

# Westgard Rules

The Nitty Gritty of Quality Control

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# What is QC?

## Why do we do it?



# Calculations

➤ Mean =  $\bar{X} = \sum X_i / n$

$\sum$  = Sum of

$X_i$  = individual measurements

$n$  = number of measurements

# Calculations

## ➤ Standard Deviation

$$S = \sqrt{\sum (X_i - \bar{X})^2 / (n-1)}$$

# Calculations

## ➤ Coefficient of Variation

$$CV = (S / \bar{X})100$$

signifies random error or imprecision

# Historically

## ➤ 95% Confidence limit

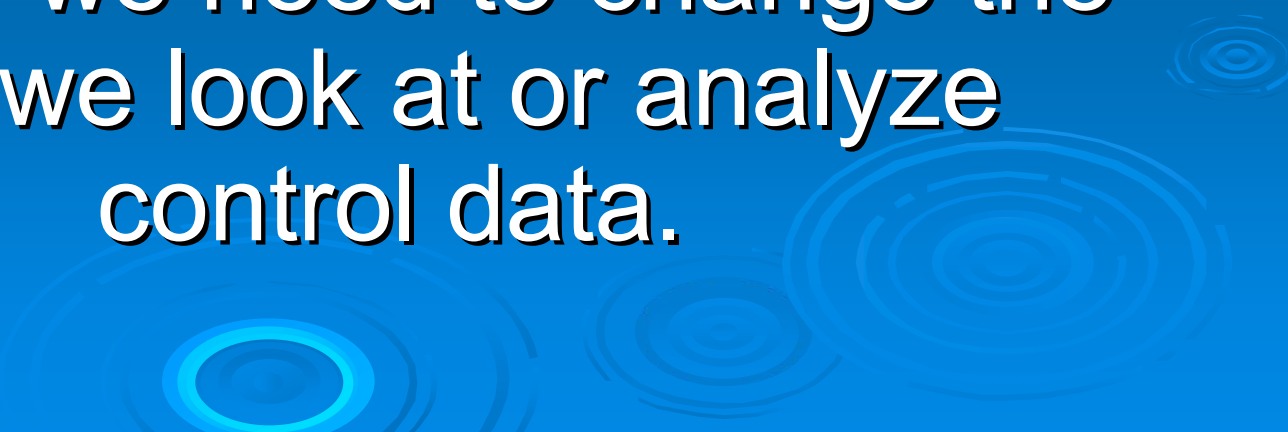
- 95 of every 100 normal patient's results would be within  $\pm 2 S$  of the mean
- 1 of every 20 controls could be out of range and that is to be expected – the analytical run would be rejected
- This rule is called the  $1_{2s}$  rule and gives a high level of false rejections or false alarms

# Rates of False Rejection

- With 1 control – false rejection rate is 5%
- With 2 controls – false rejection rate is 9%
- With 3 controls – false rejection rate is 14%

False rejections can  
become very expensive.

To diminish the false rejection  
rate without compromising  
quality, we need to change the  
way we look at or analyze  
control data.

The background of the slide is a solid blue color. In the lower right quadrant, there are several sets of concentric circles, resembling ripples in water, rendered in a lighter shade of blue. These circles are centered at different points, with one set being particularly prominent near the bottom center and others scattered towards the right edge.



# Westgard Rules

- Development of 'multi-rule' QC
  - Rules that are used in conjunction with each other to provide a high level of error detection while reducing the incidence of false rejection
  - There are different combinations of rules depending on the number of controls being used, the total allowable error and your instrumentation

# Typical Rule Combinations

- For controls run in multiples of 2 (typically chemistry)
  - $1_{3S} / 2_{2S} / R_{4S} / 4_{1S} / 10_X$
- For controls run in multiples of 3 (typically hematology, coagulation, blood gases)
  - $1_{3S} / 2 \text{ of } 3_{2S} / R_{4S} / 3_{1S} / 12_X$

# Rules

- $1_{2s}$  – refers to the historical rule of plus/minus  $2_s$  from the mean
  - with multi-rules: a warning rule to trigger careful inspection of control data
- $1_{3s}$  – refers to plus/minus  $3_s$ 
  - a run is rejected when a single control exceeds the mean  $\pm 3_s$
- $2_{2s}$  – reject the run when 2 consecutive controls exceed the mean  $\pm 2_s$

# Rules

- $R_{4s}$  – when 1 control in a group exceeds the mean  $\pm 2_s$  and another control exceeds the mean in the other direction by  $2_s$ 
  - reject run
- $4_{1s}$  – when 4 consecutive control measurements are on one side of the mean either  $\pm 1_s$ 
  - Warning rule or a rejection rule depending on the accuracy of your instrument

# Rules

- $10_x$  – 10 consecutive control measurements fall on one side of the mean
  - If within 1 s, warning
  - If between 1 and 2 s, reject
- $2\text{of}3_{2s}$  – reject the run when 2 of 3 controls exceed the mean  $\pm 2_s$

# Rules

- $9_x$  – reject when 9 consecutive control measurements fall on one side of the mean
- $7_T$  – reject when seven control measurements trend in the same direction, either higher or lower

# Random Errors

- Random Errors – these errors affect the reproducibility or precision of a test system.
  - Usually  $1_{3s}$  or  $R_{4s}$  rules
  - can be due to variations in line voltage, pipettes, dispensers, contamination, volume dispensed, bubbles in lines of reagents, etc.

# Systematic Errors

- Systematic Errors – (bias, shifts and trends) – these errors affect the accuracy of the test system.
  - Usually  $2_{2s}$ ,  $4_{1s}$ , or  $10_x$  rules
  - can be due to calibration lot changes, temperature changes in incubator unit, light source deterioration, electronics, reagent lot changes, etc.



# Accuracy –vs- Precision

- Accuracy – how close you are to the correct value
- Precision – how close together your results are to each other



# Define Your QC Protocol

- Each lab needs to define its' QC protocol based on the number of controls used, the accuracy of the instrumentation, the total allowable error, etc.
- How do you interpret the results of the controls?
- What do you do based on those results?

# QC Protocol - example

## 1. Statistical QC Procedure

- a) Use a  $1_{2s}$  as a warning rule and the  $1_{3s} / 2_{2s} / R_{4s} / 4_{1s} / 10_x$  as rejection rules with 2 control measurements

## 2. Analyze control materials

- a) Analyze 1 sample of each level of control.

# QC Protocol

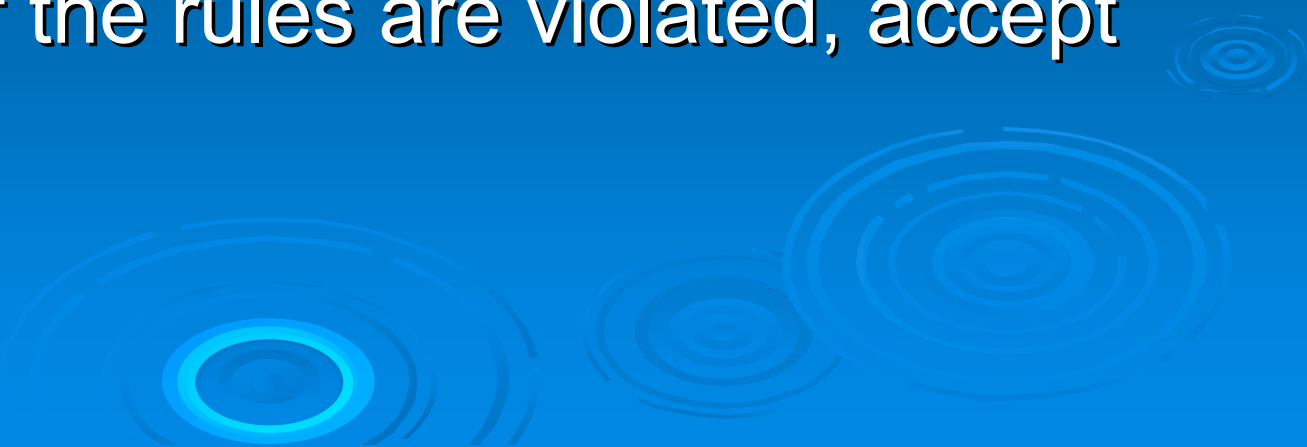
## 3. Interpretation of warning rules

- a) If both control results are within  $2s$ , report the results. If one control exceeds a  $2s$  limit, follow flow chart and if any rule is violated, reject run.

## 4. Within run inspection

- a) Inspect control results by applying rules:  $1_{3s}$  in each run and  $2_{2s}$  and  $R_{4s}$  across levels.

# QC Protocol

5. Inspect controls across runs
    - a) Apply the  $2_{2s}$  rule with each level across the last two runs.
    - b) Apply the  $4_{1s}$  rule within each control level across the last 4 runs and across the last 2 runs of both levels.
  6. If none of the rules are violated, accept the run.
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# Problem Solving

➤ If a run is out of control, investigate the process and correct the problem.

❖ **Do not automatically repeat the control!**


**What do you need to do to investigate the process?**

- Determine the type of error based on your rule violation (random or systematic)
- Relate the type of error to the potential cause
- Inspect the testing process and consider common factors on multi-test systems
- Relate causes to recent changes
- Verify the solution and document the corrective action

To help us investigate  
the problem, we need  
to look at our QC / QA  
Records

What records do we need?

# Instrument Information & Validation

- Reportable range (linearity)
  - Precision and Accuracy studies
  - Analytical sensitivity / specificity
  - Reference range
  - Proficiency testing results
  - Reagent logs
  - Problem logs
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# QC Documents / Logs

- Preventative maintenance
  - Scheduled and unscheduled
  - Reason for maintenance
  - Frequency and length of downtime
  - Signs of instrument deterioration
- Calibration and Calibration Verification
  - Lot numbers and expiry of calibrators, dates of calibration, reason for calibration/verification, and by whom
- Instrument function and temperature checks
- Previous Control runs

All of these documents can be helpful when investigating errors!

# Why use Westgard Rules?

- We use Westgard Multi-rules to help us reduce costs while maintaining a high level of certainty that our analytical process is functioning properly.
- In other words to diminish the false rejection rate without compromising quality.



# Questions???

