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Research Article

Quality Control using Westgard Rules in Blood Analyzer Diagnostics

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Abstract: *In clinical chemistry laboratories, accurate and reliable testing is critical for diagnosing and managing disease. Blood analyzers, which automate the testing of various biochemical parameters, rely heavily on robust quality control (QC) measures to ensure data integrity. Westgard Rules, a statistical approach formulated by James Westgard, are widely employed to assess whether an analytical run is within control limits. These rules are applied to quality control data plotted on Levey-Jennings charts and are instrumental in distinguishing between random and systematic errors. The selection and application of these rules, whether single or multi-rule sets, significantly impact error detection and false rejection rates. This paper explores the importance of Westgard Rules in maintaining analytical precision, elaborates on each rule, and discusses their practical application across various testing environments. Additionally, the paper highlights how minimizing false rejections and maximizing error detection contributes to both operational efficiency and cost-effectiveness in clinical laboratories.*

Keywords: *Clinical Chemistry, Blood Analyzers, Quality Control (QC), Westgard Rules, Levey-Jennings Chart, Systematic Error, Random Error, Error Detection (Ped).*

I. INTRODUCTION

The field of Clinical Chemistry is involved in biochemical analysis of body fluids especially Blood, Urine and Plasma in support of diagnosis and treatment of diseases. It involves testing using chemical reactions to identify or quantify levels of chemical compounds in body fluids. Testing in Clinical Chemistry Laboratory is performed on highly automated analyzers to reduce manual errors. The analyzers utilize various methods like immunoassays, spectrophotometry, mass spectrometry etc. to assess a variety of analytes in electrolyte, cardiac panels, lipid, basic and comprehensive metabolic, liver, renal etc.

Quality control is crucial when it comes to Clinical Chemistry on Blood analyzers. While the analyzers come with their own software to monitor quality on the individual analyzers, it is imperative that the data is compared across multiple analyzers, across multiple sites or global peer data to identify trends in the readings. The QC Lots from vendors come with some form of unique identifier (based on various factors e.g. lots and date of manufacture) with pre-defined limits obtained from testing by the manufactures. And the analyzers run these QC Lots daily before testing any Patient sample to ensure the analyzer remain in statistical control and evaluate potential causes if shifts and outliers are observed.

In laboratories Westgard Rules by James Westgard is widely used, the rules Westgard formulated are to decide whether an analytical run is In-Control or Out-of-Control. These rules can be applied as single rules and as group of rules (multi-rules). Westgard rules can be applied only if your QCs are plotted with the range of +/- 3SD.

Two key factors to keep in mind in selection of rules are:

- Maximize Error Detection: Percent error detection (P ed) > 90%
- Minimize False Rejection: Percent False Rejection (P fr) < 5%

In the below sections we shall explore the details of Westgard rules. In Clinical Chemistry single rule QC procedure uses a single set of control limits such as a Levey-Jennings chart with control limits set as either the mean +/- 2SD (standard deviation) or the mean +/- 3 SD. A well-known Westgard Multirule QC using 5 different control rules to judge an acceptable

analytical run. In ImmunoAssays (Urine based drug threshold detection), Hematology (study of blood and blood disorders) Westgard rules are generally used with 2 or 4 control measurements per run, which means they are appropriate when two different control materials are measured 1 or 2 times per material, which is the case in many chemistry applications.

II. WESTGARD RULES

A. The Westgard individual rules are defined in the below section:

a)1:2S: Control value is outside +/- 2SD limits

This control rule used in Levey-Jennings chart, when the control limits are set Mean +/- 3SD. This rule is used as a warning/beginning of a systematic error. It should trigger inspection of control by following below rejection rules.

Note: If only one level of QC is being run in the Lab, 1:2S has to be a rejection rule.

Figure 1. 1:2S: Control value is outside +/- 2SD limits

b) 1:3S: Control value is outside +/- 3SD limits

This control rule used in Levey-Jennings chart, when the control limits are set Mean +/- 3SD. This rule identifies unacceptable Random error or possibly the beginning of a large systematic error. The run is rejected when a single control measurement exceeds the Mean +/- 3SD control limits.

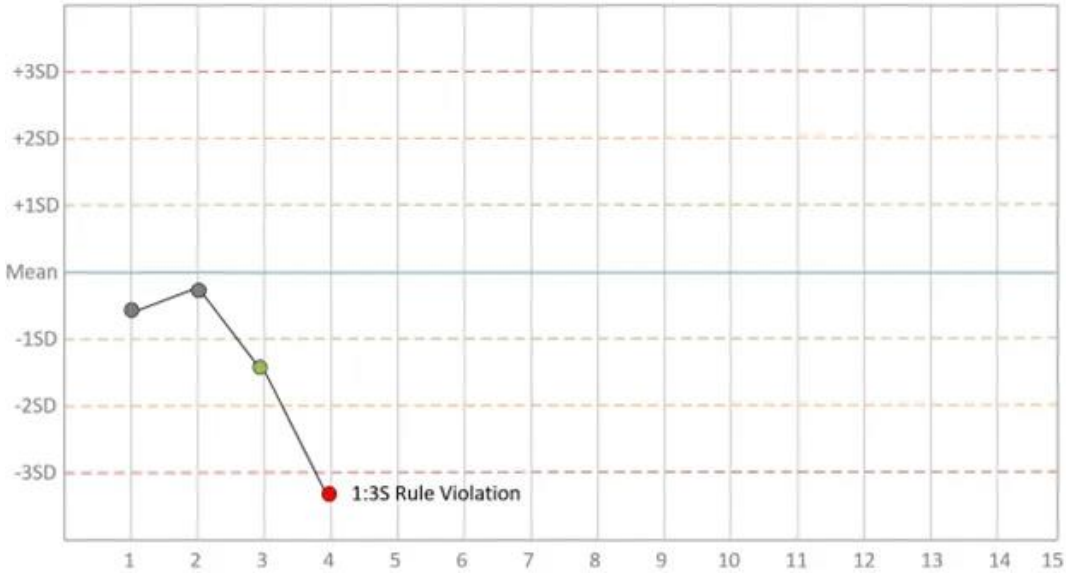

Figure 2. 1:3S: Control value is outside +/- 3SD limits

c) 2:2S: 2 consecutive control values exceed the same Mean plus 2SD OR Mean minus 2SD.
Reject when 2:2S occurs consecutively in the control measurements.

Two consecutive QC results greater than 2SD on the same side of the Mean. This rule identifies systematic error. There are two applications to this rule:

- Within-Run (in the 2 levels of QA in the same run)
- Across runs (In the same QC in 2 consecutive runs)

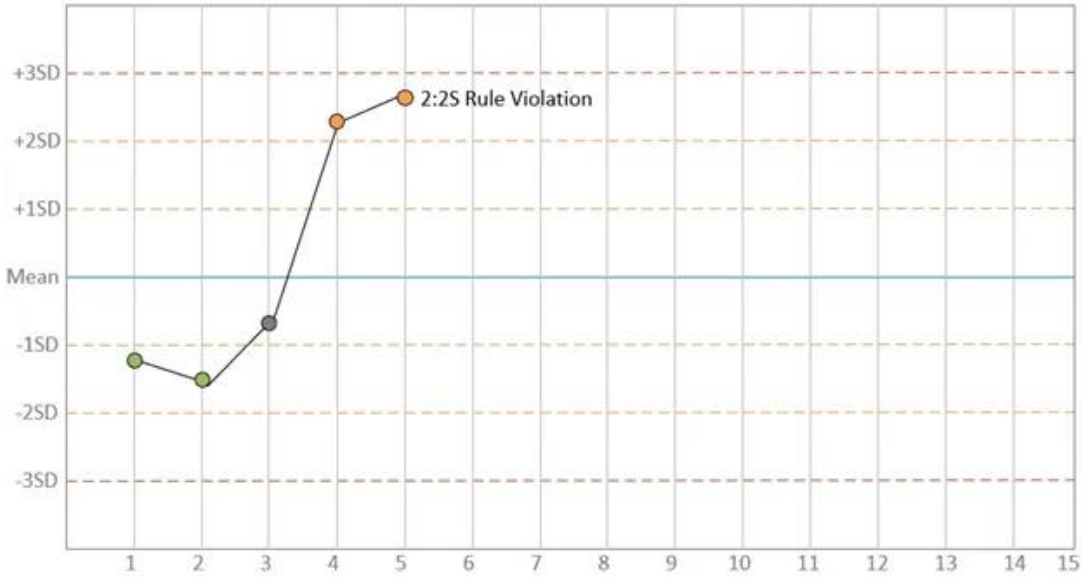

Figure 3. 2:2S: 2 consecutive control values exceed the same Mean plus 2SD OR Mean minus 2SD.

d) R:4S: When 1 value exceed +2SD and another exceeds -2SD limits.

Reject when one control measurement within the run and in a group exceeds the Mean +2SD and another exceeds the Mean -2SD. This may happen when 2 levels of control material with 4 SD difference between the 2 data points. R:4S denotes a Random Error. This rule is applicable even when the sum of the SD of the two material > 4SDs within the same run.

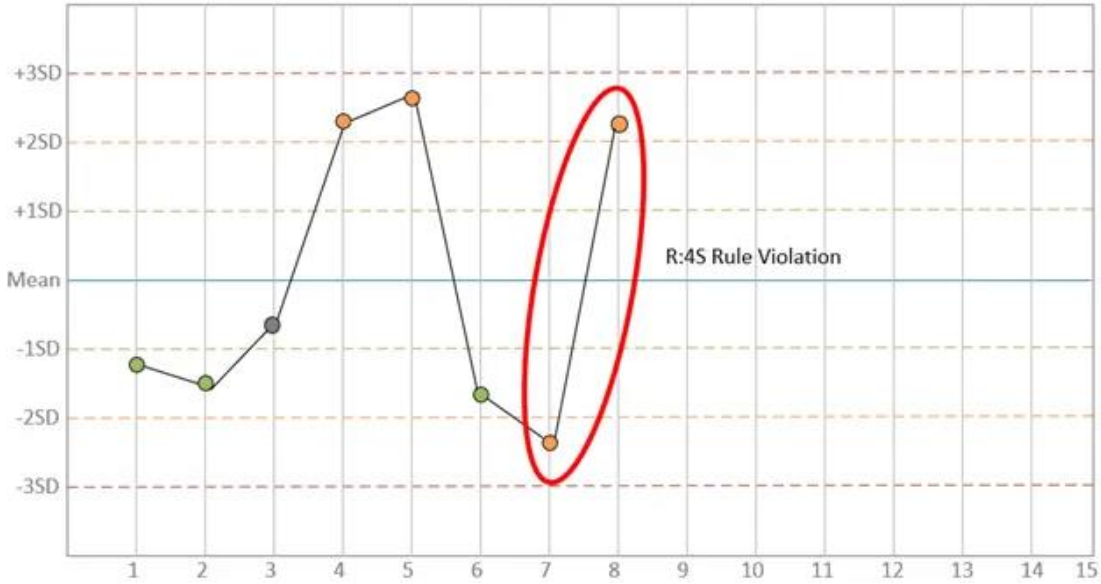

Figure 4. R:4S: When 1 value exceed +2SD and another exceeds -2SD limits.

e) 3:1S: When 3 consecutive values exceed the same mean +/- 1SD control limit.

This rule denotes a Systematic error. These are within control material or across control materials. Within control material violations indicate systematic bias in a single area of the curve, which the violation of across control materials indicates a systematic error over a broader concentration.

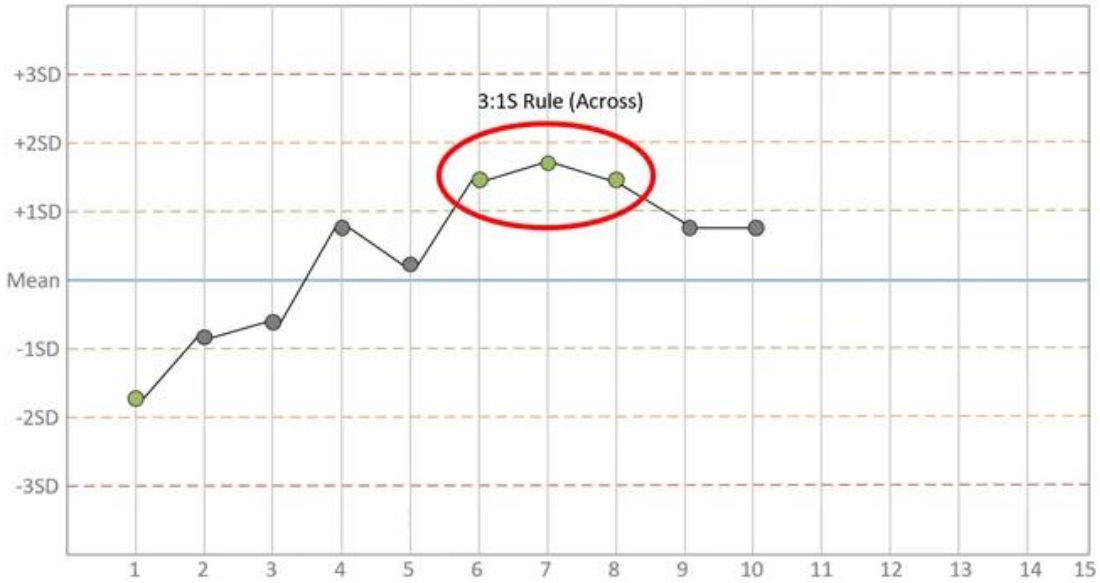

Figure 5. 3:1S: When 3 consecutive values exceed the same mean +/- 1SD control limit.

f) 4:1S: When 4 consecutive values +/- 1SD limits

Reject when 4 consecutive control measurements exceed the same Mean +1S or the same Mean -1S limits.

These are within control material or across control materials. Within control material violations indicate systematic bias in a single area of the method curve, while violation of the across control materials application indicates systematic error over a broader concentration.

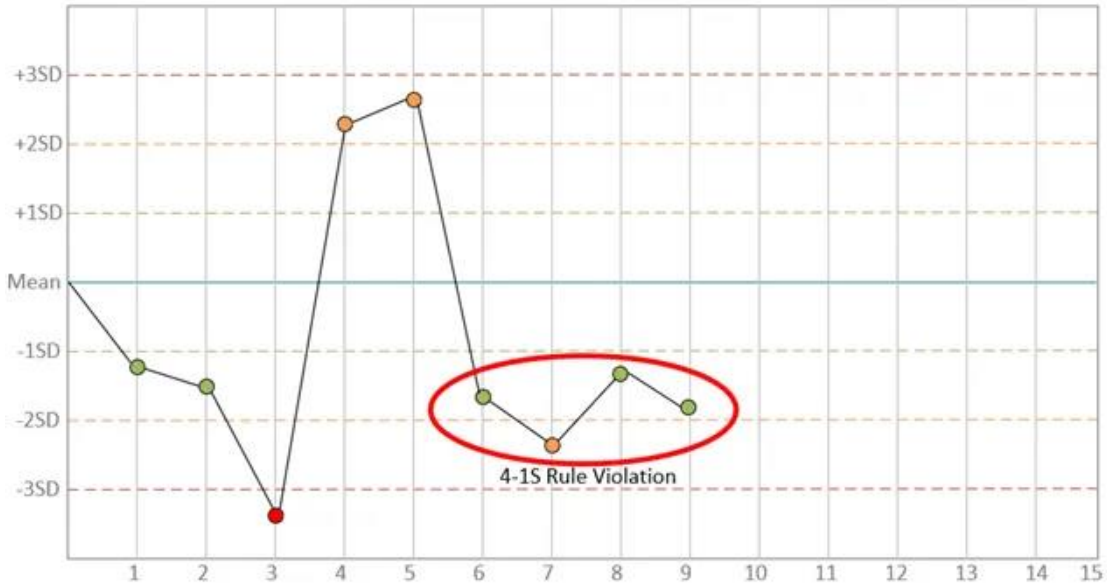

Figure 6. 4:1S: When 4 consecutive values +/- 1SD limits

g)6X, 8X, 9X, 10X, 12X: when 6, 8, 9, 10, 12 consecutive values fall on one side of the Mean.

6X, 8X, 9X, 10X, 12X denotes Systemic Errors. It is a sign of bias buildup. Reject when 10 consecutive control measurements fall on one side of the Mean. Within control materials and Across control materials are the two methods.

Within control material violations indicate systematic bias in a single area of the method curve, while violation of the across control materials application indicates systematic error over a broader concentration.

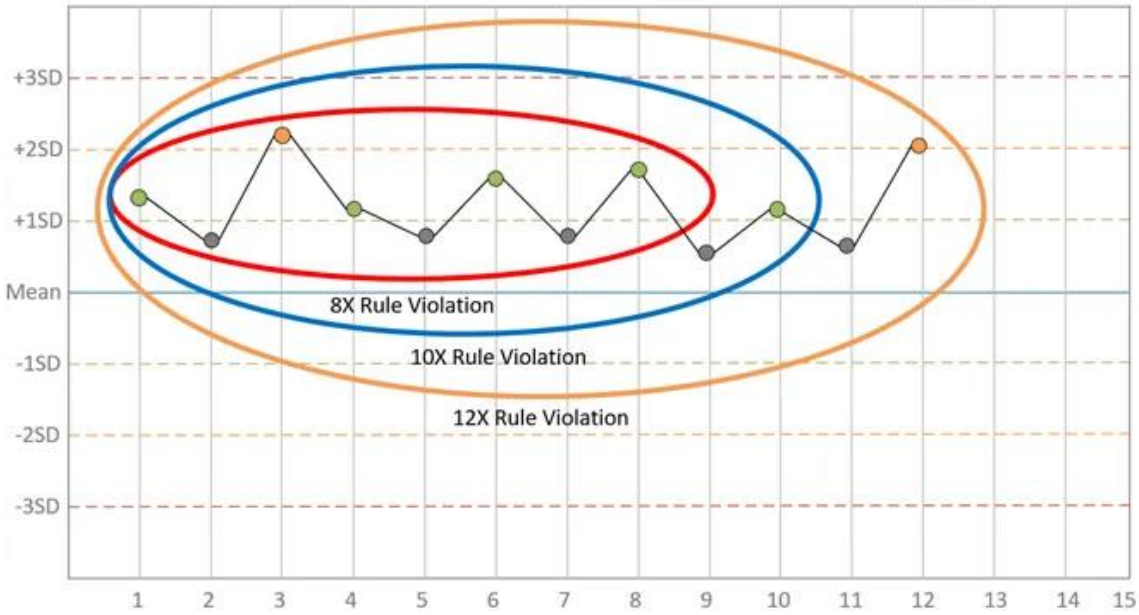

Figure 7. 6X, 8X, 9X, 10X, 12X: when 6, 8, 9, 10, 12 consecutive values fall on one side of the Mean.

h) 2of3:2S: When 2 out of 3 values exceed +/- 2SD.
Reject when 2 out of 3 control measurements exceed the same Mean plus 2SD or Mean minus 2SD limits.

Figure 8. 2of3:2S: When 2 out of 3 values exceed +/- 2SD.

i) 7T: When 7 values trend in the same direction progressively higher or lower.

Reject when 7 control measurements trend in the same direction, either they are progressively higher or progressively lower. The rule is applicable across runs. But whenever one level is trending upward/downward for 5–6 times, and the other levels are doing the same, It should be investigated.

Figure 9. 7T: When 7 values trend in the same direction progressively higher or lower.

In software we give the flexibility to choose single/multiple Westgard Rules based on individual Lab's quality standards.

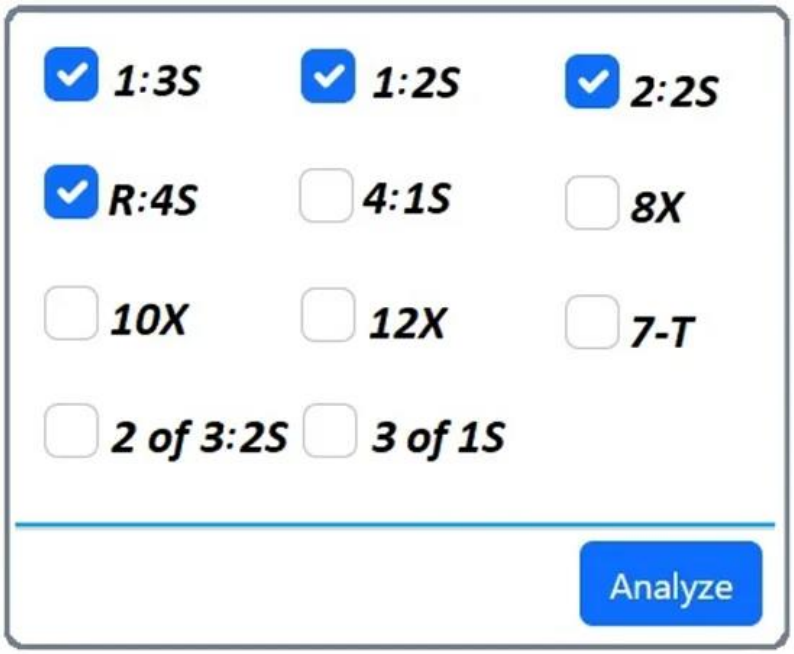

Figure 10. Single/Multiple Westgard Rules

We use the Levey Jennings Chart to establish Means and Standard Deviations. We plot the Date/Time on the X-axis. The Y-axis plot the Mean, +/-1SD, +/-2SD, +/-3SD. A sample Levey-Jennings chart is shown below. The chart shows a +2SD violation indication with a different icon style.

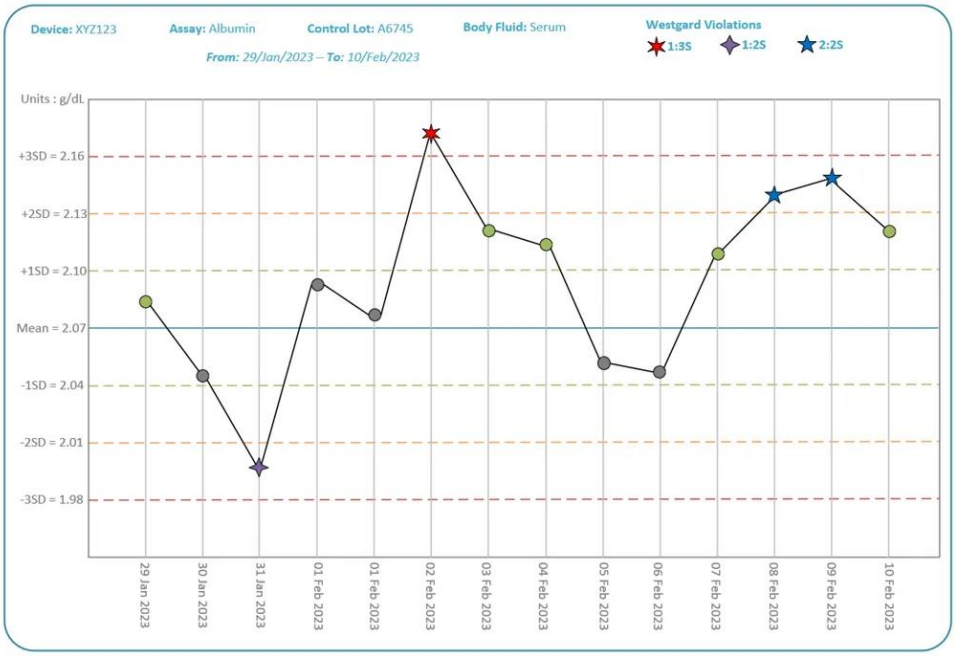

Figure 11. We plot the Date/Time on the X-axis

As said earlier, we need to Minimize False Rejection, there is a financial consideration here, we cannot reject good runs because there is a doubt. We need to minimize False Rejections. In QC rule, we have to understand 2 sets of nomenclatures.

- N and L, where N = Number of violations involved, and L = Limit Exceeded.
- Within Run/ Across Material, where 2/3 levels of QA in the same run.
- Across Run/ Within-Material, where same level (material) of QC but in 2 or more consecutive runs.

Below flow chart shows the Multi-Rule QC, which uses 5 different control rules to judge an acceptable run.

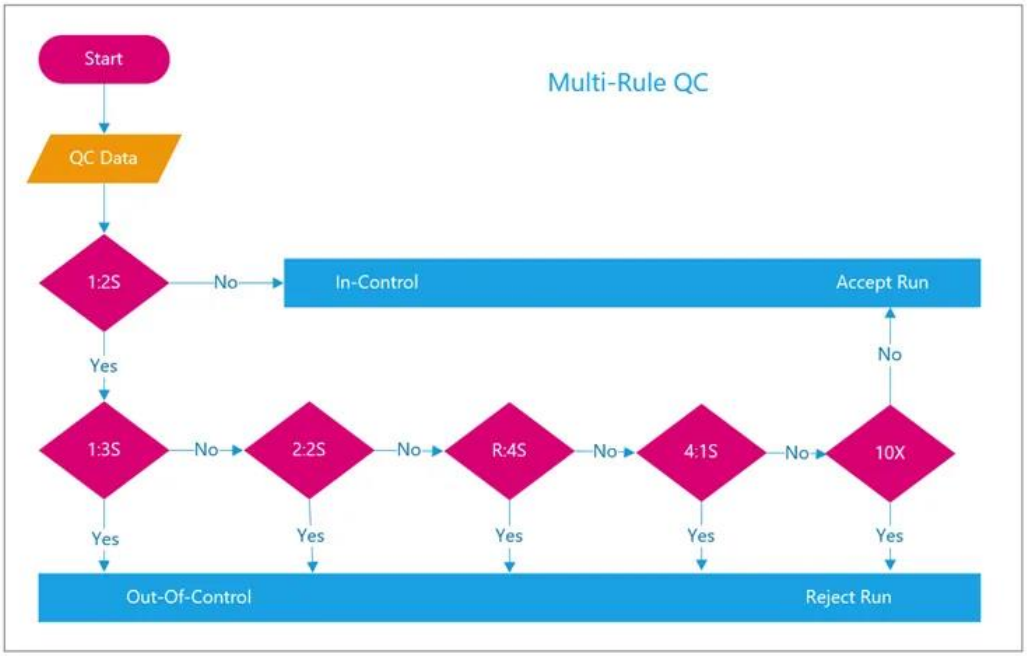

Figure 12. Multi-Rule QC, which uses 5 different control rules to judge an acceptable run.

A single rule QC with low false rejections should be adequate for error detection in most cases. Rules like 1:3S which have low false rejection rates and medically important errors can be detected > 90% of the time, then a single rule QC

procedure should be adequate. In cases where >90% error detection cannot be provided by a single rule QA, then multirole QC procedures should be considered. In general, we should avoid 1–2S control limits single rule QC in highly automated and precise analyzers, other single rule QCs is adequate to minimize waste and reduce costs. To use Multirule QA, we may need to define the quality requirements of each individual tests. Analyze the precision and accuracy achieved by your method. Also it's important to keep track of Pfr (false rejection) and Ped (error detection) of the QC procedures. Ideally Ped should be > 90% and Pfr should be < 5%.

References

1. Westgard, J.O., Barry, P.L., Hunt, M.R., & Groth, T. (1981). A multi-rule Shewhart chart for quality control in clinical chemistry. *Clinical Chemistry, 27*(3), 493–501.
2. Westgard, J.O., & Barry, P.L. (1986). Improving Quality Control by use of Multirule Control Procedures. In *Cost-Effective Quality Control: Managing the quality and productivity of analytical processes* (pp. 92–117). AACC Press.
3. Westgard, J.O., & Klee, G.G. (1996). Quality Management. In *Fundamentals of Clinical Chemistry* (4th ed., pp. 211–223). WB Saunders Company.
4. Cembrowski, G.S., & Sullivan, A.M. (1996). Quality Control and Statistics. In *Clinical Chemistry: Principles, Procedures, Correlations* (3rd ed., pp. 61–96). Lippincott.
5. Cembrowski, G.S., & Carey, R.N. (1989). Quality Control Procedures. In *Laboratory Quality Management* (pp. 59–79). ASCP Press.
6. Petersen, P.H., Ricós, C., Stöckl, D., Libeer, J.C., Baadenhuijsen, H., Fraser, C., & Thienpont, L. (1996). Proposed guidelines for the internal quality control of analytical results in the medical laboratory. *European Journal of Clinical Chemistry and Clinical Biochemistry, 34*(12), 983–999.
7. Bishop, J., & Nix, A.B. (1993). Comparison of quality-control rules used in clinical chemistry laboratories. *Clinical Chemistry, 39*(8), 1638–1649.
8. Carey, R.N. (1991). Multirule quality control procedures. *Annali dell'Istituto Superiore di Sanità, 27*(3), 419–425.
9. Barry, P.L., & Westgard, J.O. (1986). Improving Quality Control by use of Multirule Control Procedures. In *Cost-Effective Quality Control: Managing the quality and productivity of analytical processes* (pp. 92–117). AACC Press.
10. Westgard, J.O., & Klee, G.G. (1994). Quality Management. In *Textbook of Clinical Chemistry* (2nd ed., pp. 548–592). WB Saunders Company.
11. Groth, T., & Westgard, J.O. (1981). Performance characteristics of rules for internal quality control: probabilities for false rejection and error detection. *Clinical Chemistry, 27*(9), 1536–1545.
12. Bishop, J., & Nix, A.B. (1993). Comparison of quality-control rules used in clinical chemistry laboratories. *Clinical Chemistry, 39*(8), 1638–1649.