

## Quality Control

### *What is quality control (QC)?*

Quality control (QC) is an integral part of a laboratory's operation. It is defined as the observation techniques and activities used to fulfill requirements for quality. The control can be a substance, sample or procedure intended to verify performance characteristics of a system. QC should not be confused with quality assurance (QA), which encompasses everything a laboratory does to assure high quality services to its customers.

### *Establishing a QC program:*

Your QC program should be a monitoring system that provides immediate information about the acceptability of results, as well as a method for evaluating data over time. Most control material is accompanied by stated target values for the mean and standard deviations (S.D.). These stated values may be used if they correspond to the methodology and instrumentation employed by the laboratory. If they are not provided, then calculate the parameters after a statistically significant number of control determinations have been completed (repetitions of 20 or more). Develop control charts using the mean and S.D. to record the results of the control. Establish criteria for acceptability, e.g. by applying Westgard rules to analyze the data. Also, develop policies and procedures for remedial action for QC failures and apply them as needed to maintain accurate and reliable test results.

### *What to look for on QC charts?*

1. Excessive scatter – points are widely scattered above and below the mean. Shows poor reproducibility of results. Common cause is operator variability in pipetting or inattention to critical steps in the procedure.
2. Bias – majority of points fall either above or below the mean. The two most common causes are an error in calibration or an error in reconstituting a control material.
3. Drift or trend – QC results move away from the mean in a particular direction over an extended period of time. Causes are outdated reagents, deterioration in reagents or instrument is losing its calibration.
4. Shift – controls suddenly change from moving above and below the mean to a line that is either always above the mean or always below the mean. Common causes are: recalibration was just performed; change in reagent lot; sudden deterioration of reagent (possibly not refrigerated overnight); new analyst; major change instrument performance.

### *Benefits of QC:*

- Demonstrates analytical capability of laboratory personnel.
- Monitors the stability of test methods or systems.
- Assesses the accuracy and precision of test results and test methods.
- Alerts the analyst if there is a problem with the reagent, test method, or instrument.
- Allows the laboratory to track the overall performance of a test procedure over time.
- Detects random and systemic errors.