Westgard Rules

The Nitty Gritty of Quality Control

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What is QC?

Why do we do it?

Calculations

- Mean = $\overline{X} = \sum X_i / n$

  $\sum$ = Sum of

  X_i = individual measurements

  n = number of measurements

Calculations

- Standard Deviation

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

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 +/- 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} / $2of3_{2S}$ / 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 ± 3_s
- 2_{2s} – reject the run when 2 consecutive controls exceed the mean ± 2_s

Rules

- R_{4s} – when 1 control in a group exceeds the mean ± 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 ± 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

- $2of3_{2s}$ – reject the run when 2 of 3 controls exceed the mean ± 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???