Wake Forest™
Baptist Medical Center

Point-of-Care Testing

Quality Control

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Updated: 09/02/15

Quality Control:

Why we do it

and

How we use it

Quality Control - A process for maintaining standards

Definition:

A method of monitoring the repeat testing of known standard materials to ensure precision, accuracy, reliability and consistency of test results.

*****Designed to detect, reduce, and correct any problems with the analyzer, operator, or reagents before patient testing is performed and results released**

*****Used to validate that the test system will give accurate patient results**

*****The process must be ongoing to ensure that, if a problem occurs, appropriate action is taken to resolve it and to immediately detect recurrences or new instances of a problem.**

Important Terms:

Known standard materials – **used as controls and have a specific range of acceptable results**

Precision – **the quality of being reproducible or exact; related to reproducibility and repeatability, the degree to which repeated measurements under unchanged conditions show the same results**

Accuracy – **the degree of closeness of measurements of a quantity to that quantity's true value**

*****In order for a result to be valid, it must be precise and accurate.**

Liquid Quality Control (QC):

- **Used to validate performance of analyzer, operator, and test reagents**
- **Most commonly consists of 2 levels — normal and abnormal (low and high)**
- **In some instances, 3 levels of controls are used (low, mid, high)**
- **Acceptable ranges can be found on the lot specific insert that comes with each box of liquid QC.**
- **Document ALL liquid QC results on the QC logs, including QC failures and corrective actions taken. This helps track on-going problems.**
- **You MUST ensure QC results are within acceptable limits PRIOR to proceeding with patient testing.**
- **NEVER REPORT PATIENT RESULTS IF QC HAS FAILED!**

WHY do we do QC?

- **POCT results are considered laboratory results and are subject to federal CLIA regulations**

- **CLIA regulations require that:**
  1. **Controls/QC be done as specified in manufacturer's instructions (or as established by the laboratory) if they meet/exceed the requirements below**
  2. **At least one time each day patient testing is performed**
  3. **Must run 2 levels of control for each quantitative procedure**
  4. **Must run a negative and positive control for each qualitative procedure**

- **If QC results are not within expected limits, then patient results may also be affected.**

- **This has a direct impact on safe patient care. Inappropriate patient treatment may occur if inaccurate laboratory results are reported.**

Liquid Quality Control: WHEN?

- **Should be performed:**
  - **On each new shipment and lot number of test tubes/cartridges PRIOR to patient use**
  - **At a minimum, liquid QC is required once per month—some tests may have additional QC frequency requirements. For example, Hemochron ACT, AVOX, and Medtronic require WEEKLY liquid QC.**
  - **If analyzer or reagent performance is in question**
  - **Post repair or maintenance procedure**

After performing liquid QC:

- **Make sure the values are within acceptable range or “PASS”**
- **If QC fails – STOP!!**
- **Begin troubleshooting procedures**
- **Patient results may not be accurate if QC does not work – do not report patient results**

Quality Control Troubleshooting

1. The first step to take is to check:
   - The correct level of QC is being tested
   - Expiration date of QC
   - Sample is mixed well –follow specific test procedure for mixing QC
2. The next step to take is to repeat QC:
   - If still out of range, use new control and/or new reagent cartridge
   - If QC has been done 3 times, STOP and…
     1. Do not perform patient testing
     2. Document all actions on the analyzer problem log and/or the QC log (Istat users should email POCT office)
     3. Remove analyzer and tubes/cuvettes/reagents/cartridges from use
     4. Contact the Clinical Laboratory Point-of-Care Testing Coordinator at 713-4136, 713-4137, or 713-0377 and Clinical Engineering

Quality Control Responsibility

- **If <u>you</u> perform patient testing, <u>you</u> are responsible for ensuring the required QC has been performed on the analyzer and reagents.**

- **<u>Everyone</u> who performs patient testing must also perform electronic and liquid QC at least once during the year.**

- **NEVER use an analyzer for patient testing if required QC checks are not within acceptable limits.**

Other Resources:

- **Clinical Laboratory Point of Care Testing Coordinators 713-4136, 713-4137, or 713-0377**
- **Operator's Manual and WFBMC policies/procedures/guidelines for particular test methods**
- **Site manager**

Congratulations

- You have completed the Overview of Quality Control Module.
- This presentation only provides a general overview of Quality Control information and does not replace policies/ procedures/guidelines for specific testing sites.