Wake Forest Baptist Medical Center	Quality Control (QC) Management Policy Lab Admin 9	Dept:	Pathology
		Effective Date:	June 1997
		Revised Date:	October 16, 2018
		Contact:	Lab Compliance, QA, POC and Safety
Name & Title: Gregory J. Pomper, MD CLIA Lab Director		Date:	12/7/18
Signature:			

1) **General Procedure Statement:**

   a. **Scope:** Defines the Wake Forest Baptist Health (WFBH) Department of Pathology's Quality Control (QC) policy statement. Each laboratory section of Wake Forest Baptist Health Department of Pathology is required to monitor the entire testing process through the use of quality control (QC) samples. This policy provides rules and guidelines that apply to the QC testing and monitoring processes throughout the Department of Pathology.

   b. **Responsible Department/Party/Parties:**
      i. Procedure owner: Department of Pathology
      ii. Procedure: Department of Pathology
      iii. Supervision: Laboratory Compliance, QA, POC and Safety Section and the CLIA Laboratory Director
      iv. Implementation: Department of Pathology CLIA Laboratory Director, Section Medical Directors, Section Managers and Department of Pathology Administrative Director

2) **Definitions:**

Quality Control (QC) - Quality control is designed to detect, reduce, and correct deficiencies in a laboratory's internal analytical process prior to the release of patient results.

CLIA – Clinical Laboratory Improvement Amendments

CLSI - Clinical and Laboratory Standards Institute

CAP – College of American Pathology

AABB – American Association of Blood Banks

ASHI – American Society for Histocompatibility and Immunogenetics

COLA - Commission on Office Laboratory Accreditation

TJC – The Joint Commission

FDA – The Food and Drug Administration

IQCP- Individualized Quality Control Plan

3) Policy Statement:

Quality Control (QC) in the clinical laboratory is a system designed to increase the probability that each result reported by the laboratory is valid and can be used with confidence by the provider to make a diagnostic or therapeutic decision. QC procedures detect analytical errors and, when used and monitored properly, alert analysts to problems that might limit the usefulness of the test. In practice, most QC procedures operate by submitting controls (sample materials well characterized by previous testing) to the laboratory testing process, and comparing the results of current testing to an expected range of values derived from previous testing.

1. The laboratory is responsible for selecting the appropriate quality control (QC) material for the test method. The laboratory is not required by CLIA regulations to use the specific QC product recommended by the test manufacturer, however the chosen material must meet the manufacturer's requirements for monitoring the test and QC testing must occur at the minimum frequency specified by the manufacturer. The laboratory must ensure that the testing requirements meet any regulatory requirement, such as CLIA, CAP, AABB, ASHI, COLA, TJC or FDA. Selecting the appropriate controls includes the number of controls performed per run or per day, the analytical concentrations (low, medium, high, etc.), the frequency of testing control materials and the placement of the controls in the analytical process.

2. For clinical methods, the laboratory must choose QC material that, if available, is of a similar matrix to that of patient specimens and the QC material must be treated in the same manner as patient specimens and go through all analytic test phases. If calibration material is used as a control material, the calibrator must be from a different lot number than that used to establish a cut-off value or to calibrate the test system.

3. If control materials are not available, the laboratory must have an alternative mechanism to detect immediate errors and monitor test system performance over time. This alternative system must be included in the test validation and must be approved by the Laboratory Director.

4. If the manufacturer does not specify a frequency for performing QC, the laboratory must determine the interval in which the measuring system is expected to be stable. CLIA requires that QC be tested, at minimum, every 24 hours that testing occurs. QC must also be tested after calibration, after a change in reagents, after maintenance, and after replacement of a critical part. For new procedures, QC may need to be performed more frequently until the stability of the assay is firmly established.

5. All results of QC testing must be recorded for the date performed, either manually or electronically. Over time, rotate QC testing among all personnel who perform patient testing.

6. For quantitative testing, QC results must be evaluated using appropriate statistics for the number of controls and the method. Establish means and standard deviations to calculate appropriate control limits.

7. Each test system that has an extraction phase must include a control material capable of detecting errors in the extraction process.

8. Molecular amplification procedures must include two control materials (positive and negative) and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition.

9. Each electrophoretic procedure must include, concurrent with patient specimens, at least one control material containing the substances being identified or measured.

10. Each batch of media must be checked for sterility, if sterility is required for testing. Each batch of media must be checked for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response. All media used at the WFBH Microbiology Lab must have QC checks performed either by [Media Unit] or the laboratory performing testing.

11. CLIA no longer exempts performance of in-house QC on commercially prepared microbiological culture media that is controlled by the manufacturer in accordance with CLSI guidelines. This exception has been rescinded and the laboratory is now responsible for performing its own media checks or developing an Individualized Quality Control Plan (IQCP) for this process.

12. QC results must be reviewed and evaluated for trends or shifts in performance prior to releasing patient results. Qualitative QC results must meet test expectations. All corrective actions must be documented and included in the supervisory review. DO NOT REPORT TEST RESULTS IF QC IS OUTSIDE ACCEPTABLE LIMITS.

13. Each laboratory must specify in writing the type of QC to be tested for each procedure, the frequency of testing, the QC acceptance criteria for each test and the actions to take if the QC results are unacceptable. These criteria may be included in the test procedure or in a separate document.

14. Laboratory supervisors are responsible for reviewing QC results and monitoring QC statistics at intervals adequate to assess the analytical process. The review may occur electronically or on paper, however it must be documented in a manner that will be accessible to CMS or other regulatory surveyors.

15. CLIA Individualized Quality Control Plan (IQCP)

a. If the QC being performed for a laboratory test does not meet or exceed the CLIA requirement for testing QC, the laboratory must develop an IQCP for this test. An IQCP includes a risk assessment (RA), Quality Control Plan (QCP) and Quality Assessment (QA).

b. Contact the Laboratory Compliance POC Office for assistance if an IQCP is required.

16. Failures to follow the QC policy will result in the need to complete the CAPA process and document the event as part of the monthly QA reporting process for the lab section in which it occurred.

4) Review/Revision/Implementation:

a. Review Cycle: 2 years
b. Office of Record: Department of Pathology, Laboratory Compliance, QA, POC and Safety.

5) **Related Policies:** N/A

6) **References, National Professional Organizations, etc.:**

1. Clinical and Laboratory Standards Institute (1999); Statistical Quality Control for Quantitative Measurements, Approved Guideline – 2nd Edition, CLSI Document C24-A

2. CLSI, Wayne, PA. 3. Centers for Medicare & Medicaid Services, Center for Clinical Standards and Quality/Survey & Certification Group, S&C: 15-17 CLIA, January 9, 2015.

3. Federal Register (2003), January 24, 2003, 42 CFR Part 493. Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services; CMS.

7) **Attachments:** N/A

8) **Revision Dates: October 16, 2018**