

QUALITY CONTROL

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QUALITY CONTROL DEFINED

- A process that a laboratory uses to ensure the quality of the lab's overall analytic performance
 - Used in a way that identifies problems as soon as they occur and allows appropriate action to be taken to fix the problem
 - Must document the problem and how it was solved

QUALITY CONTROL MATERIAL





- Should be treated the same as patient specimens
- Quantitative control material should test:
 - High level
 - “normal” level
 - Low level if clinically relevant

QUALITY CONTROL MATERIAL

- Purchased material
 - Assayed: Should have a mean and standard deviation set forth by the manufacturer
 - Unassayed:
 - Must analyze over a period of time to determine statistical analysis
 - Run in parallel with existing lots
 - 20 values over 20 runs (we do a month here)
 - Low volume: 20 values on fewer than 20 runs usually acceptable

WHAT ARE WE MEASURING

- QC is analyzing accuracy, precision, systematic error, and random error

	Accurate	Inaccurate (systematic error)
Precise		
Imprecise (reproducibility error)		

WHAT ARE WE MEASURING

- Random error:
 - Caused by unknown and unpredictable changes
 - precision issues
 - Can be environmental, instrumental, user
 - ex/ temperature variance; using the wrong calculation; temp
 - There is “acceptable” random error - defined by standard deviation (ex/ within 3SD)

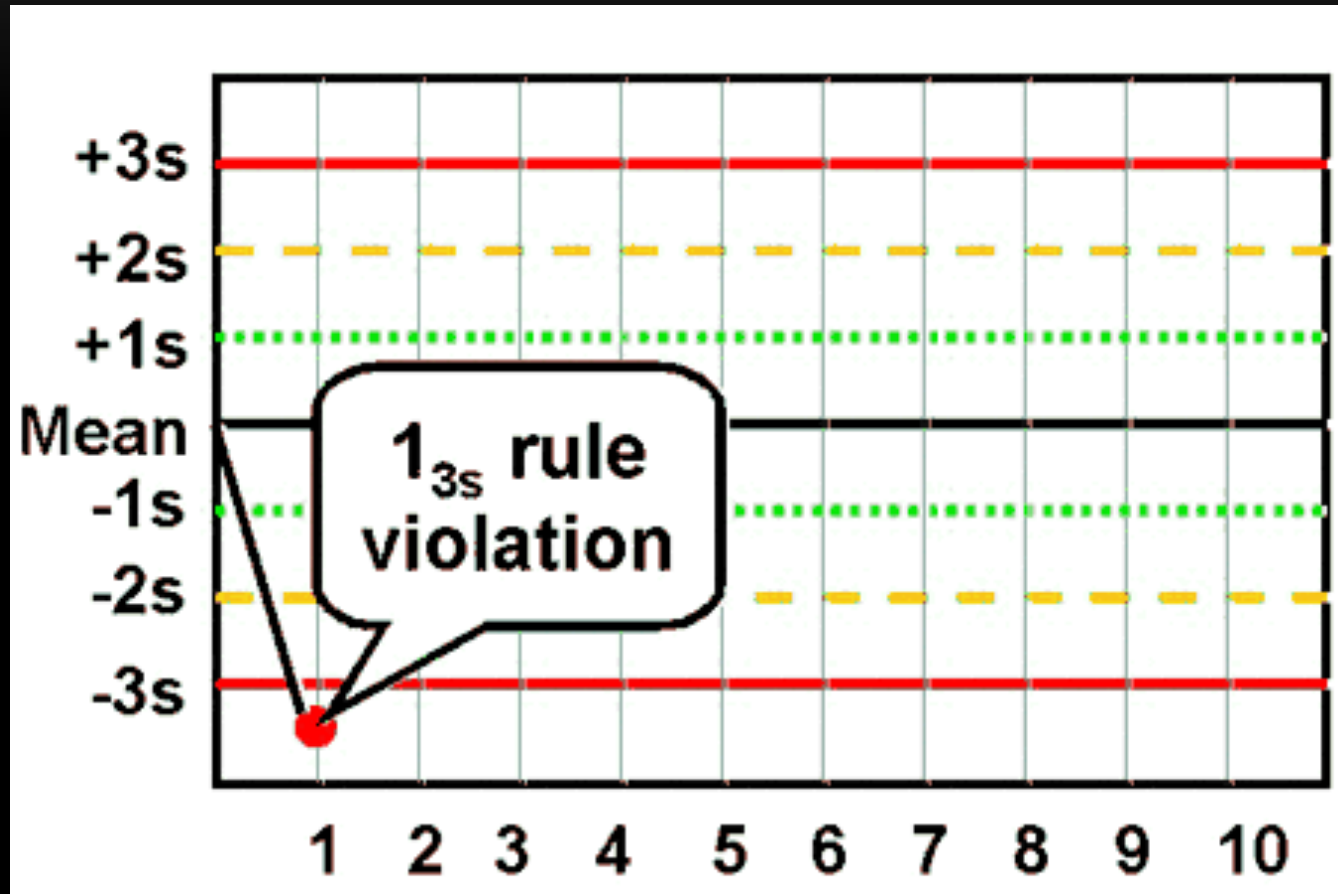
WHAT ARE WE MEASURING

- Systematic error:
 - Happens “every” time the analysis is performed
 - Usually comes from measurements
 - Instrument error (most common)
 - ex/ method measures too high; out of calibration; poorly prepared reagents
 - User error
 - ex/ not using pipette or scale appropriately;
 - Can have good precision but not accurate

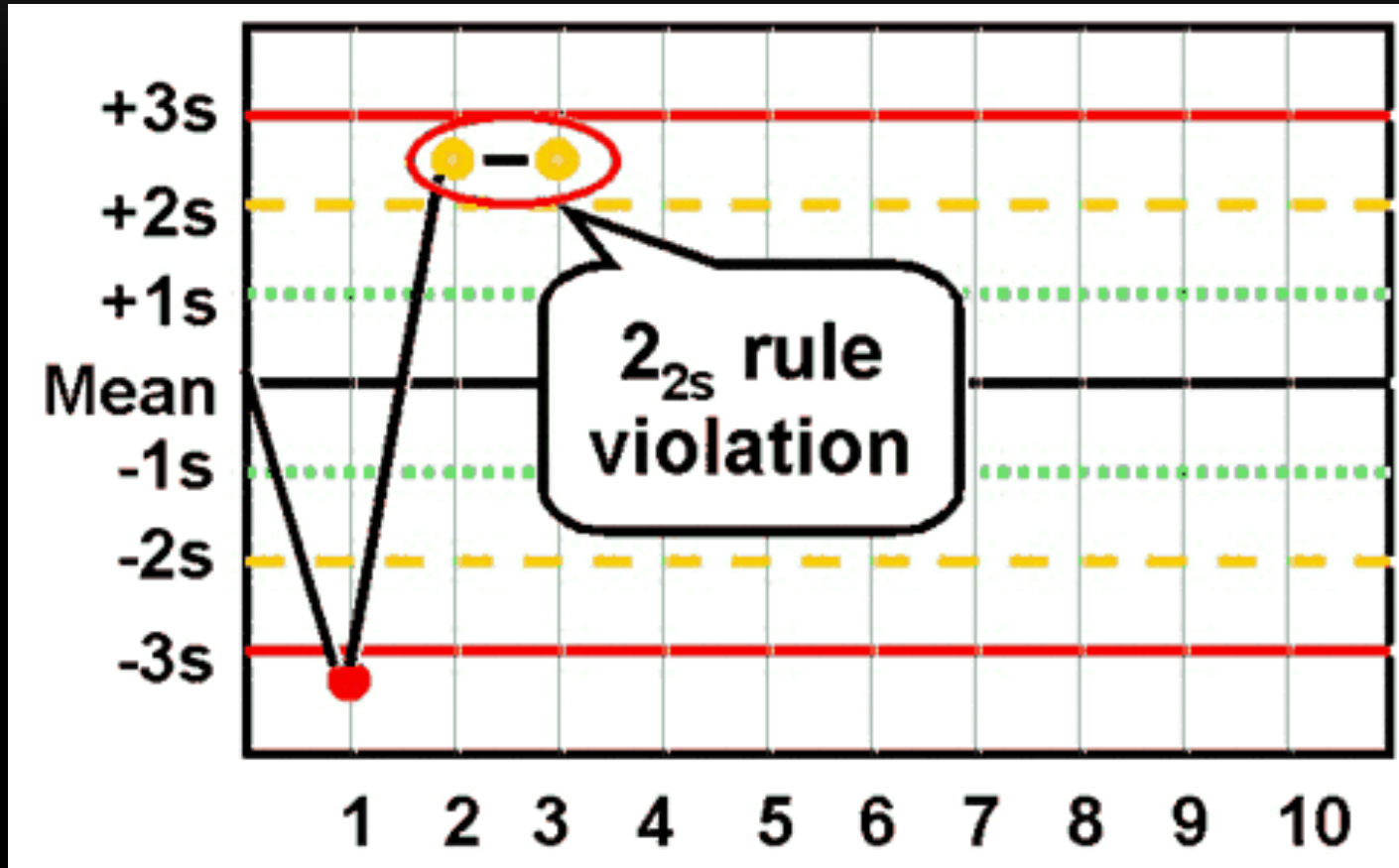
WESTGARD RULES – HOW WE DETECT ERROR

- Westgard is a clinical chemist who developed a system of quality control “rules” to help detect error
- Use a Levy-Jennings chart for each analyte and each control level to determine which rules are out

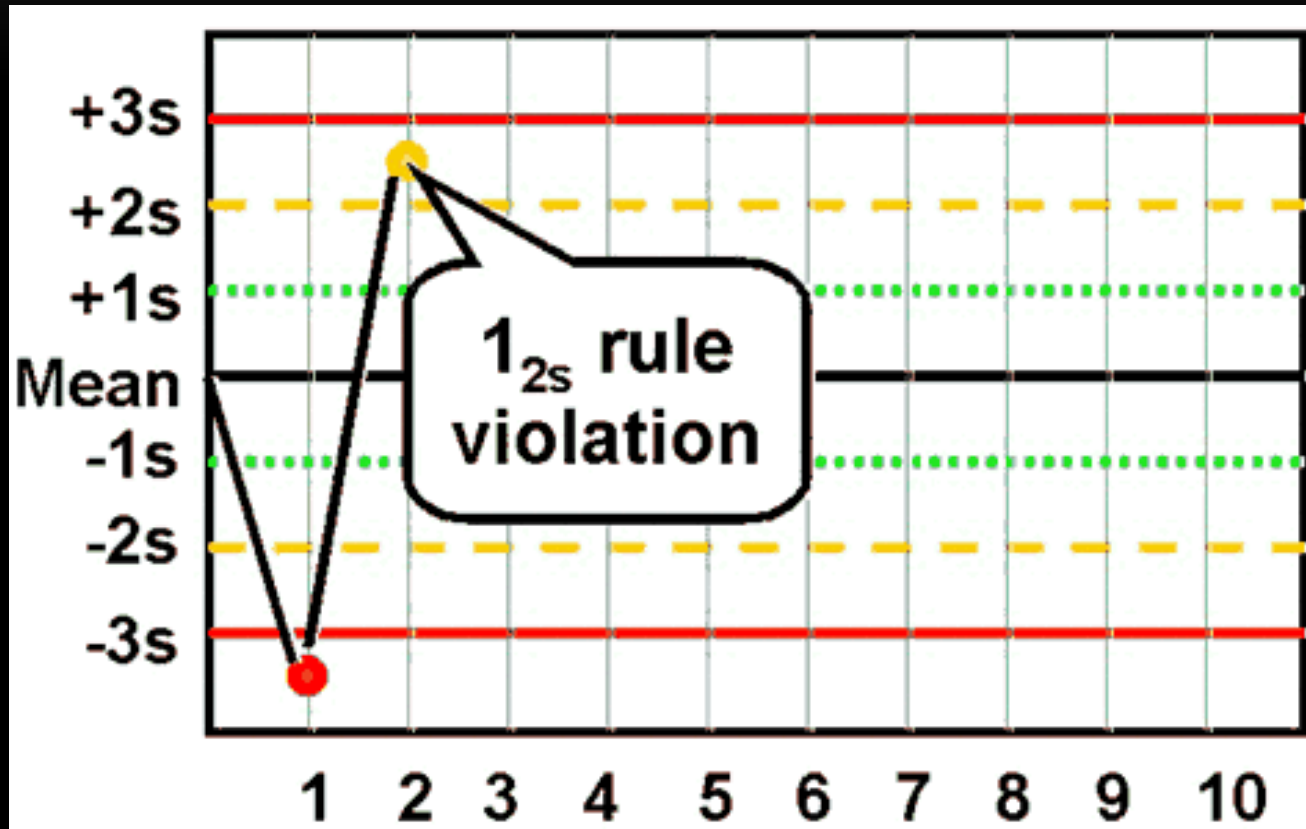
WESTGARD RULES METHODIST USES CURRENTLY



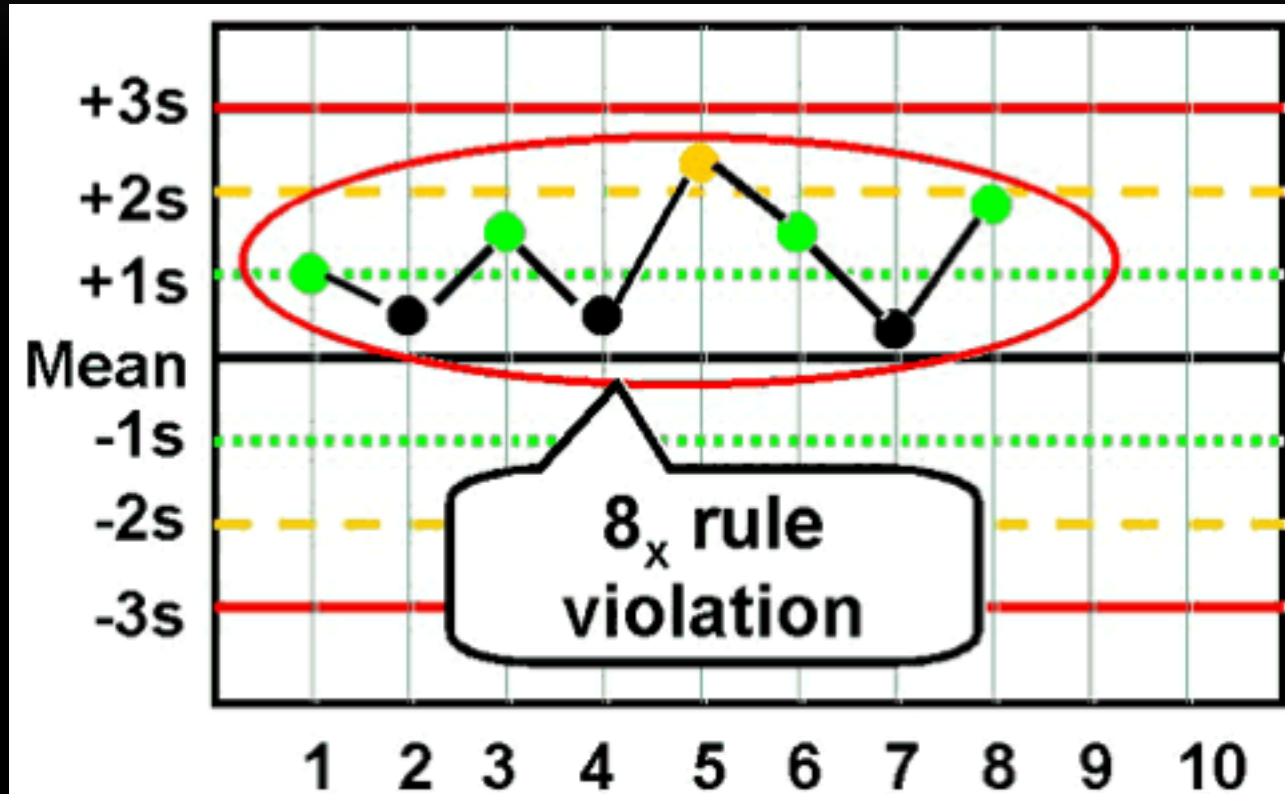
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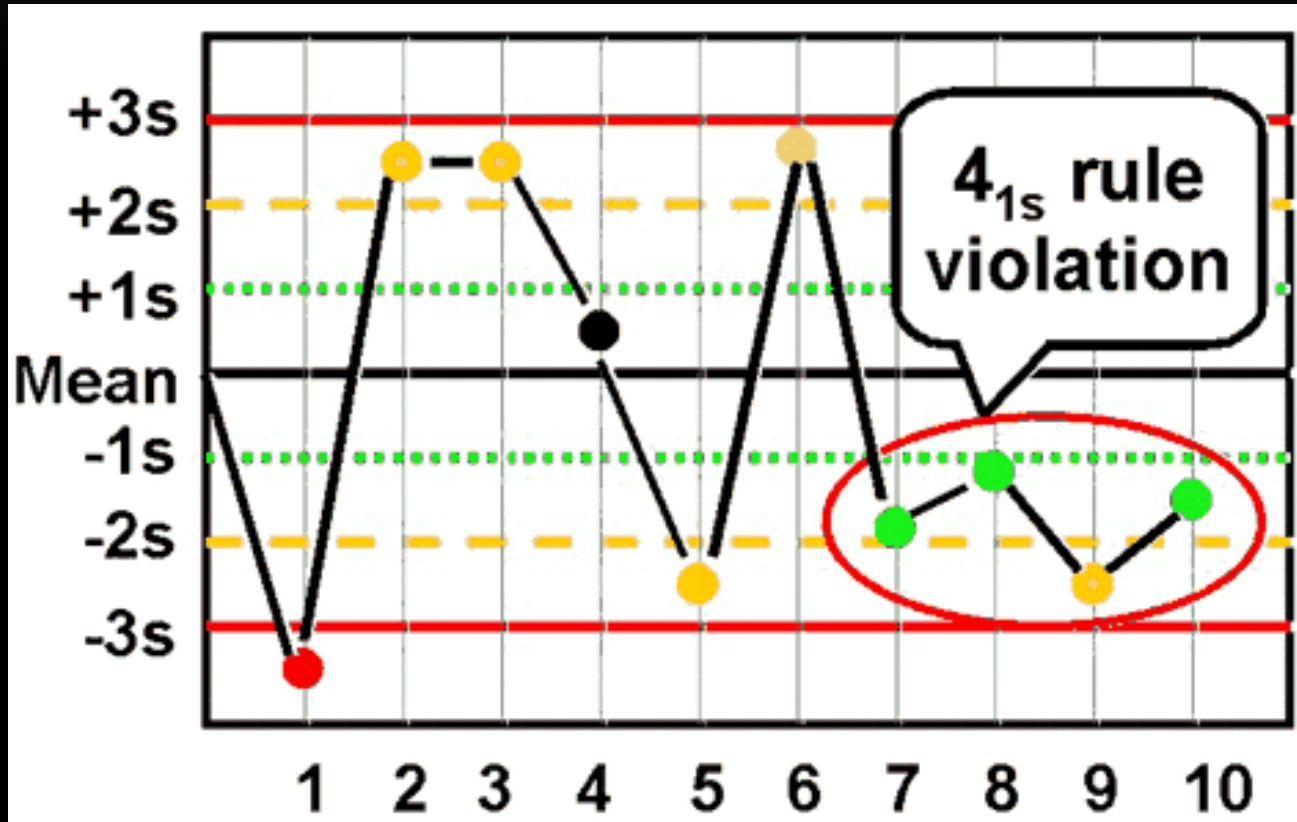
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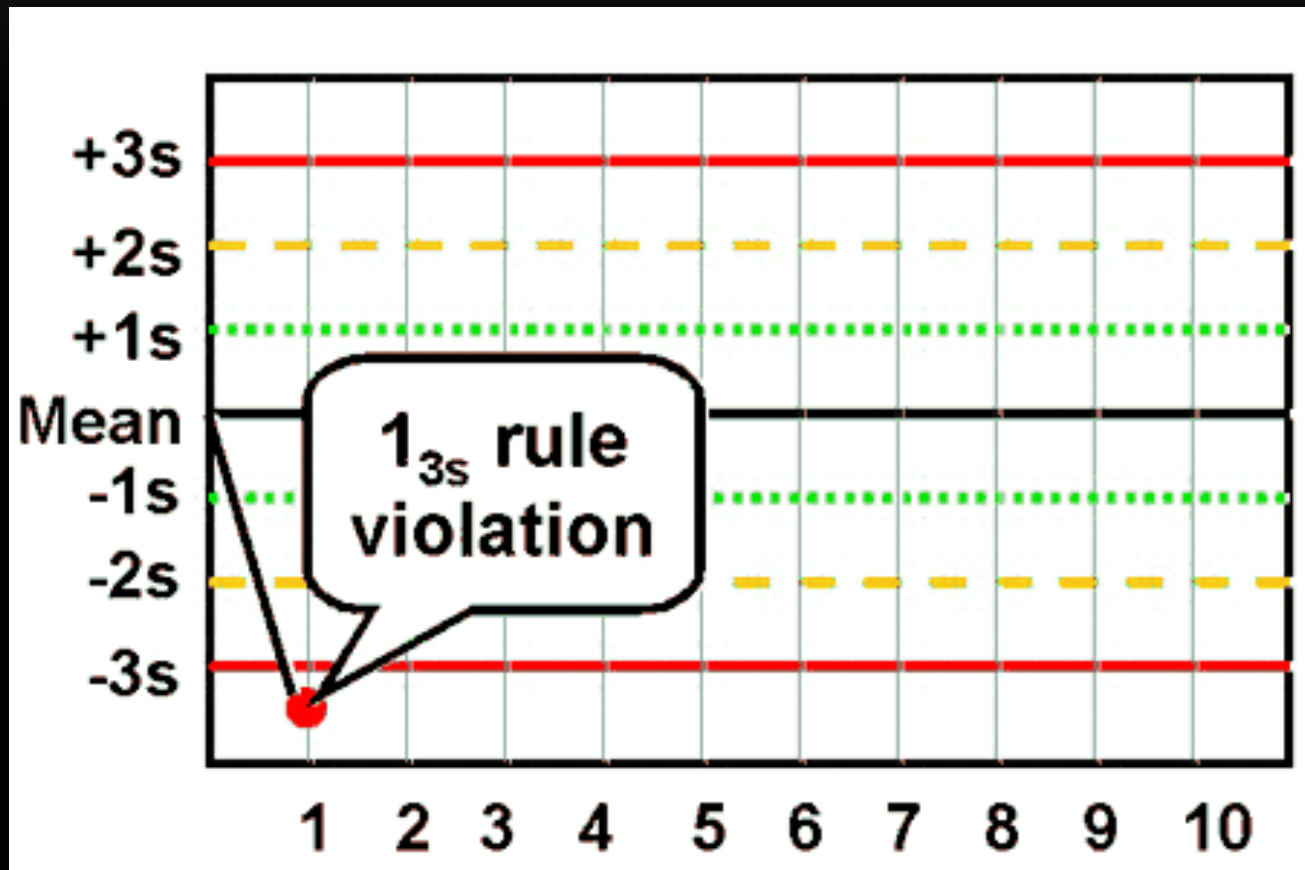
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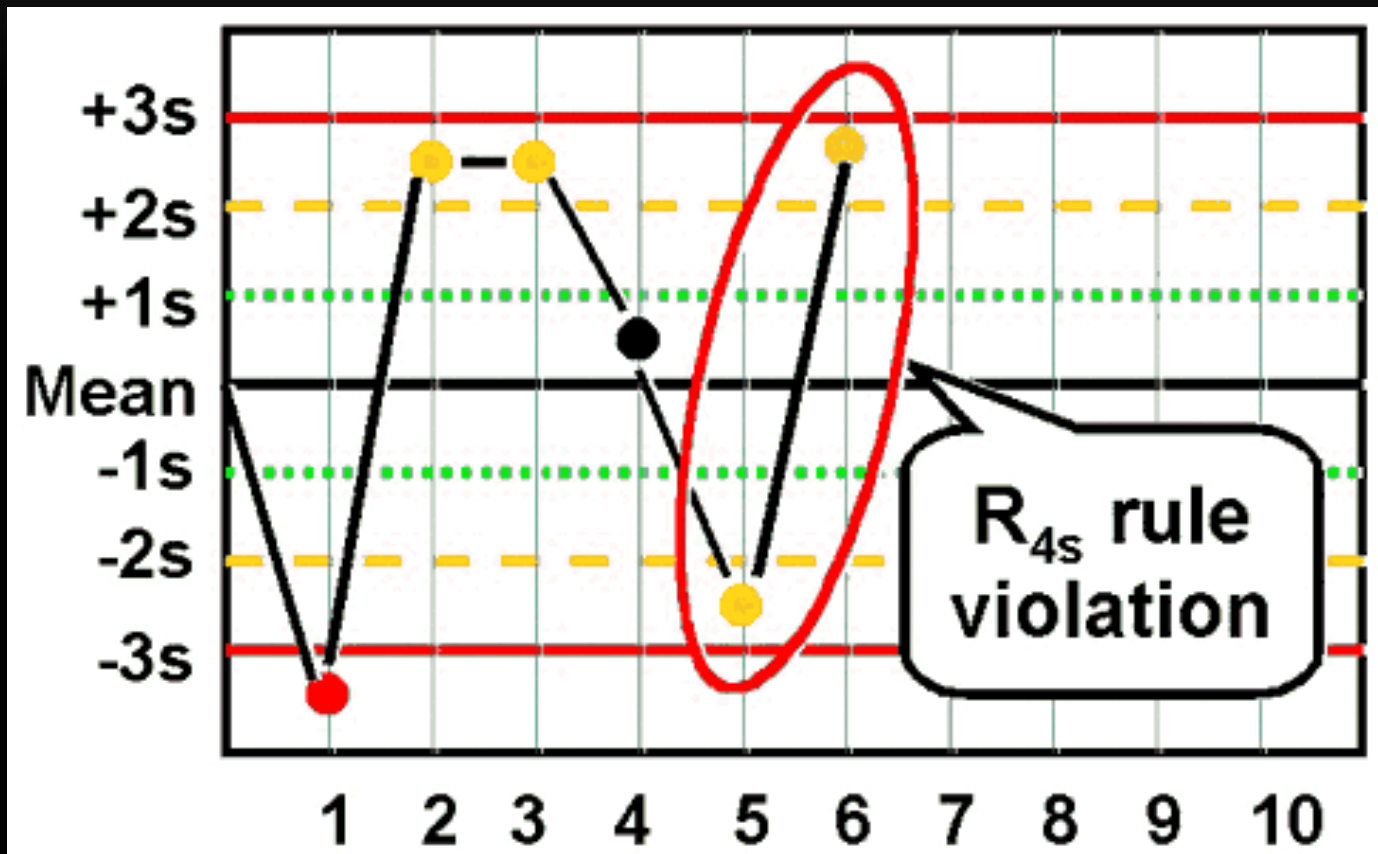
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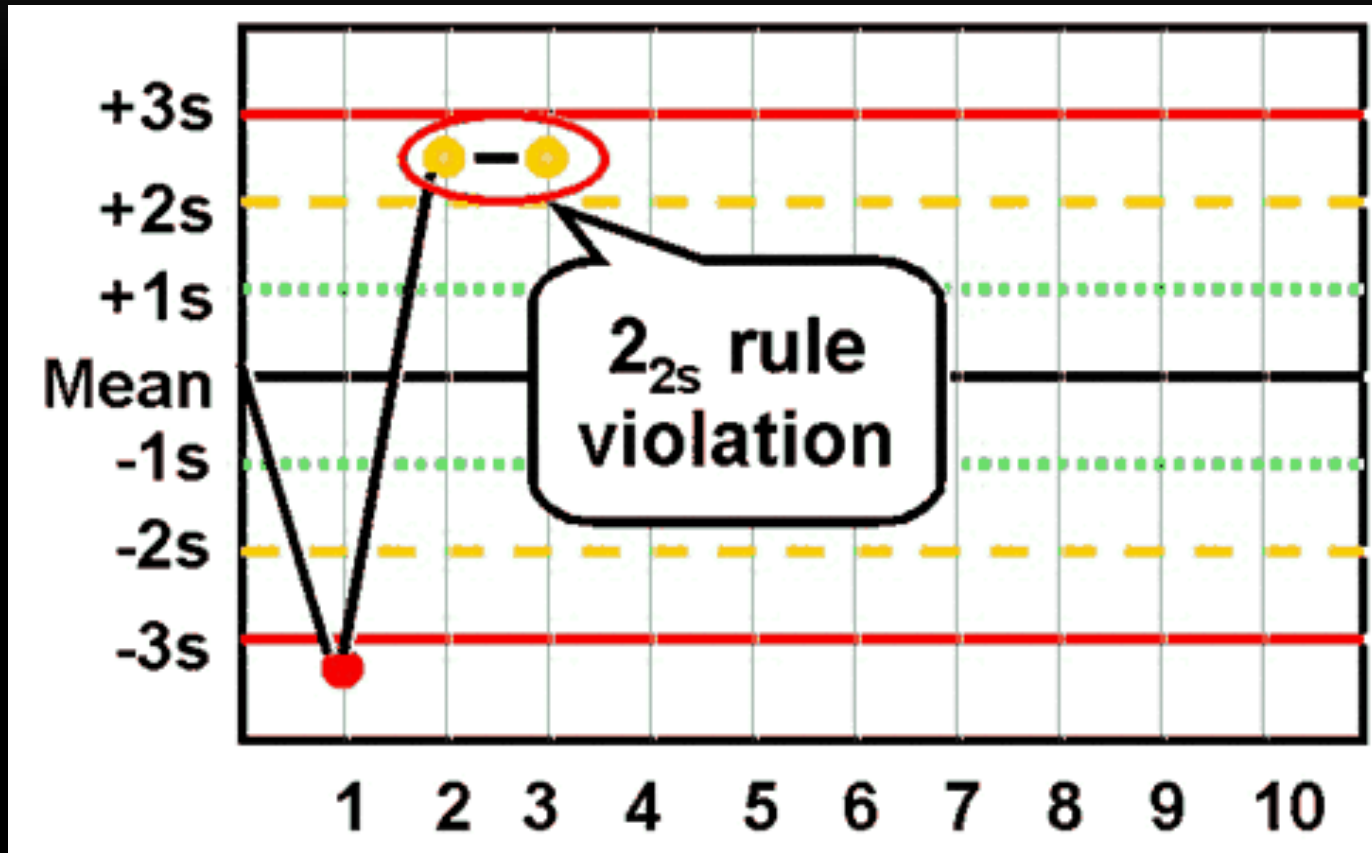
FUTURE WESTGARD RULES



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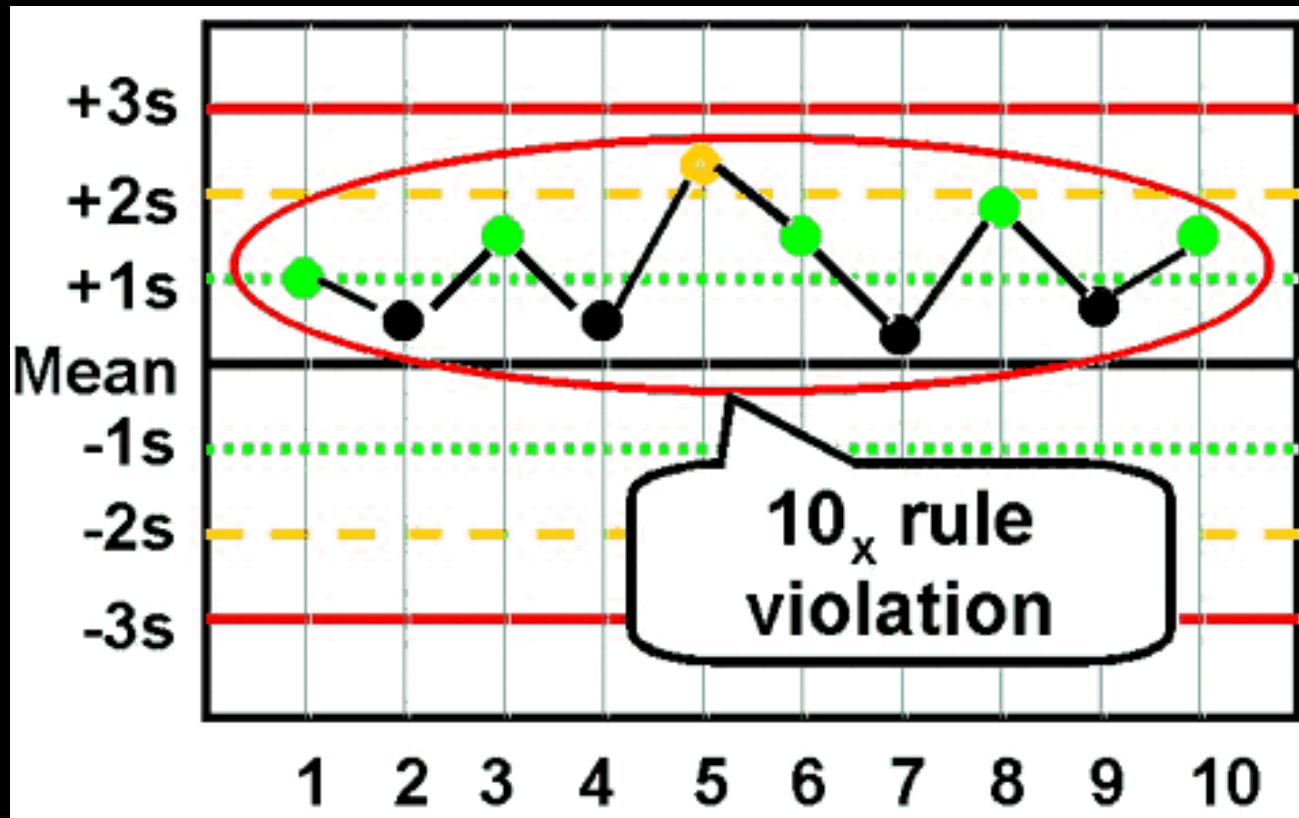


FUTURE WESTGARD RULES

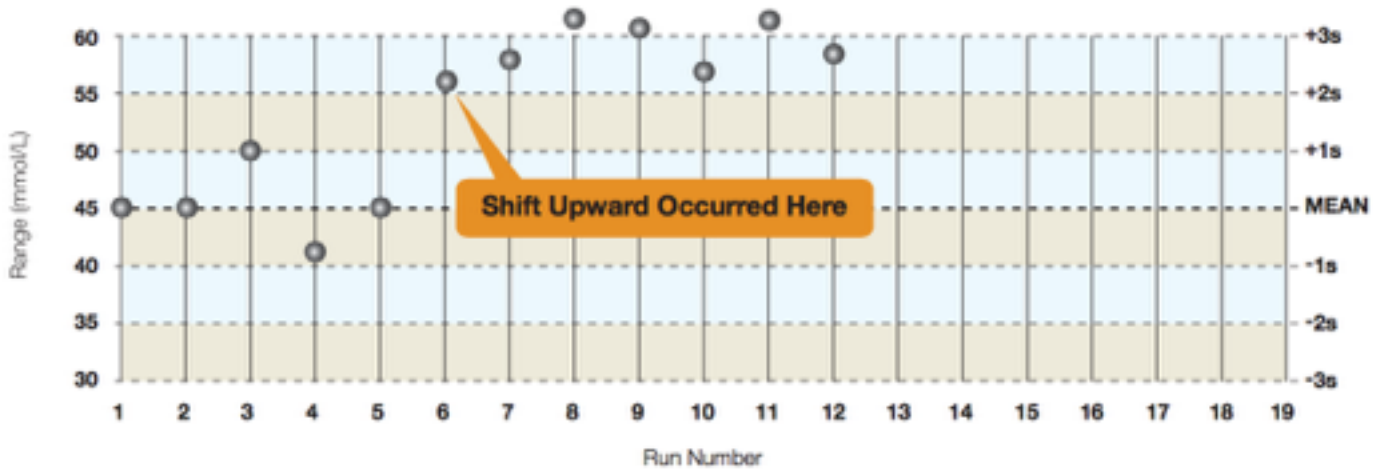
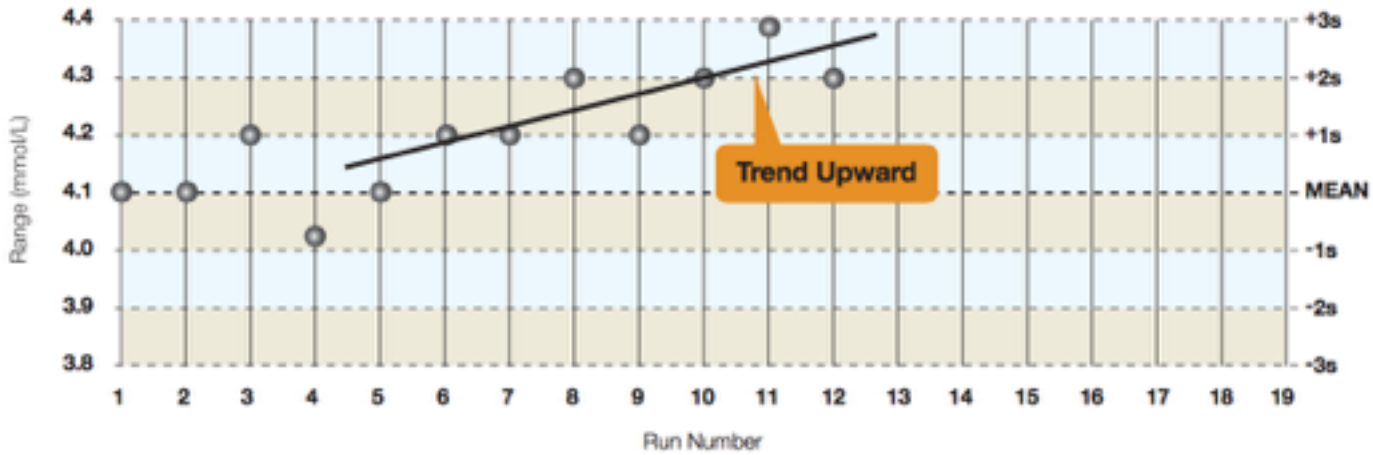


FUTURE WESTGARD RULES

- We will use this rule with an additional 1-2S rule before it becomes a rejection

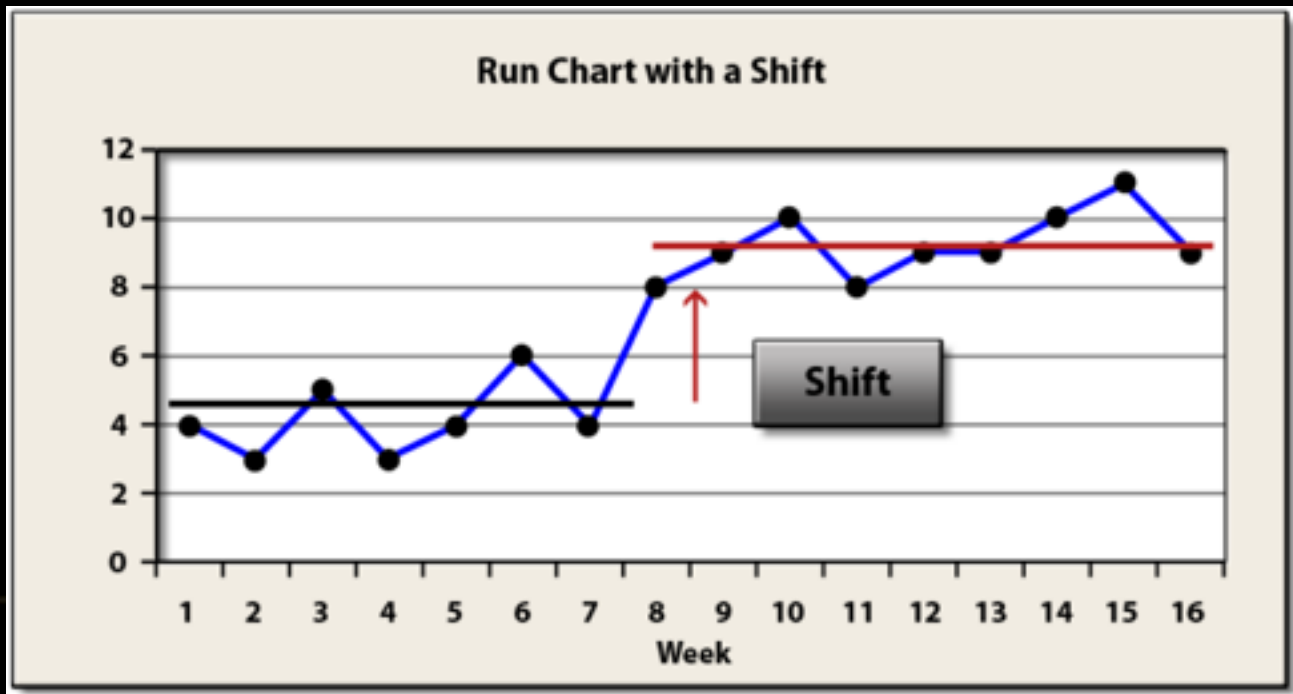


SHIFTS AND TRENDS



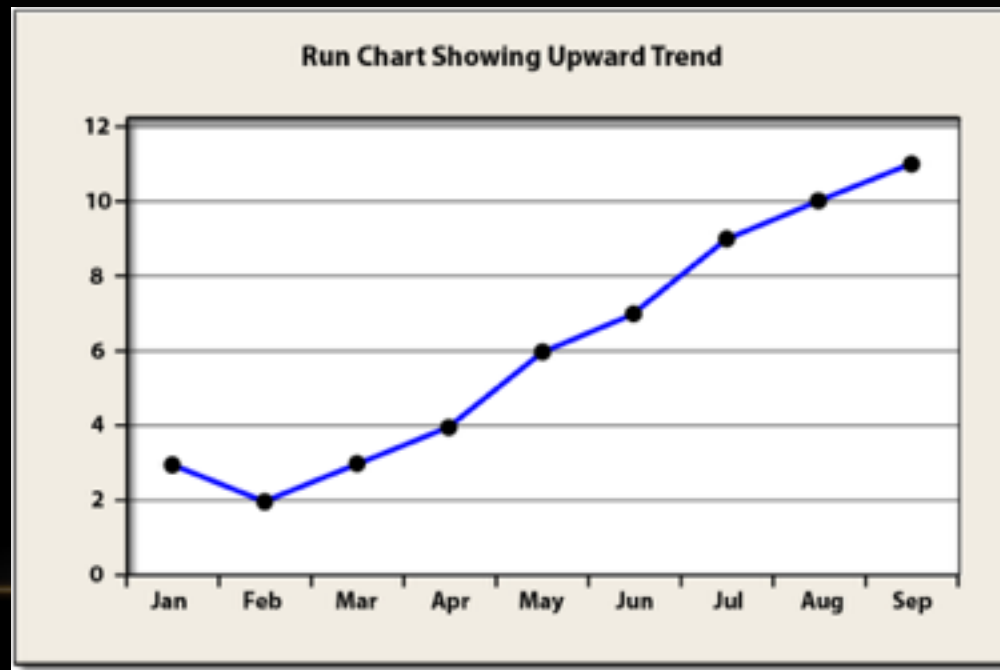
HOW CAN WE USE LEVY JENNINGS

- Shift is a sudden change that then stays at that level
 - could be change in reagent formulation, failure or change in light source, change in temperature, etc



TREND

- Gradual loss of reliability in the test system
 - accumulation of debris, light source deteriorating, old reagents, old control material



OTHER STATISTICS INVOLVED

- CV (Coefficient of Variation)
 - standard deviations increase with an increase in analyze concentration, so this helps alleviate that increase
 - CV allows us to look at precision of the assay
 - across lot numbers, method comparison,

$$\mathbf{CV = (s \div \bar{X}) 100}$$

Where:

s = standard deviation

\bar{X} = mean

OTHER STATISTICS INVOLVED

- Coefficient of Variation Ratio:

$$\text{CVR} = \frac{\text{Within Laboratory CV}}{\text{Peer Group CV}}$$

- Anything less than 1.0 indicates your laboratory's precision is better than the peer group
- If the ratio is greater than 1.5, an investigation if warranted
- If greater than 2.0, it is time for corrective action

OTHER STATISTICS INVOLVED

- Standard Deviation Index:

$$\text{SDI} = \frac{(\bar{X}_{\text{Lab}} - \bar{X}_{\text{Group}})}{S_{\text{Group}}}$$

- A perfect comparison between labs would be 0.0
- Anything less than 1.25 is acceptable
- >1.5 needs an investigation into the test system
- >2.0 needs corrective action

REMINDER - FUTURE WESTGARD RULES

