Westgard Rules

The Nitty Gritty of Quality Control

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What is QC?

Why do we do it?
Calculations

- Mean = \( \bar{X} = \frac{\sum X_i}{n} \)
  - \( \sum \) = Sum of
  - \( X_i \) = individual measurements
  - \( n \) = number of measurements
Calculations

- Standard Deviation

\[ S = \sqrt{\frac{\sum (X_i - \bar{X})^2}{n-1}} \]
Calculations

- Coefficient of Variation

\[ CV = \left( \frac{S}{\bar{X}} \right) \times 100 \]

signifies random error or imprecision
Historically

- **95% Confidence limit**
  - 95 of every 100 normal patient’s results would be within +/- 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.
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)
  - $1_{3S} / 2_{of3_{2S}} / R_{4S} / 3_{1S} / 12_X$
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 $\pm 2s$ and another control exceeds the mean in the other direction by $2s$
  - reject run

- $4_{1s}$ – when 4 consecutive control measurements are on one side of the mean either $\pm 1s$
  - 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

- $2_{of3_{2s}} -$ 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.
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
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???