

QC HIGHLIGHTS

- QC is part of the laboratory's Quality System consisting of their quality assurance, proficiency testing, and personnel competency.
- The **laboratory director** has the overall responsibility to determine the laboratory's QC program.
- The laboratory must establish the number, type and frequency of testing control materials that monitor the complete analytical process:
 - Must detect **immediate** errors caused by test system failures, adverse environmental conditions and operator performance.
 - Must monitor **over time** the accuracy, precision of test performance that may be influenced by changes in test system performance and environmental conditions and operator performance.
- The basic QC requirement is to perform two levels of QC materials each day of testing, unless specialty requirements apply; i.e., external QC that functions the same as patient specimens.
- If no commercial QC is available, the laboratory must devise an alternative mechanism for QC; e.g., proficiency testing samples, patient specimens with known values, split samples with another lab or another person within the lab, or other creative means.
- Equivalent Quality Control (EQC) is a choice!
- Manufacturer's recommendations, suggestions or requirements **MUST** be followed.
- It's ok for different laboratories using the same test system to choose different EQC options based on test system stability, comfort level and competency.
- Labs can use historical data for EQC as long as it meets the criteria for the evaluation process in the guidelines.
- If a lab experiences one QC failure during the evaluation process or EQC ongoing, they may repeat it once, if it is ok, they can continue without restarting. The lab's proficiency testing, quality assurance, and personnel competency (Quality System) must demonstrate no problems in order to continue EQC.
- If the lab has multiple devices, their lab's personnel must perform an evaluation process on all analytes, devices. Manufacturers can assist but not perform the evaluation process.
- All CLIA QC requirements that are "new to that lab" are considered educational and will not be cited on the 2567.
- The surveyor should provide the laboratory guidance and resources, like the brochures and guidelines, to help them with their QC program.