

Using a Levey-Jennings Chart to Evaluate Run Quality

The laboratory needs to document that quality control materials are assayed and that the quality control results have been inspected to assure the quality of the analytical run. This documentation is accomplished by maintaining a QC Log and using the Levey-Jennings chart on a regular basis. The QC Log can be maintained on a computer or on paper. The log should identify the name of the test, the instrument, units, the date the test is performed, the initials of the person performing the test, and the results for each level of control assayed. Optional items for the log include: method

and the assay temperature (usually included for enzymes). There should be room to write in actions taken to resolve any situation which is identified as “out-of-control” or unacceptable and a place for documentation of supervisory review.

Once the QC results are entered into the QC Log, they should be plotted on the Levey-Jennings chart. When the results are plotted, an assessment can be made about the quality of the run. The technologist/technician performing the test should look for systematic error and random error.

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

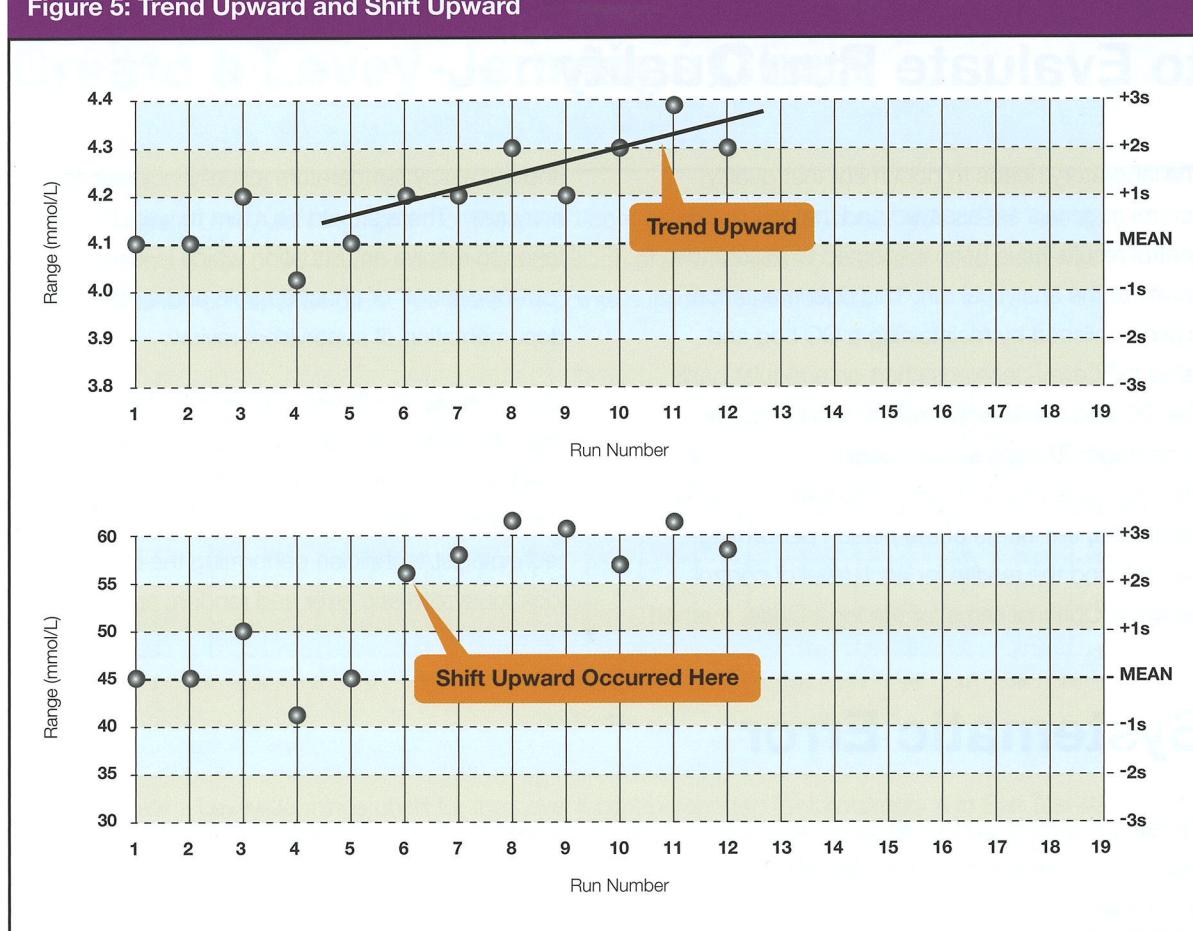
An example of trending on a Levey-Jennings chart is provided in Figure 5.

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

An example of a shift in test system performance is provided in Figure 5.

Figure 5: Trend Upward and Shift Upward

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 $\pm 3s$ 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.¹⁰ There are six basic rules in the Westgard scheme. These rules are used individually or in combination to evaluate the quality of analytical runs.

RULE

1_{2s}

This is a warning rule that is violated when a single control observation is outside the $\pm 2s$ 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 $\pm 2s$ limits is an acceptable random error. Patient results can be reported.

RULE

1_{3s}

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

¹⁰ There are several laboratory QC software packages that use the Westgard scheme. Unity Real Time® software from Bio-Rad Laboratories is one such package. It not only uses the basic six rules, but unlike other laboratory QC software packages, it also uses additional applications for evaluation of run quality. The Westgard Rules can be used manually in concert with Levey-Jennings charts, but manual application is less efficient.

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

Figure 6: 1_{2s} Rule

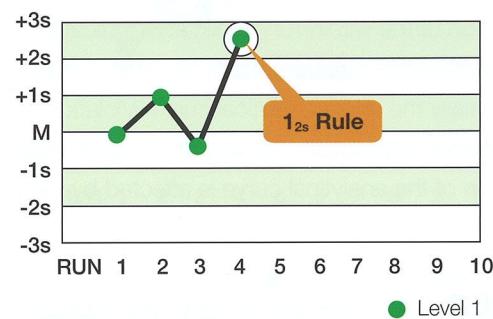
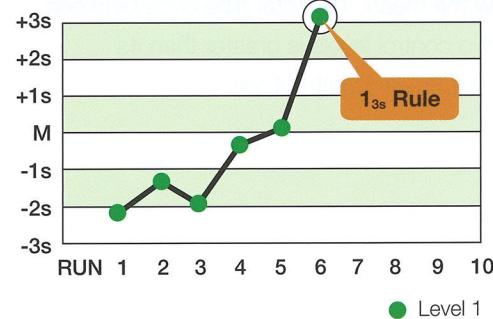


Figure 7: 1_{3s} Rule



RULE**2_{2s}**

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

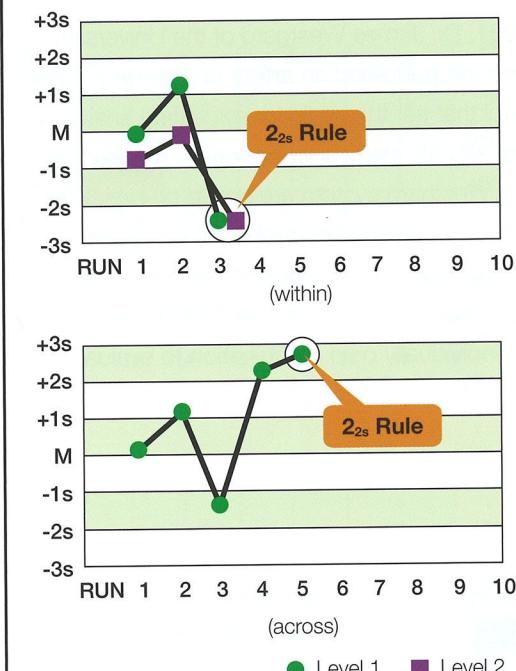
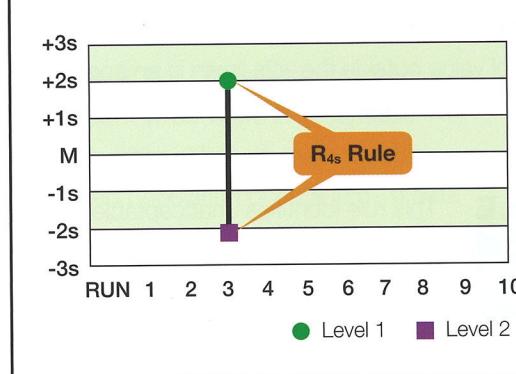
- Two consecutive QC results
- Greater than 2s
- On the same side of the mean

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 1_{2s} 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.¹¹

RULE**R_{4s}**

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 +2.8s 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).

Figure 8: 2_{2s} Rule**Figure 9: R_{4s} Rule**

¹¹ This rule also applies to trilevel (three level) controls. Whenever any two of the three levels violate the criteria for this rule within the run, unacceptable systematic error may be present and must be resolved.

Violation of any of the following rules does not necessarily require rejection of the analytical run. These violations typically identify smaller systematic error or analytical bias that is not often clinically significant or relevant. Analytical bias may be eliminated by performing calibration or instrument maintenance.

RULE**3_{1s}**

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

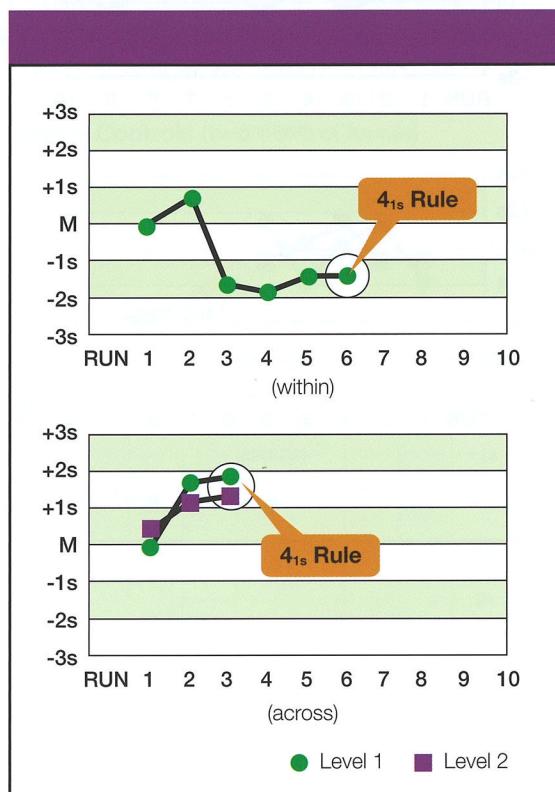
- Three consecutive results
- Greater than 1s
- On the same side of the mean

RULE**4_{1s}**

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 3_{1s} and 4_{1s} 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.¹²



¹² Use of 3_{1s} detects smaller analytical bias than 4_{1s} and is said to be more sensitive to analytical bias.

Self Test #5

Continued

Chart 3

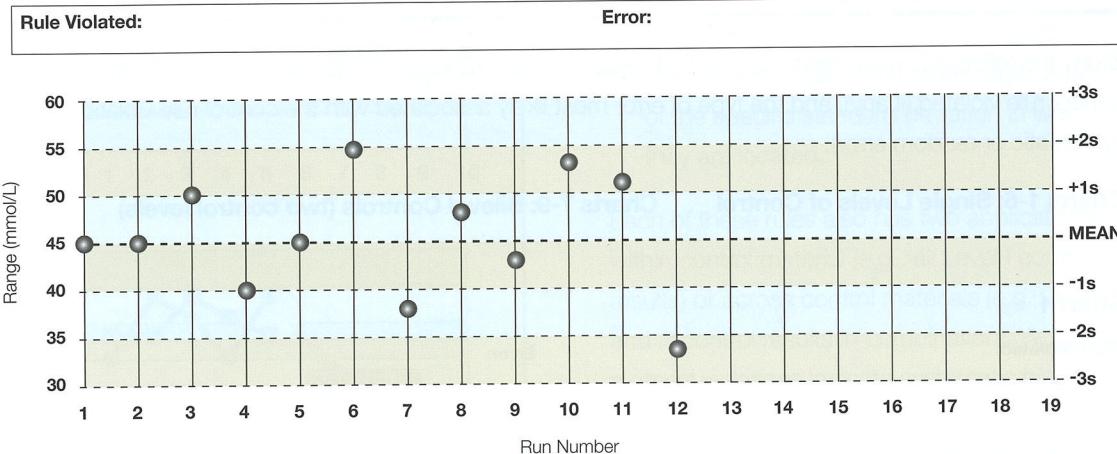


Chart 4

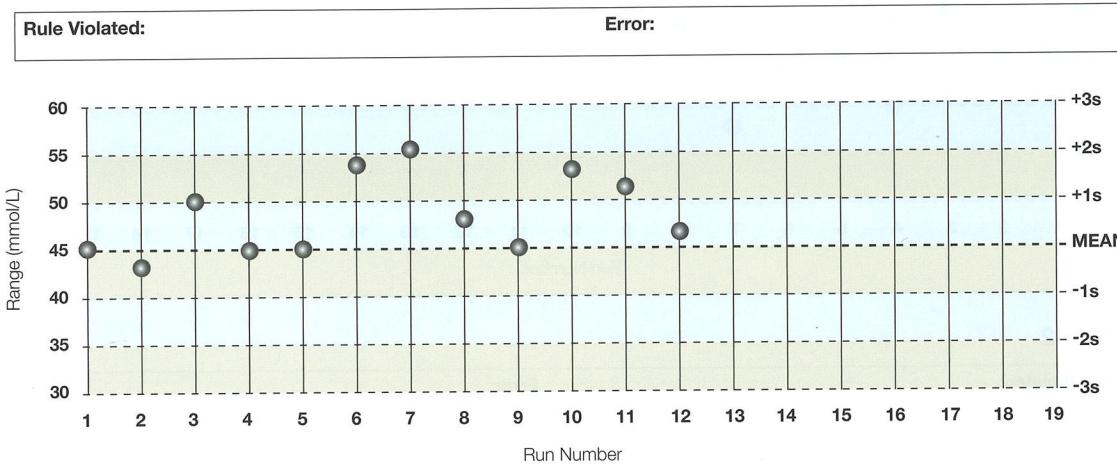
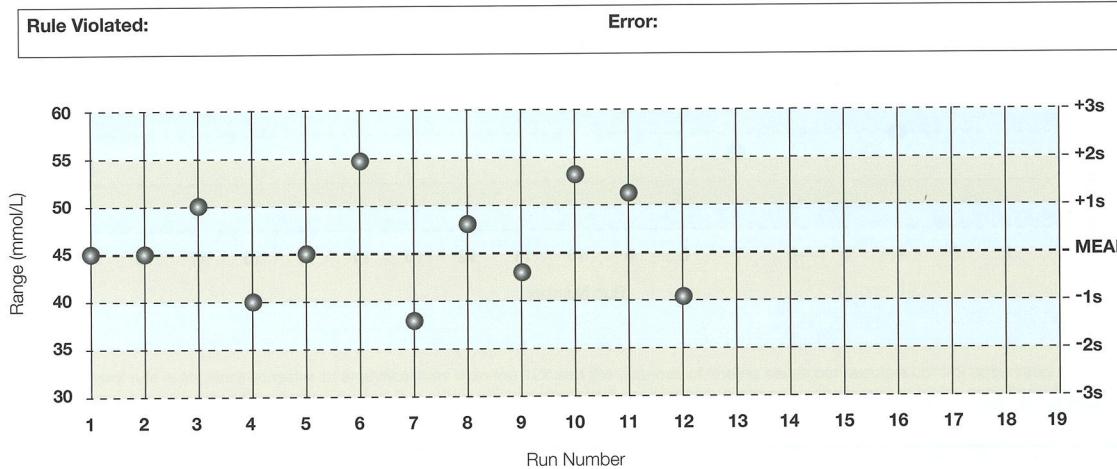


Chart 5



Self Test #5

Continued

Chart 6

Rule Violated:

Error:

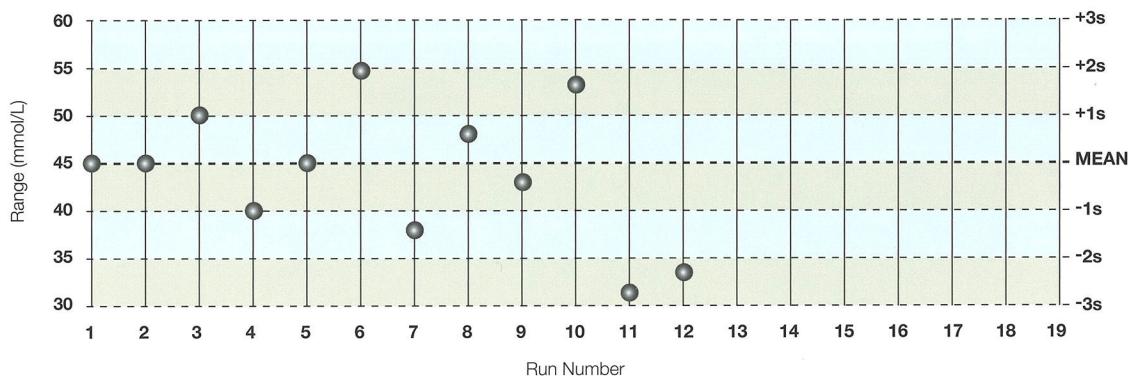


Chart 7

Rule Violated:

Error:

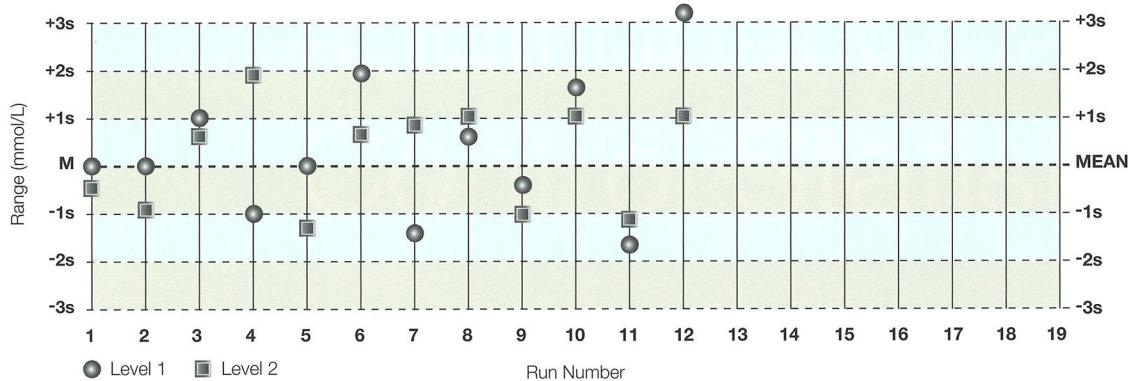
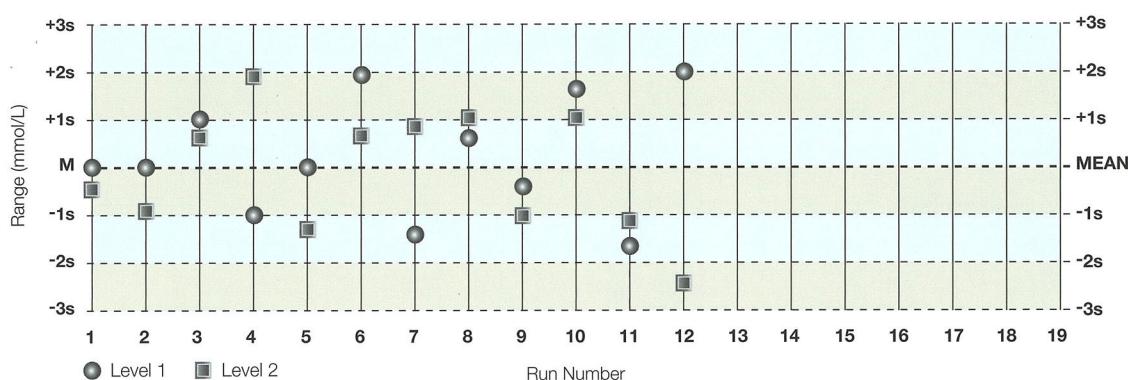


Chart 8

Rule Violated:

Error:



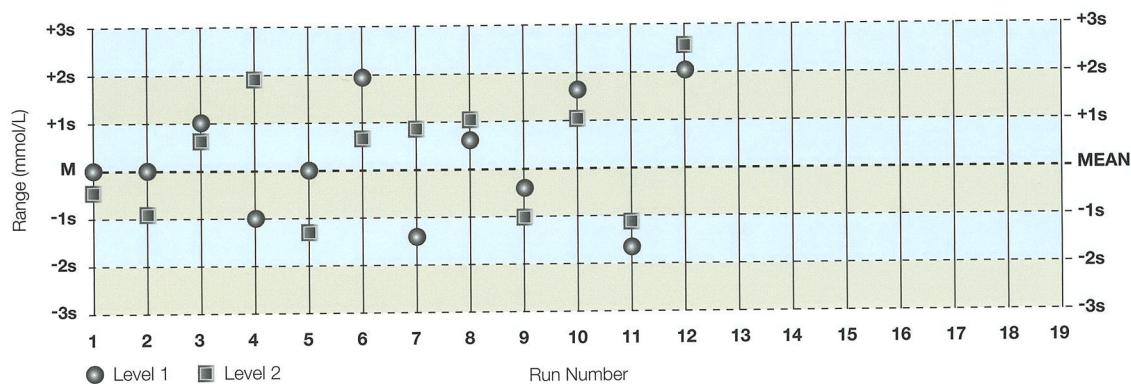
Self Test #5

Continued

Chart 9

Rule Violated:

Error:



Answers to Self Test on Page 55