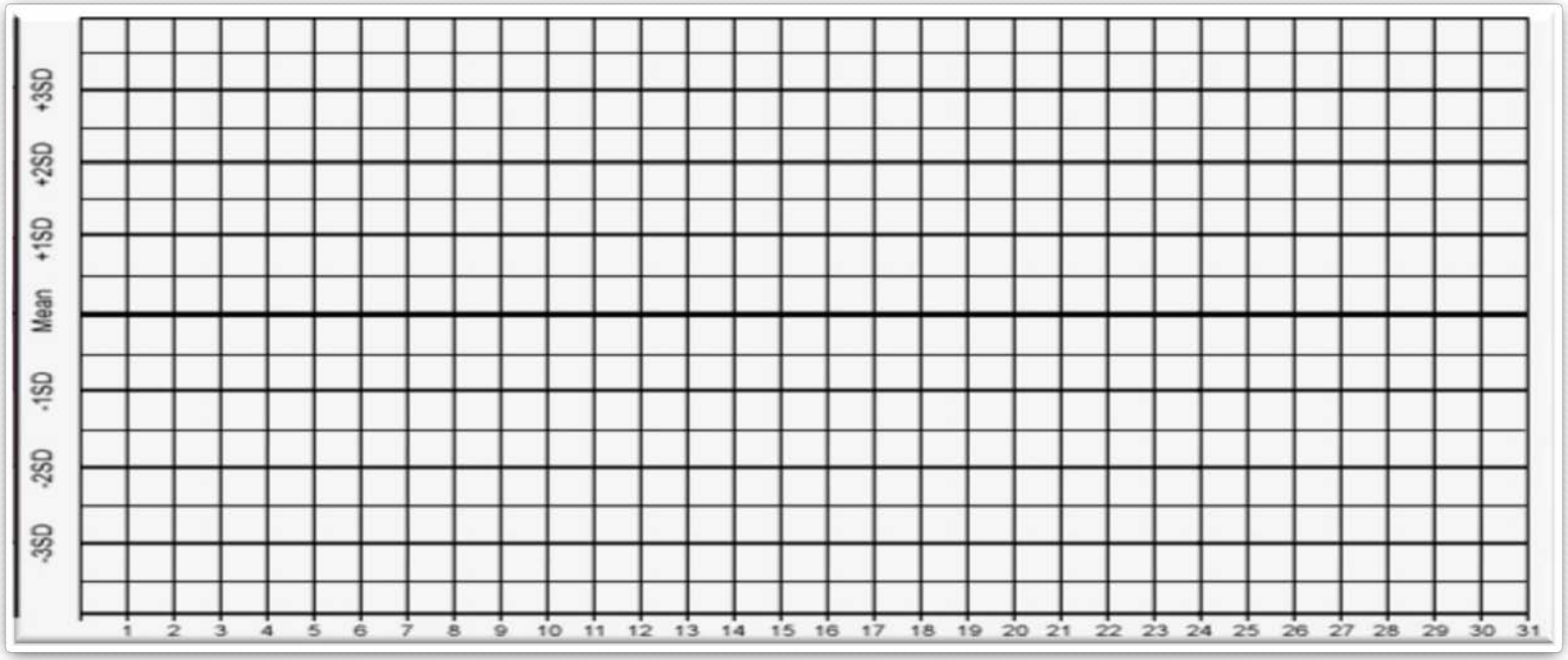
In 1950, S. Levey and E.R. Jennings suggested the use of Dr. Shewhart's control chart in the clinical laboratory.

Dr. Walter A. Shewhart

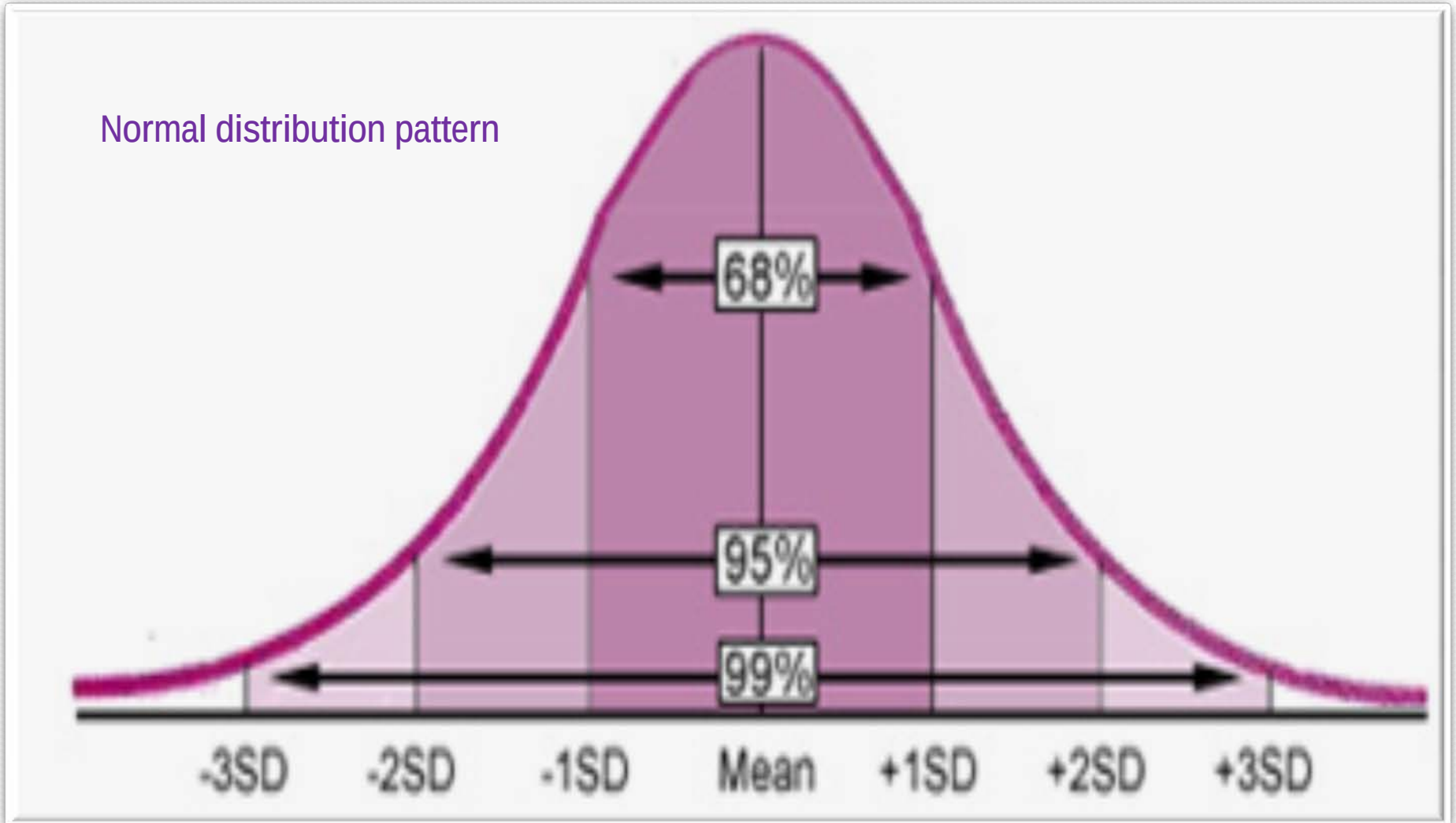
Father of statistical quality control

What is Levey-Jennings (L-J) chart?

- X-axis - the days of the month (time interval)
- Y-axis. - control observations



What is L-J chart?



How to create L-J chart?

By using common materials

- Manually - arithmetic graph paper
- MS Excel Software in computer
- Quality software program like
  - MedLab QC
- Automated hematology analyzer inbuilt quality software program

How to create L-J chart?

By using simple statistics

- Mean → TARGET
- Standard Deviation (SD)
- ± 1SD
- ± 2SD
- ± 3SD
- Coefficient of Variation (CV %)

→ CONTROL LIMITS

Creating L-J chart …

- The mean and standard deviation of the control being used should be determined based on at least 20 measurements over 20 days. Reference: http://www.medialabinc.net/levey-jennings-keyword.aspx

Or

- Statistical data should be determined based on >10 measurements. *(In case of perishable and less quantity control material).*

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Creating L-J chart …

First step – Calculate Target Value

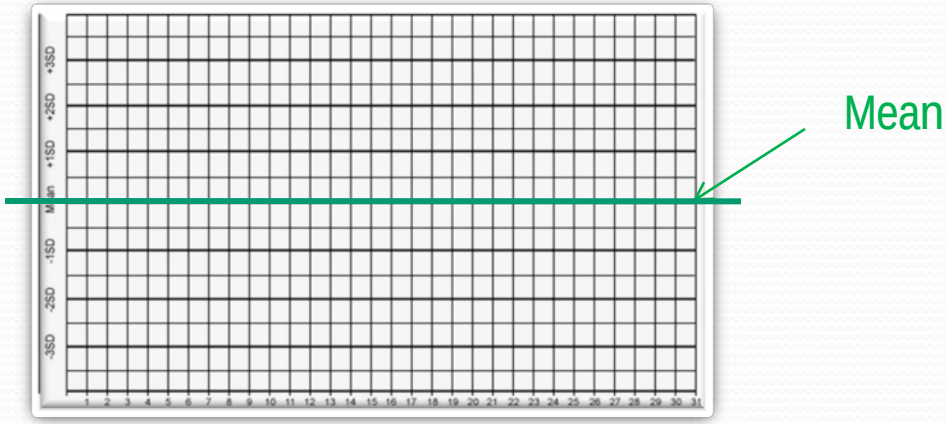
- Mean ($\overline{x}$) is the sum of all the measurements (Σ) divided by the number of measurements (n)

- Formula $\overline{x} = \sum x_i / n$

  Where

  x_i = each data point

  n = the number of data points in the set



Creating L-J chart …

Second step – Calculate Dispersion from target value i.e. Standard deviation (SD)

- SD quantifies the degree of dispersion of data points about the mean.
- SD is used to set limits upon which control result acceptability is determined.

SD Calculation

Where,

$$S.D. = \sqrt{\frac{\sum\left(x - \bar{x}\right)^2}{n-1}}$$

$\sum$ = sum of

x = any single observed value

$\bar{x}$ = average value

n = total number of observed values

Here **n** = 20

Mean

$\bar{x}$ = 2000 / 20 = 100

SD

SD = √ 157 / (20-1)

SD = 2.87

Calculation Procedure	No. of runs	A (x_i)	B ($x - x_i$)	C $(x - x_i)^2$
1. List values in column A	1	95	-5	25
2. Add column A, comes to 2000	2	100	0	0
3. Divide total of column A by	3	101	+1	1
no. of values (see mean	4	102	+2	4
formula), comes to 100	5	97	-3	9
4. This is the average or mean	6	103	+3	9
value	7	101	+1	1
5. In column B list the difference	8	99	-1	1
in values of column A from	9	98	-2	4
the average values of column	10	100	0	0
A from the average value	11	95	-5	25
100, disregard + or – signs	12	101	+1	1
6. Square each value and place	13	105	+5	25
in column C	14	100	0	0
7. Add values in column C	15	98	-2	4
8. Divide the total of column C	16	101	+1	1
by number of values minus 1	17	97	-3	9
(see SD formula)	18	106	+6	36
9. Determine the square root of	19	100	0	0
8.37 which comes to 2.89.	20	101	+1	2
this is the standard deviation		**2000**		**157**

Creating L-J chart …

Third step – Calculate Control Limits (± 1SD, ± 2SD, ± 3SD)

Mean + (3 x SD) = + 3SD

Mean + (2 x SD) = + 2SD

Mean + (1 x SD) = + 1SD

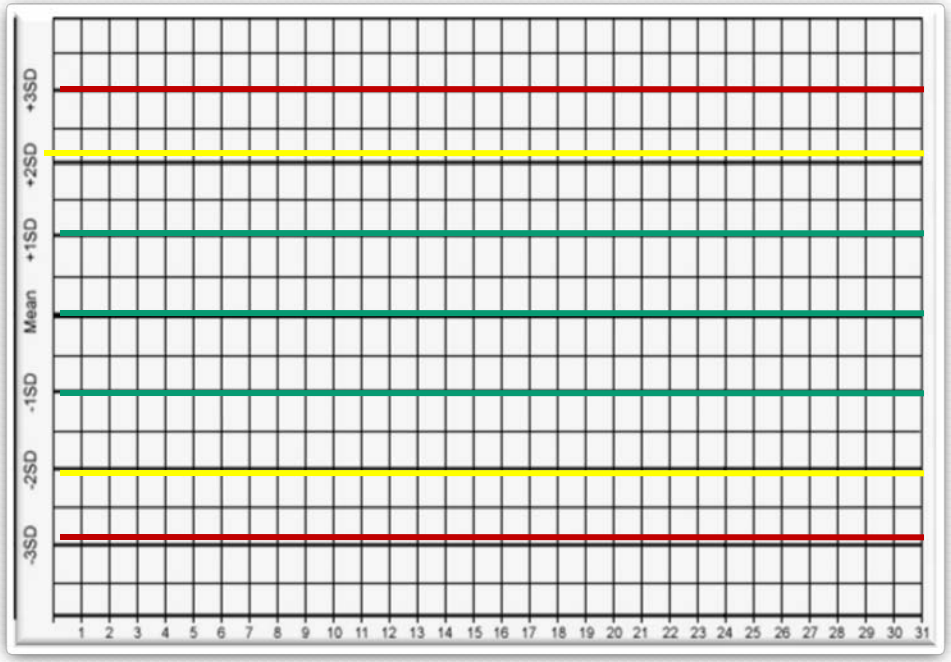
Upper Control Limits

Mean - (1 x SD) = - 1SD

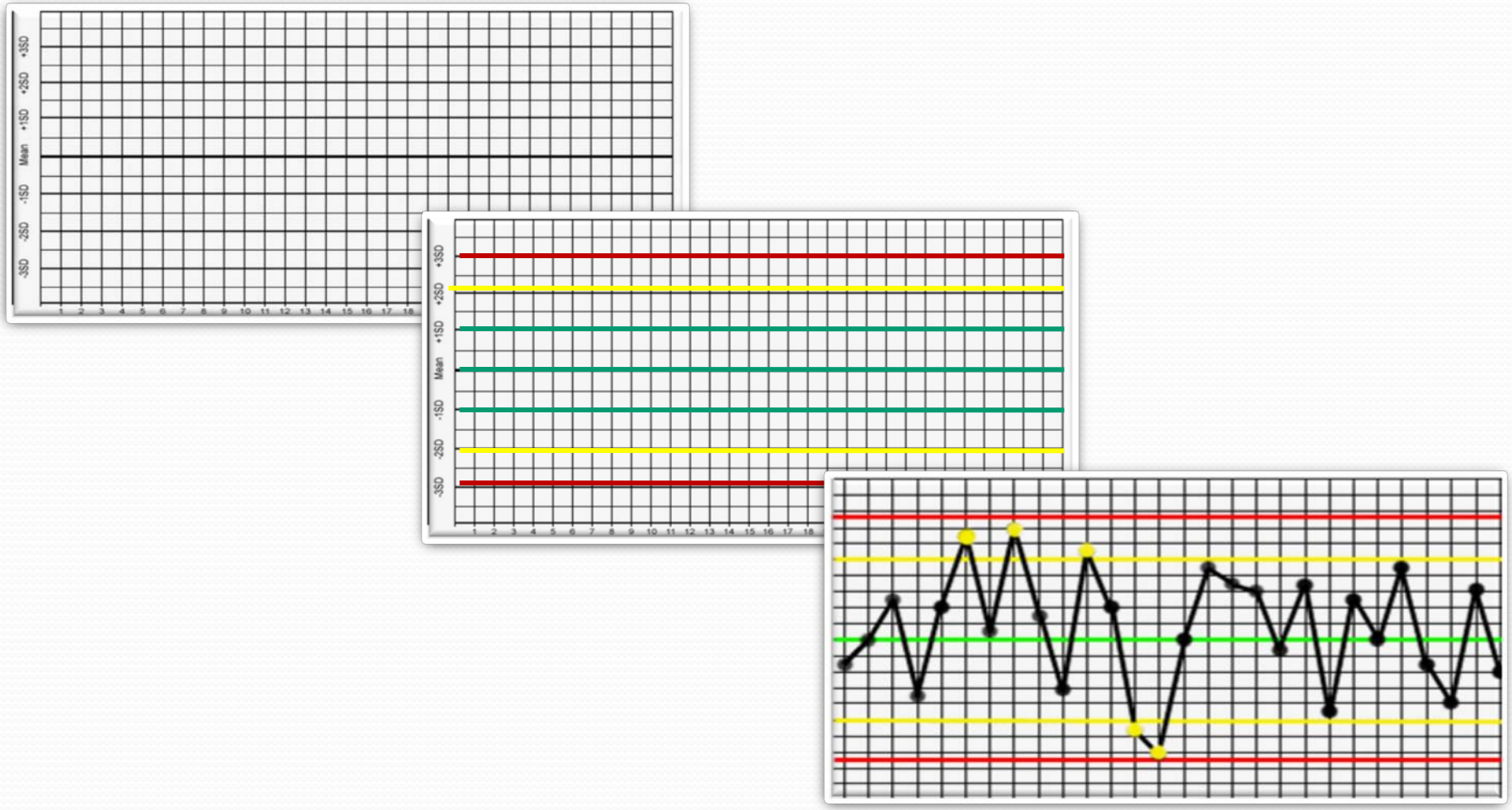
Mean - (2 x SD) = - 2SD

Mean - (3 x SD) = - 3SD

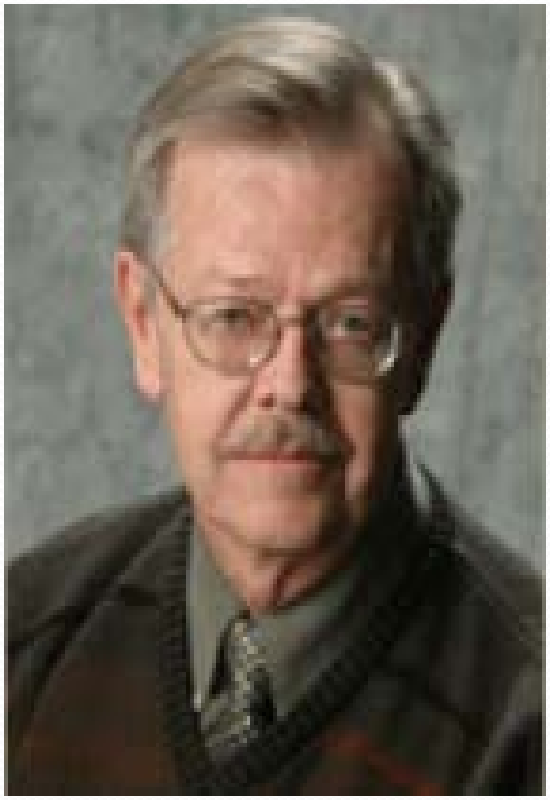
Lower Control Limits



L-J chart is ready for QC monitoring



L-J chart Interpretation



Dr. James O Westgard

Westgard Rules (WR)

WR decide whether an analytical run is

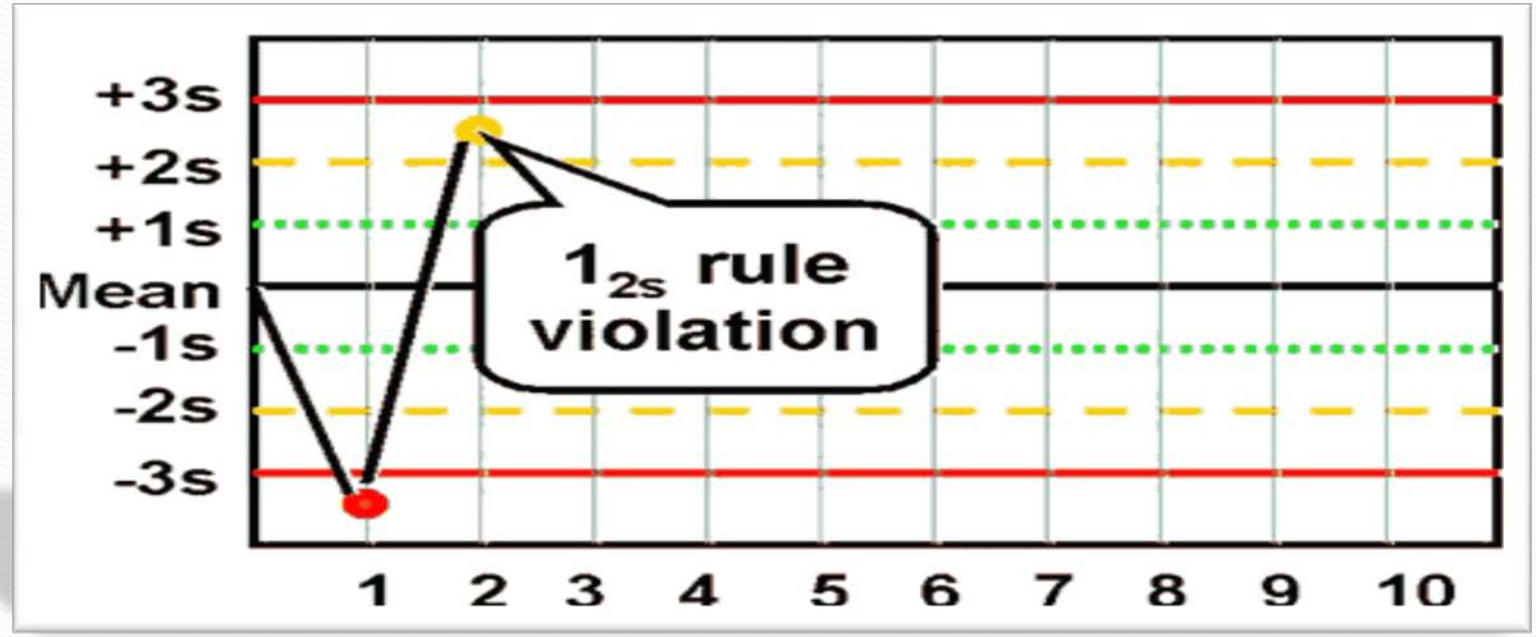
in-control or out-of-control.

L-J chart Interpretation

1_{3S} - A run is rejected when a single control measurement exceeds the mean plus 3SD or the mean minus 3SD control limit (>±3SD).

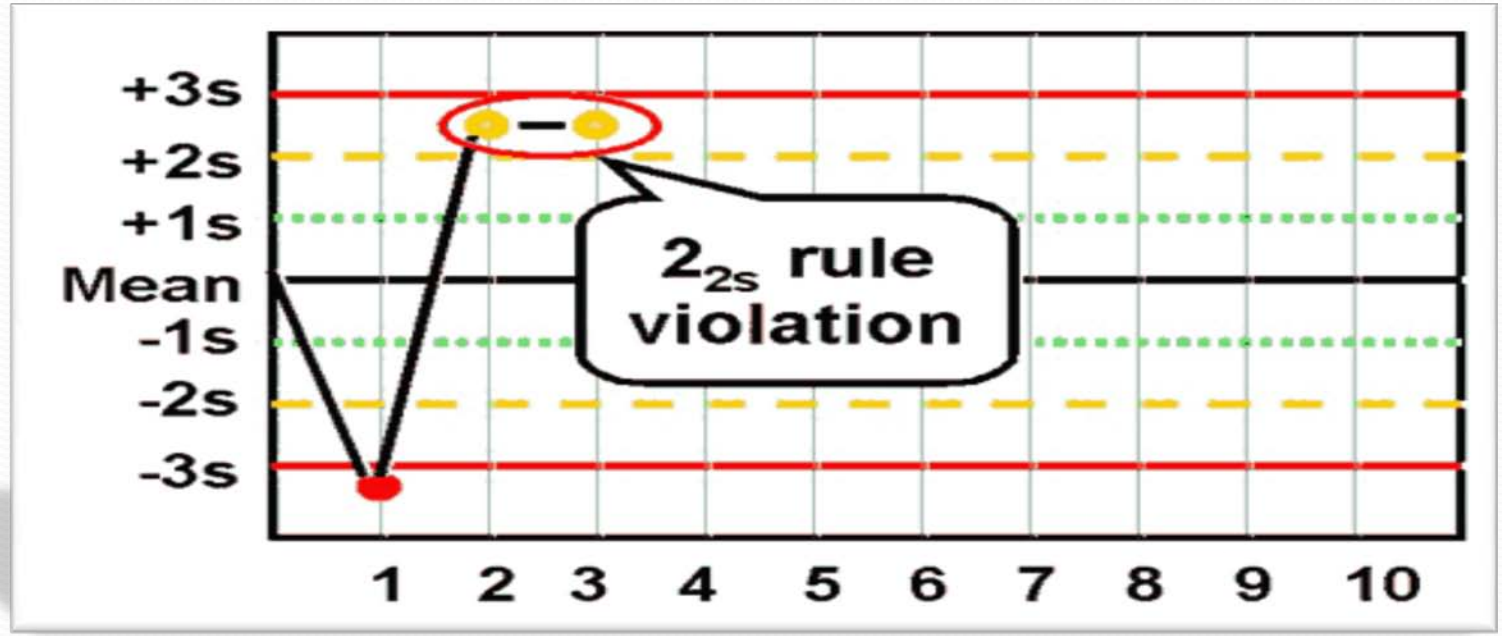
L-J chart Interpretation

1_{2S} -This rule is used as a warning rule to trigger careful inspection of the control data by the following rejection rules.



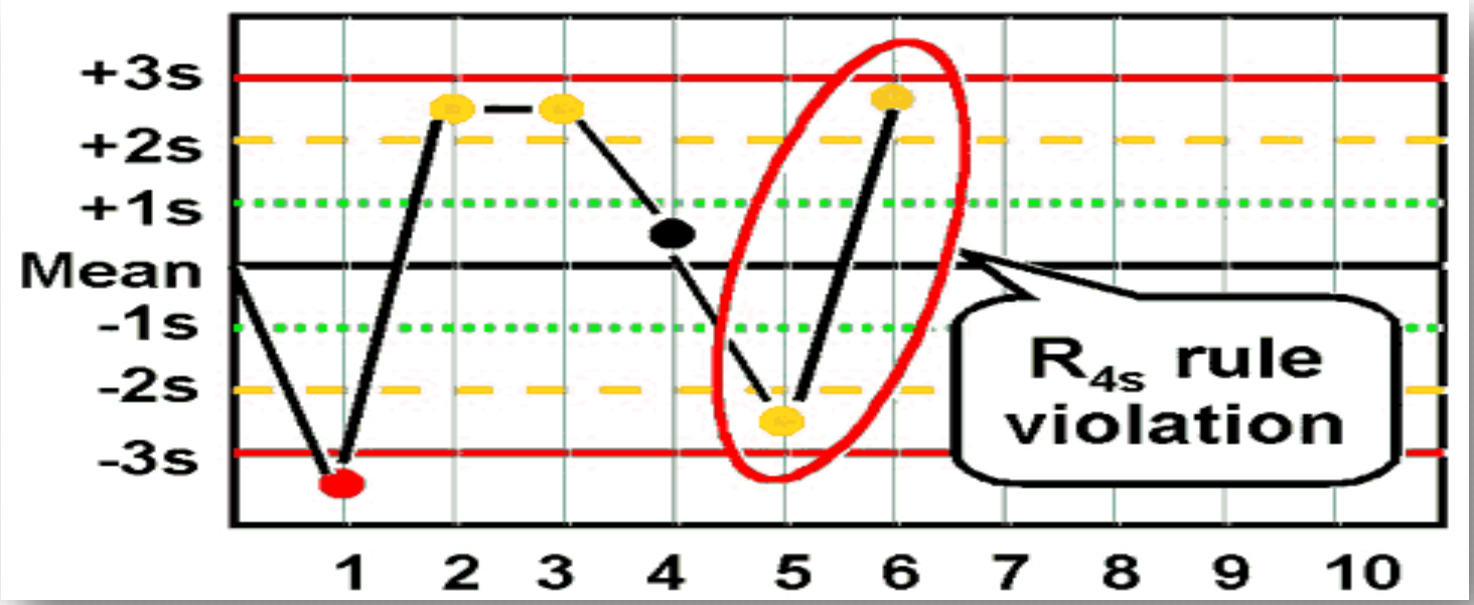
L-J chart Interpretation

2_{2s} - reject when 2 consecutive control measurements exceed the same mean plus 2SD or the same mean minus 2SD control limit.



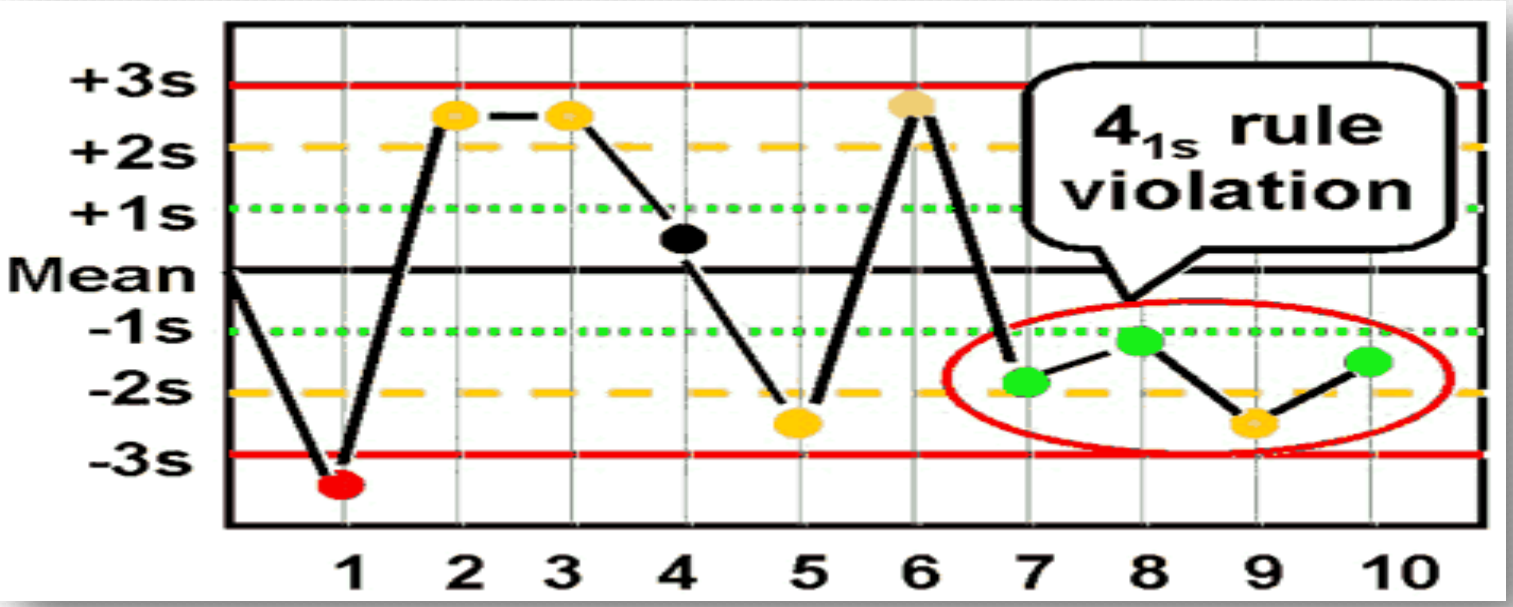
L-J chart Interpretation

R_{4s} - reject when 1 control measurement in a group exceeds the mean plus 2SD and another exceeds the mean minus 2SD.



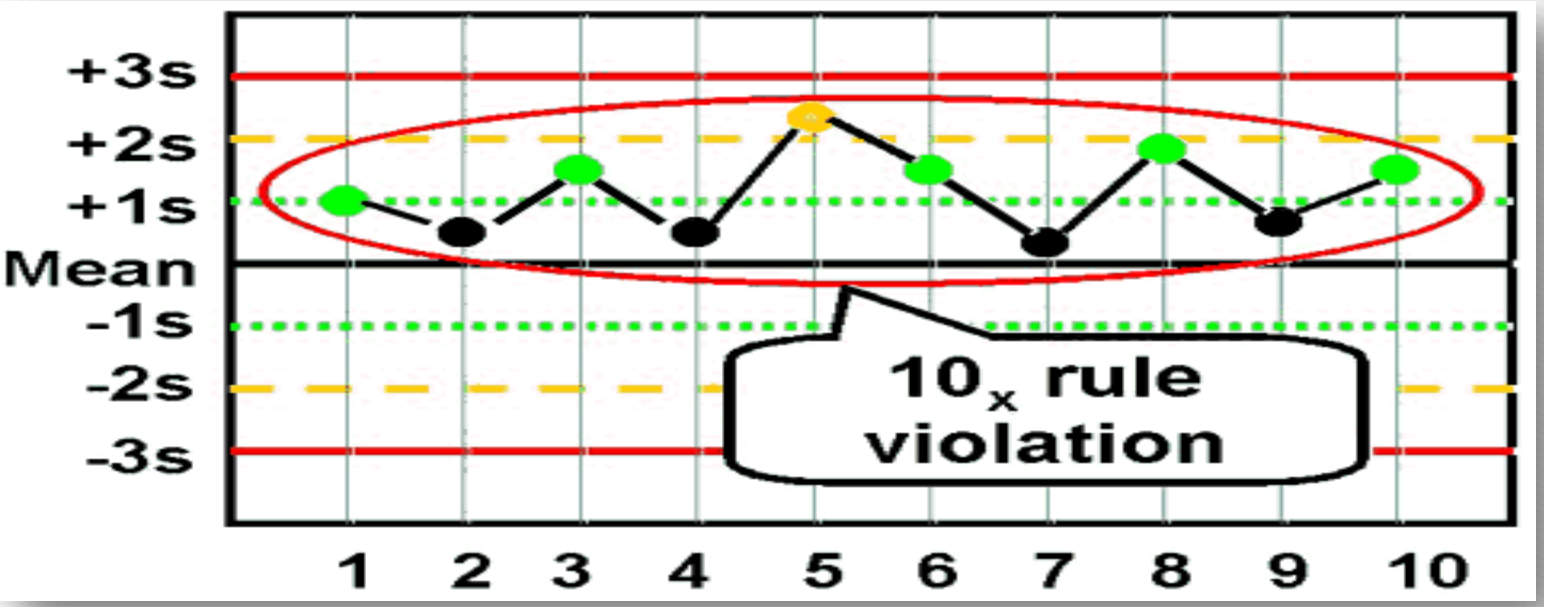
L-J chart Interpretation

4_{1s} - reject when 4 consecutive control measurements exceed the same mean plus 1SD or the same mean minus 1SD control limit.



L-J chart Interpretation

10_x - reject when 10 consecutive control measurements fall on one side of the mean.



L-J chart Interpretation

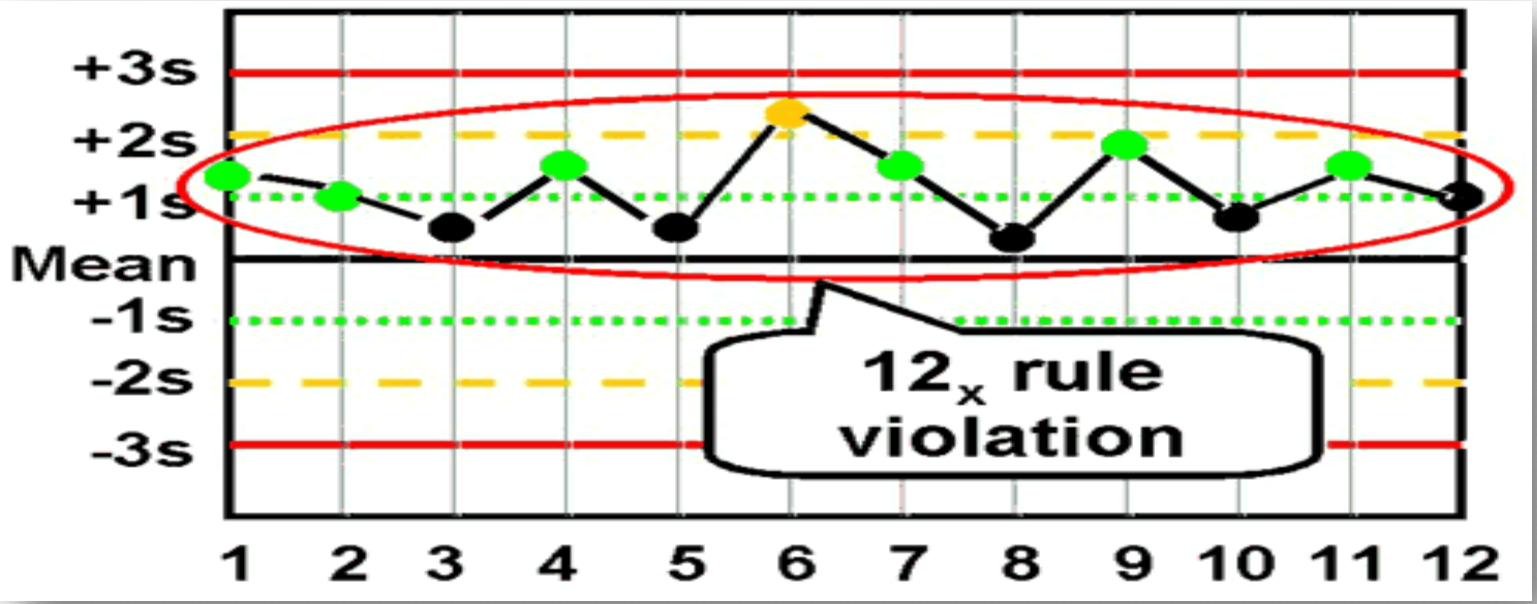
Modification of 10_x

8_x - reject when 8 consecutive control measurements fall on one side of the mean.

L-J chart Interpretation

Modification of 10_x

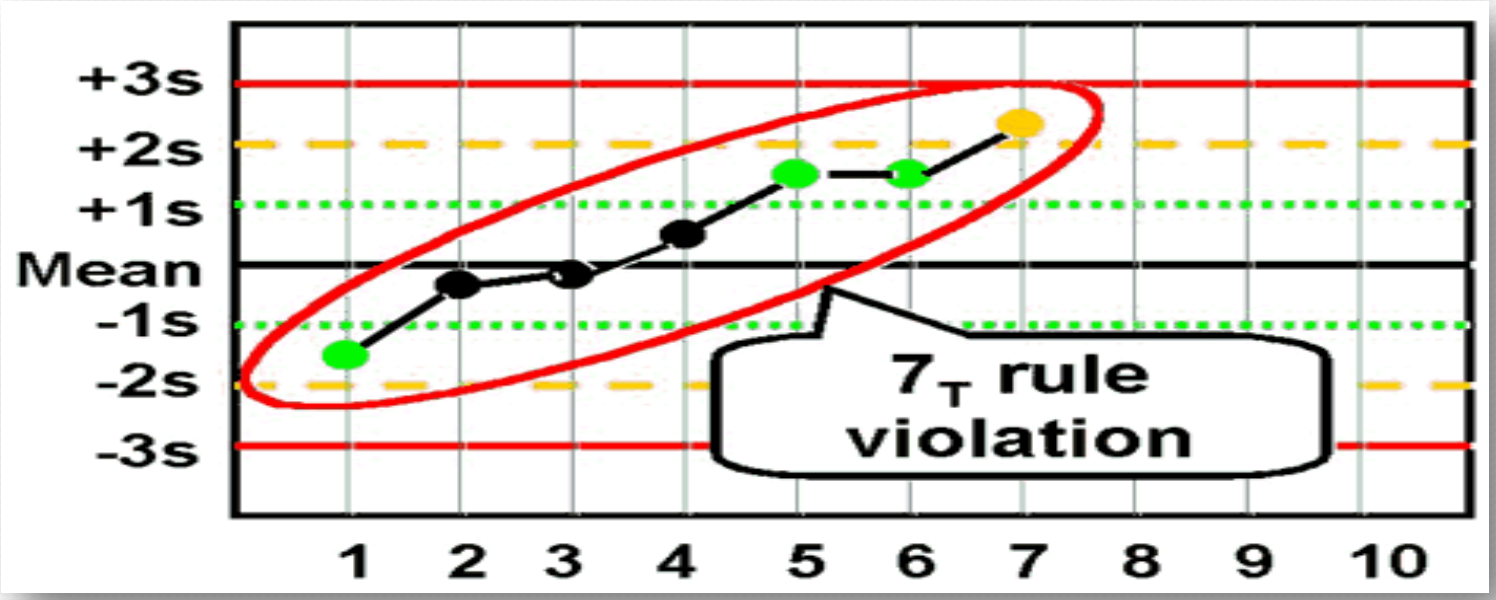
12_x - reject when 12 consecutive control measurements fall on one side of the mean.



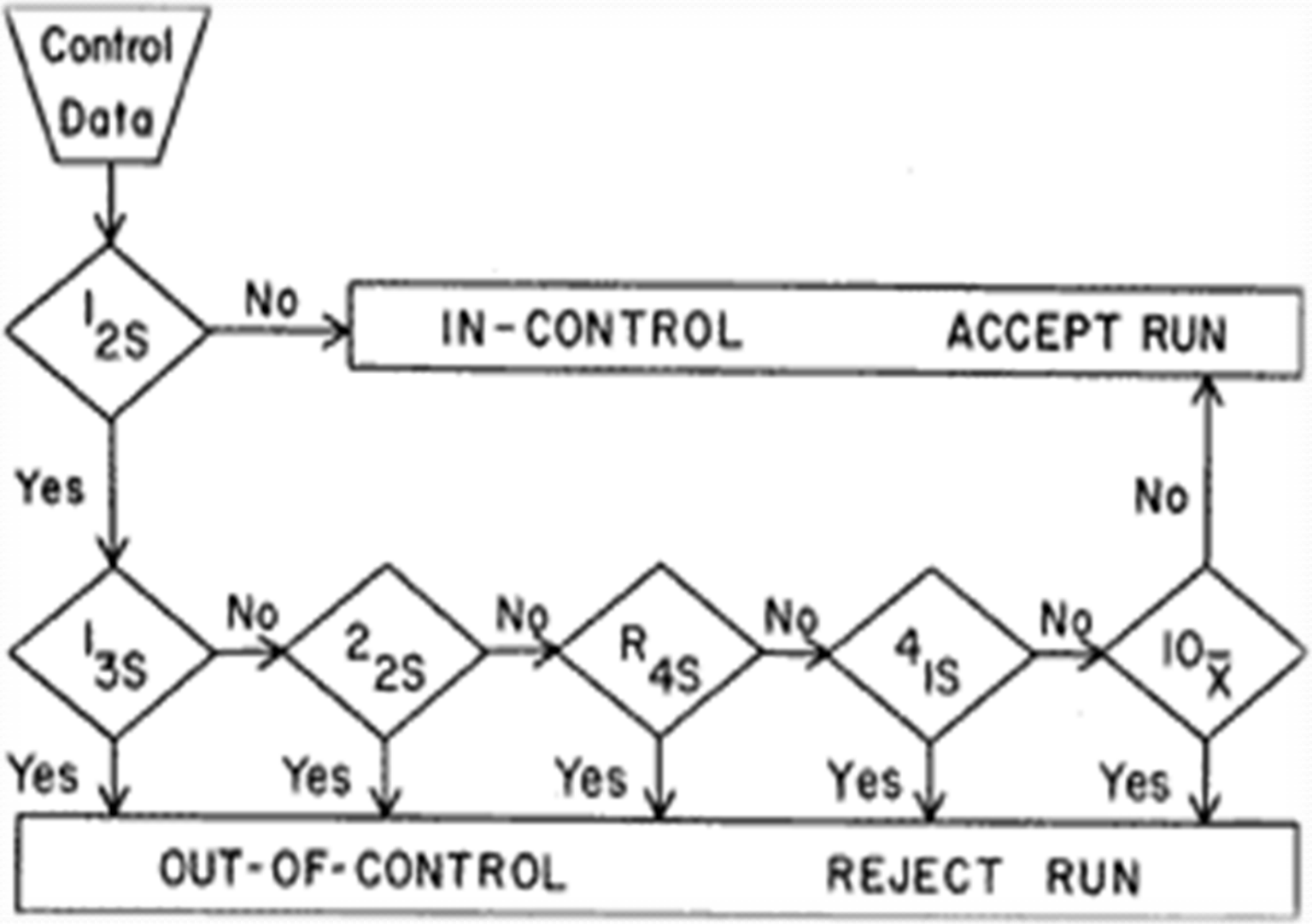
L-J chart Interpretation

Look for a "trend"

7_T - reject when seven control measurements trend in the same direction, i.e., get progressively higher or progressively lower.



Summary of L-J Interpretation

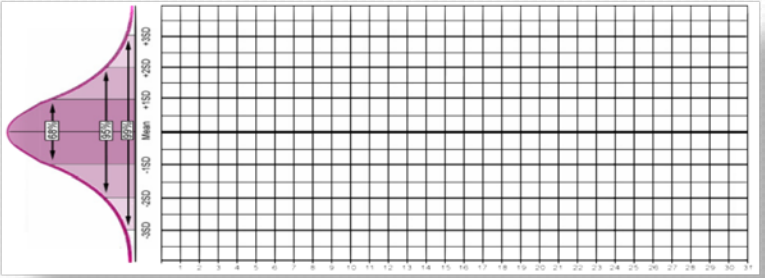


How many L-J's?

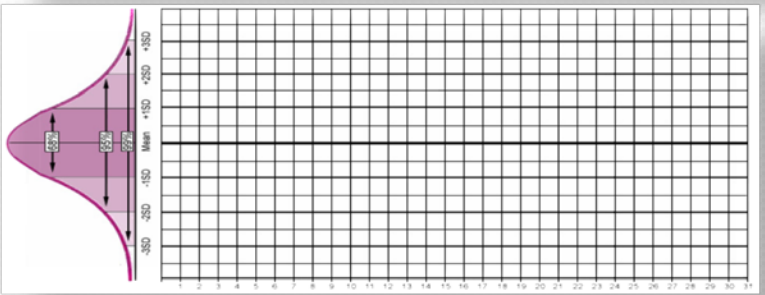
There should be a **separate control chart** for :

- normal and abnormal controls of each parameter being monitored

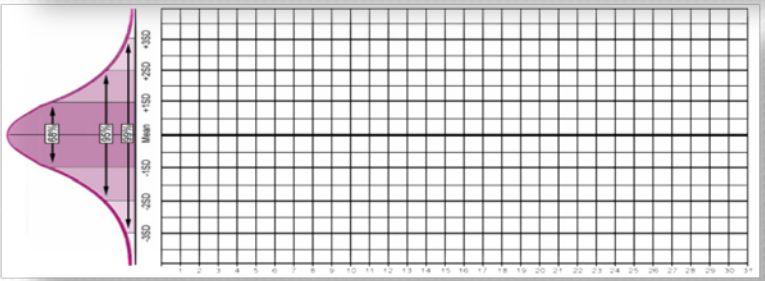
WBC (Low)



WBC (Normal)



WBC (High)



When a rule is violated…

Warning rule = use other rules to inspect the control points

Rejection rule = “out of control”

- Stop testing
- Identify and correct problem
- Repeat testing on patient samples and controls
- Do not report patient results until problem is solved and controls indicate proper performance

Dispersion simplified

Coefficient of variation (%CV)

- CV is another way of indicating standard deviation, related to the actual measurement, so that variation at different levels can be compared.
- Formula

$$C.V. = \frac{S.D.}{\overline{X}} \times 100$$

- It is expressed as a percentage (%CV).

Lab can establish their own 'Cut Offs'

CBC parameters	Acceptable %CV
WBC	4.0 %
RBC	3.0 %
Hemoglobin	2.0 %
MCV	2.0 %
Platelet	9 %

Improved %CV
3%
2.5%
1.0%
1.5%
7%

Quality Indicator – ↓%CV is continual improvement"

Application in hematology

May not be limited to:

- Automated 5-part and 3-part differential cell counter
- Automated coagulometers
- Flowcytometers

Summary

Q : Why Statistical evaluation is required?

Ans : Validates test accuracy and reliability.

Thank you…