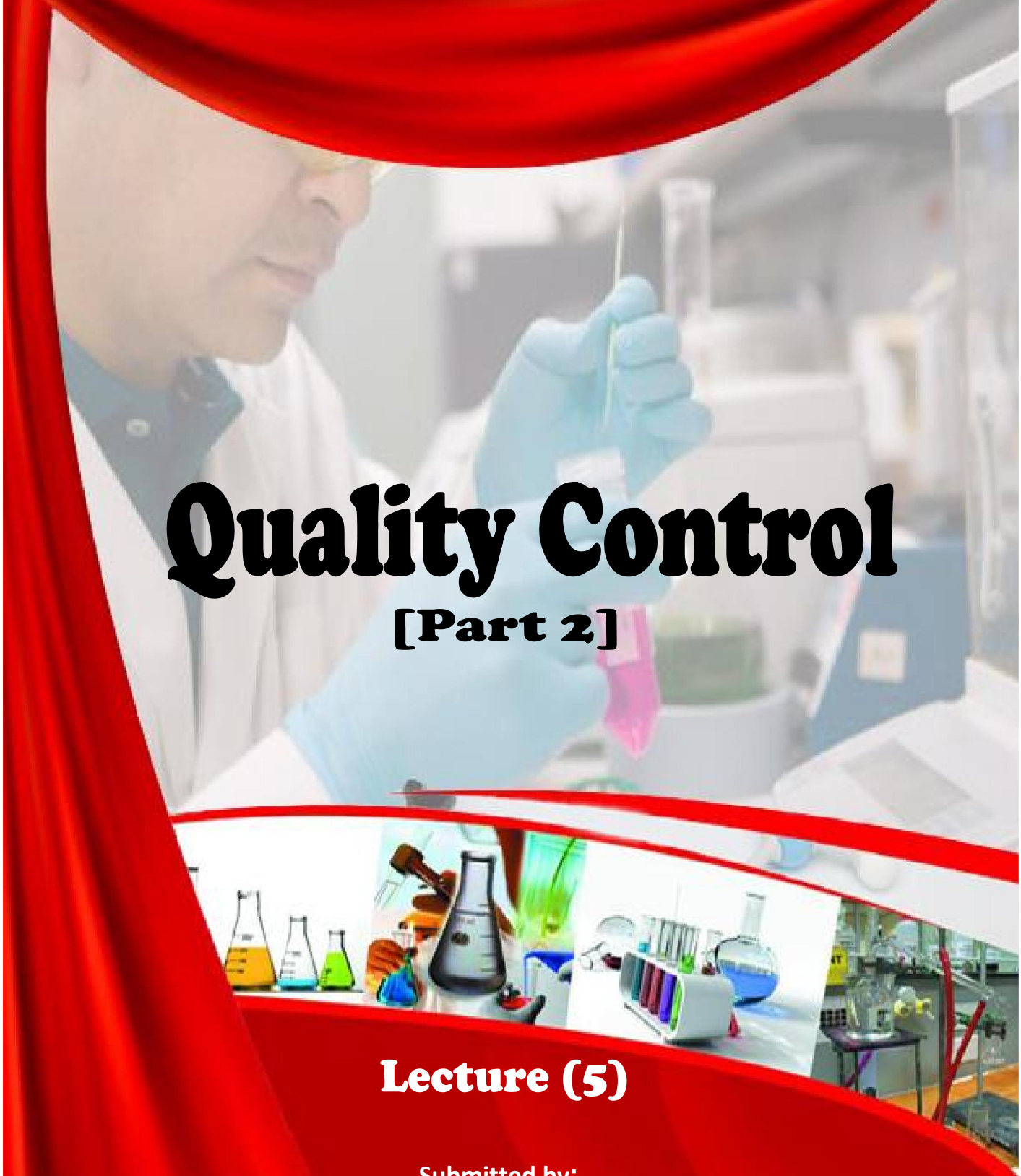
Al-Rasheed University College
Medical Analysis Department
Clinical Chemistry Lab.
Fourth Stage

كليـــــة الرشيد الجامعـــــة
قســـــم التحليلات المرضيـــة
مختبر الكيميـــاء السريريـــة
المرحلـــــة الرابعـــــة



Quality Control

[Part 2]

Lecture (5)

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Levey-Jennings Chart

❶ Creating a Levey-Jennings Chart:

Standard deviation is commonly used for preparing Levey-Jennings (L-J or LJ) charts. The Levey-Jennings chart is used to graph successive (run-to-run or day-to-day) quality control values. A chart is created for each test and level of control. The first step is to calculate decision limits.

These limits are ±1s, ±2s and ±3s from the mean. The mean for the Level I potassium control in Table 1 is 4.1 mmol/L and the standard deviation is 0.1 mmol/L. An examples on how ±1s, ±2s and ±3s quality control limits are calculated.

❶ Calculating Quality Control Limits

These ranges are used with the mean to construct the Levey-Jennings chart

±1s range is 4.0 to 4.2 mmol/L

4.1 – (0.1) (1) = 4.0

4.1 + (0.1) (1) = 4.2

±2s range is 3.9 to 4.3 mmol/L

4.1 – (0.1) (2) = 3.9

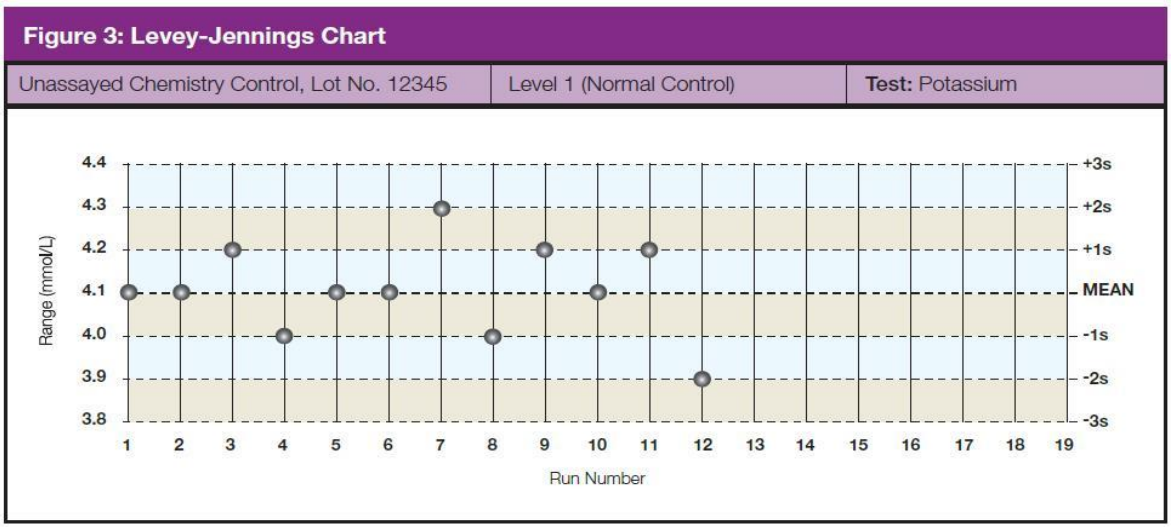
4.1 + (0.1) (2) = 4.3

±3s range is 3.8 to 4.4 mmol/L

4.1 – (0.1) (3) = 3.8

4.1 + (0.1) (3) = 4.4

Figure 3: Levey-Jennings Chart



❹ Systematic Error

Systematic error is evidenced by a change in the mean of the control values. The change in the mean may be gradual and demonstrated as a **trend** in control values or it may be abrupt and demonstrated as a **shift** in control values.

➲ Trend:

A **trend** indicates a gradual loss of reliability in the test system. Trends are usually subtle. Causes of trending may include:

•• Deterioration of the instrument light source
•• Gradual accumulation of debris in sample/reagent tubing
•• Gradual accumulation of debris on electrode surfaces
•• Aging of reagents
•• Gradual deterioration of control materials
•• Gradual deterioration of incubation chamber temperature (enzymes only)
•• Gradual deterioration of light filter integrity
•• Gradual deterioration of calibration.

➲ Shift:

Abrupt changes in the control mean are defined as shifts. Shifts in QC data represent a sudden and dramatic positive or negative change in test system performance. Shifts may be caused by:

•• Sudden failure or change in the light source.
•• Change in reagent formulation.
•• Change of reagent lot.
•• Major instrument maintenance.

•• Sudden change in incubation temperature.

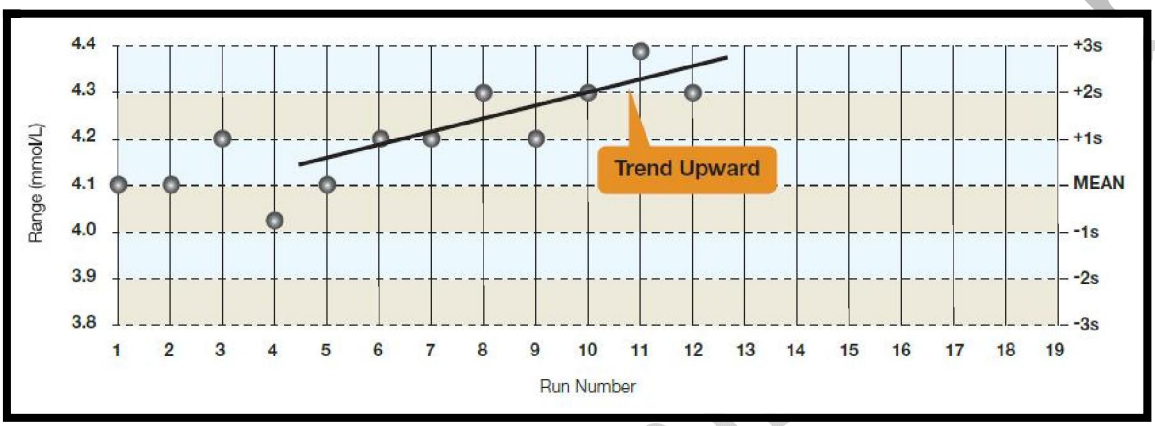
(enzymes only).

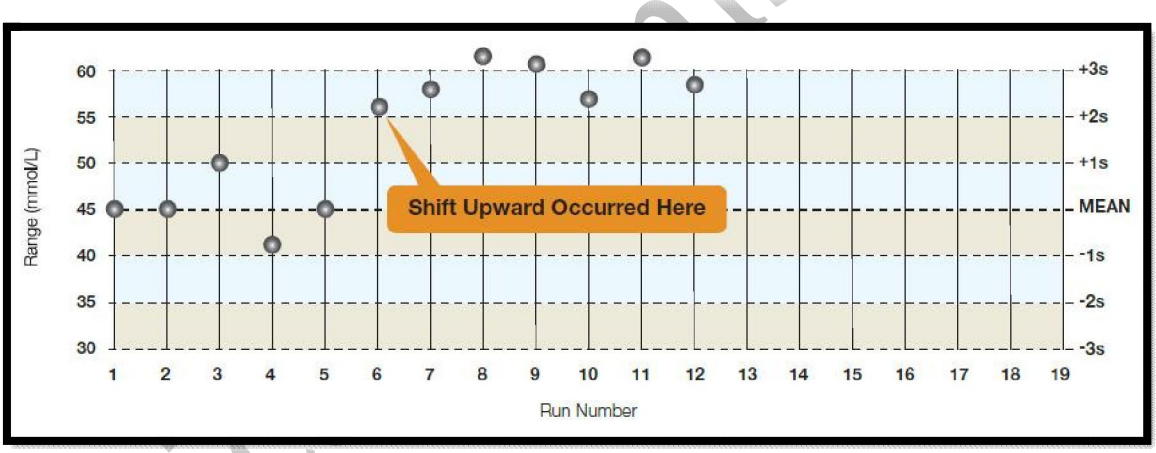
•• Change in room temperature or humidity.

•• Failure in the sampling system.

•• Failure in reagent dispense system.

•• Inaccurate calibration/recalibration.





Random Error

Technically, random error is any deviation away from an expected result. For QC results, any positive or negative deviation away from the calculated mean is defined as random error. There is acceptable (or expected) random error as defined and quantified by standard deviation. There is unacceptable (unexpected) random error that is any data point outside the expected population of data (e.g., a data point outside the ±3s limits).

Westgard Rules:

In 1981, Dr. James Westgard of the University of Wisconsin published an article on laboratory quality control that set the basis for evaluating analytical run quality for medical laboratories. The elements of the Westgard system are based on principles of statistical process control used in industry nationwide since the 1950s. There are six basic rules in the Westgard scheme. These rules are used individually or in combination to evaluate the quality of analytical runs.

Westgard devised a shorthand notation for expressing quality control rules. Most of the quality control rules can be expressed as NL where N represents the number of control observations to be evaluated and L represents the statistical limit for evaluating the control observations. Thus **1**3**s** represents a control rule that is violated when one control observation exceeds the **±3s** control limits.

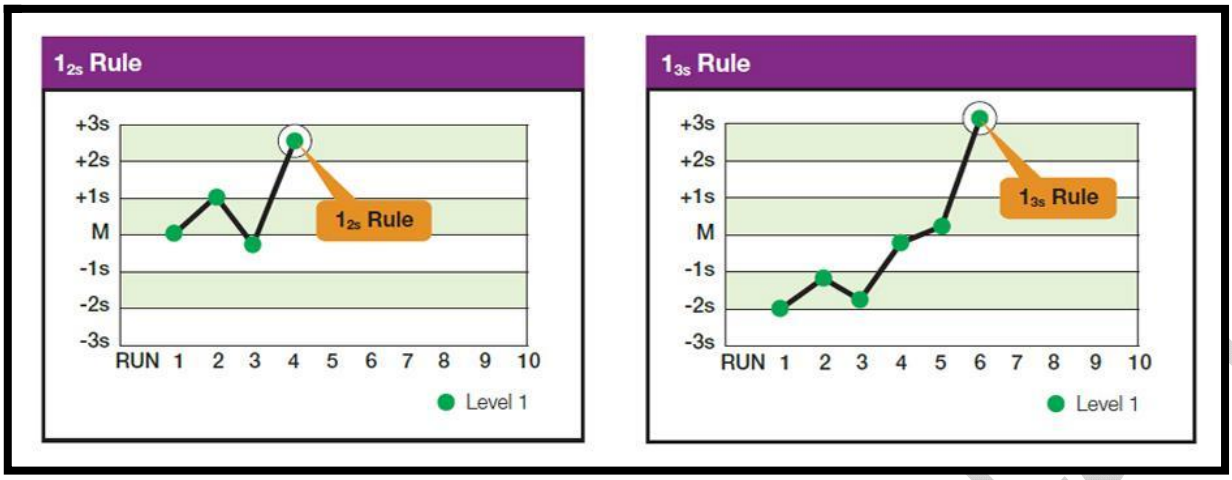
1_{2s} Rule

This is a warning rule that is violated when a single control observation is outside the **±2s** limits. Remember that in the absence of added analytical error, about 4.5% of all quality control results will fall between the **2s** and **3s** limits.

This rule merely warns that random error or systematic error may be present in the test system. The relationship between this value and other control results within the current and previous analytical runs must be examined. If no relationship can be found and no source of error can be identified, it must be assumed that a single control value outside the **±2s** limits is an acceptable random error. Patient results can be reported.

1_{3s} Rule

This rule identifies unacceptable random error or possibly the beginning of a large systematic error. Any QC result outside **±3s** violates this rule.



2_{2s} Rule

This rule identifies systematic error only. The criteria for violation of this rule are:

•• Two consecutive QC results

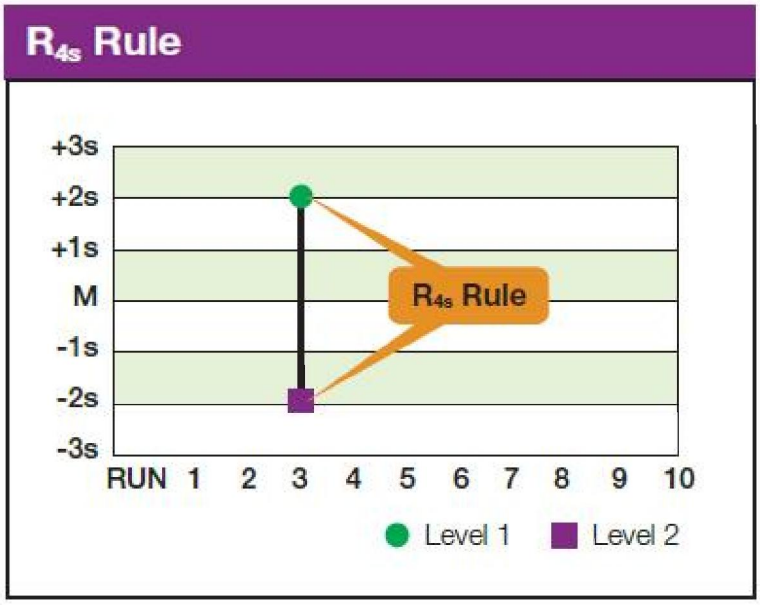
•• Greater than 2s

•• On the same side of the mean

There are two applications to this rule: within-run and across runs. The within-run application affects all control results obtained for the current analytical run. For example, if a normal (Level I) and abnormal (Level II) control are assayed in this run and both levels of control are greater than **2s** on the same side of the mean, this run violates the within-run application for systematic error. If however, Level I is -1s and Level II is +**2.5s** (a violation of the **12s** rule), the Level II result from the previous run must be examined. If Level II in the previous run was at **+2.0s** or greater, then the across run application for systematic error is violated. Violation of the within-run application indicates that systematic error is present and that it affects potentially the entire analytical curve. Violation of the across run application indicates that only a single portion of the analytical curve is affected by the error.

R_{4s} Rule

This rule identifies random error only, and is applied only within the current run. If there is at least a 4s difference between control values within a single run, the rule is violated for random error. For example, assume both Level I and Level II have been assayed within the current run. Level I is +**2.8**s above the mean and Level II is **-1.3s** below the mean. The total difference between the two control levels is greater than 4s (e.g. **[+2.8s** – **(-1.3s)**] = 4.1s).



3_{1s} Rule:

The criteria which must be met to violate this rule are:

•• Three consecutive results.

•• Greater than 1s.

•• On the same side of the mean.

4_{1s} Rule:

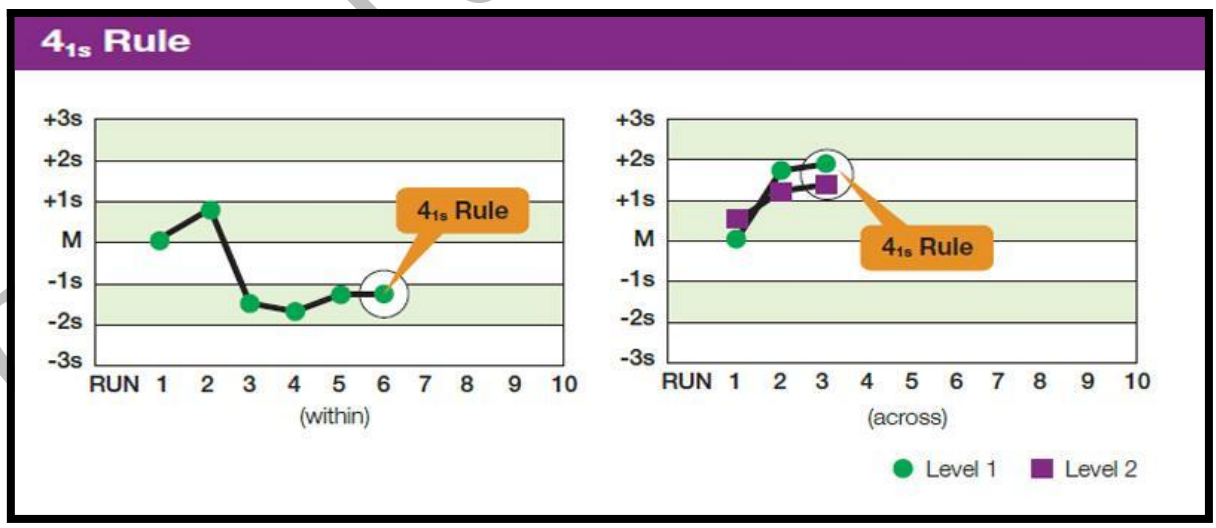
The criteria which must be met to violate this rule are:

•• Four consecutive results.

•• Greater than 1s.

•• On the same side of the mean.

There are two applications to the 31s and 41s rule. These are within control material (e.g. all Level I control results) or across control materials (e.g., Level I, II, and III control results in combination). 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.



$7\bar{x}$, $8\bar{x}$, $9\bar{x}$, $10\bar{x}$, $12\bar{x}$ Rule:

These rules are violated when there are:

•• 7 or 8, or 9, or 10, or 12 control results

•• On the same side of the mean regardless of the specific standard deviation in which they are located.

Each of these rules also has two applications: within control material (e.g., all Level I control results) or across control materials (e.g. Level I, II, and III control results in combination). 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 bias over a broader concentration.