Wake Forest Baptist Medical Center	Individual Quality Control Plan (IQCP) for the WFBMC Department of Pathology	Dept:	Pathology
		Effective Date:	June 1, 2016
		Revised Date:	June 3, 2019
		Contact:	Laboratory Compliance, Quality and Safety
Name & Title: CLIA Laboratory Director		Date:	6/4/19
Signature: Guy Pomper			

General Policy Statement:

It is the policy of the laboratories of The Department of Pathology at Wake Forest Baptist Medical Center to follow the guidelines of CAP and CLIA to ensure quality control (QC) procedures are in place to monitor the accuracy and precision of the complete testing process. Quality practices and procedures are implemented within each section of the laboratory to meet the unique testing environment representative of that section. Each laboratory section is required to evaluate their QC procedures to determine if the Individual Quality Control Plan (IQCP) can or should be implemented for tests in their area. For each non-waived test performed, the laboratory section must either implement the IQCP approach or follow the guidelines for QC as determined by the manufacturers insert or CLIA regulations in given instances where the manufacturer's instructions are absent or less stringent. All CLIA specialties and subspecialties are eligible for IQCP except Anatomic and Surgical Pathology and must complete all required assessment documentation to meet CLIA and/or CAP standards if they elect to follow and IQC plan.

All sections are encouraged to utilize the same purchased software when preparing their IQCP. Current IQCP's in use for this department have been prepared using IQCP E-Optimizer which satisfies the CAP Standard COM.50300 for Risk Assessment determination for each test.

a) **Scope**: All sections within the WFBMC Department of Pathology shall adhere to the processes outline in this document if they choose to utilize an IQC plan instead of following manufacturer's or CLIA's guidelines for performance of quality control.

b) Responsible Department/Party/Parties:
   i. Policy Owner: Department of Pathology
   ii. Procedure: Department of Pathology
   iii. Supervision: The CLIA Laboratory Director and/or Section Medical Director, along with the Section Mangers shall supervise the overall Quality Control plan for each section of the laboratory which includes the IQCP.
   iv. Implementation: The CLIA Laboratory Director and/or Section Medical Director, along with the Section Mangers shall supervise the implementation of the IQC plan for each section of the laboratory.

1) **Definitions:** For purposes of this Policy, the following terms and definitions apply:

   a) **WFBMC**: Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), all on-site subsidiaries as well as those off-site governed by WFBMC policies and procedures.

b) **Policy**: As defined in the Policy on Creating and Amending Policy, a statement of principle that is developed for the purpose of guiding decisions and activities related to governance, administration, or management of care, treatment, services or other activities of WFBMC. A policy may help to ensure compliance with applicable laws and regulations, promote one or more of the missions of WFBMC, contain guidelines for governance, and set parameters within which faculty, staff, students, visitors and others are expected to operate.
c) **CLIA**: Clinical Laboratory Improvements Amendments
d) **CAP**: College of American Pathology
e) **Waived Test**: Test of low complexity as designated by the FDA
f) **Non-waived Test:** Test designated as moderate or high complexity by the FDA.
g) **Quality Control**: (QC) – A process to ensure the test system is performing as expected.
h) **Individual Quality Control Plan (IQCP):** For each non-waived test performed, the laboratory section must either implement the IQCP approach or follow the guidelines for QC as determined by the manufacturers insert or CLIA regulations in given instances where the manufacturer's instructions are absent or less stringent.

2) **Policy Guidelines:**
a) **General Requirements**:

This policy is designed to inform laboratory sections of the required components of a compliant IQCP process. Many different laboratory accreditation agencies as well as CLIA provide in-depth online resources to walk you through the entire IQCP process. Purchased software packages are also available for use and are an accepted means of assistance for the laboratory. Laboratory sections within the Department of Pathology are encouraged to utilize E-Optimizer. The E-Optimizer product meets CAP requirements for IQCP Standard GEN.50300.

All IQCP plans must include:

- Risk Assessment (RA)
- Quality Control Plan (QCP)
- Quality Assessment (QA)

i. **Risk Assessment**: A risk assessment identifies and evaluates the potential failures and sources of errors in your testing process. It must include at minimum evaluation of 5 components:
   (a) Specimen
   (b) Test system
   (c) Reagent
   (d) Environment
   (e) Testing Personnel

Note: A compliant plan must evaluate each of the five components listed, however, you may identify additional risk factors to consider. Therefore individual section plans may not be limited to just these five components. Risk Assessments should be re-evaluated at least annually for any changes or updates that may change the overall risk assessment first performed. Document the annual reviews using the recommended CAP IQCP forms (examples provided as attachments to this procedure).

ii. **Quality Control Plan:** A Quality Control Plan describes practices, procedures and resources needed by the lab to ensure quality patient testing. The plan includes measures to assure the accuracy and reliability of test results and the quality of testing is adequate for

patient care. At a minimum the plan must include the number, type and frequency of testing control materials as well as criteria for acceptable quality control.

The plan must also:

i. Provide for immediate detection of errors for each phase of testing
ii. Require the lab perform QC as specified by the manufacturer's instructions but not less than the manufacturer's instructions
iii. Indicate that the Lab Director has reviewed, signed and date the QCP documents.

iii. **Quality Assessment**: Consists of a two-fold process. The first part includes a means of identifying problems that arise from the deviation of written policies and procedures whereas the second consists of the corrective action that follows the problem identification. The entire QA process should be used to determine if the quality activities you have in place are working as indicated in the QCP.

The laboratory must establish a review system for the ongoing monitoring of the effectiveness of their QCP's (should be reviewed at least annually). The monitoring should include, but is not limited to, the following components: specimen, test system, reagent, environment, and testing personnel. Reevaluate the QCP when changes occur in any of the above components.

If the laboratory discovers a testing process failure, the laboratory must conduct an investigation using the CAPA (Corrective Action/Preventative Action Process) to identify the cause of the failure and its impact on patient care. The investigation must include documentation of all corrections, corresponding corrective action(s) for all patient results affected by the testing process failure, and evaluation of the effectiveness of the corrective action(s) taken. The laboratory must implement the correction(s) and corresponding corrective action(s) necessary to resolve the failure and reduce the risk of recurrence in the future. If necessary, the laboratory must update the risk assessment with the new information and modify the QCP, as needed.

c) CAP requires the completion of additional forms for inspection purposes. Each lab section incorporating IQCP in their area must complete:
   - The List of Individualized Quality Control Plans Form
   - The Individual Quality Control Plan Summary Form (for each test).

4) Review/Revision/Implementation

a) Review Cycle: This policy shall be reviewed by the Department of Pathology at least every 2 years from the effective date unless otherwise stated by regulation.

b) Office of Record: The Department of Laboratory Pathology shall house this policy within their document control system.

5) Related Policies N/A

6) Governing Law or Regulations

CLIA Standards 42CFR493.1250 and 42CFR493.1256(d)
CAP Standards: All Common COM.50200, 50300, 50400, 50500, 50600

7) Attachments

Attachment A: Example of CAP List of Individualized Quality Control Plans

Attachment B: Example of CAP List of Individualized Quality Control Plan Summary Form
Attachment C: IQCP Consideration Flowchart

8) Revision Dates:

Review Date	Revision Date	Signature
	1/9/2019 by MH formatting changes, added flowchart and reference to standards	
	6/3/2019 by MH. Minor revision. Included reference to CAP Standard COM.50300	

Attachment A

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List of Individualized Quality Control Plans

Laboratories: Complete the fields below for each IQCP in use and present to the inspector during the on-site inspection. Laboratories with different CAP and/or CLIA numbers must complete separate forms.
Inspectors: Refer to Inspector Instructions in the IQCP section of the All Common Checklist for instructions on identifying a sampling of IQCP records to review in detail.

Laboratory Name: _____ **CAP Number:** _____

Laboratory Section Department	Instrument/Device Include name, manufacturer, model, and number of instruments (if applicable)	Tests List all tests included under the IQCP	Test Sites If used in more than one area	Implementation /Revision Date

Attachment B

Laboratory Section/Department:	Instrument/Device/Tests:	Date:

	QA Process/Monitor	Issues Identified	Corrective Actions Taken
☐	Quality Control performed appropriately and reviewed monthly	QC issues resolved?	
☐	Temperature log sheets completed and reviewed monthly	Out of range or missing temperatures resolved?	
☐	Maintenance logs completed and reviewed monthly	Incomplete data? Corrective actions recorded?	
☐	Instrument issues resolved and recorded	Instrument failures or downtime?	
☐	Proficiency testing performed and reviewed	Unsuccessful PT performance?	
☐	Sampling of personnel training/competency reviewed	Retraining needed?	
☐	Sampling of patient results reviewed	Reporting errors corrected?	
☐	Relevant quality indicators reviewed	Turnaround time, corrected reports, specimen rejection, etc?	
☐	Laboratory occurrence reports	Corrective actions completed?	
☐	Complaint reports	Physician or care giver concerns?	
☐	ICCP (approval) by laboratory director or designee		
☐			
☐			
☐			
☐			

- Have test process failures been identified?
    a. Assess the use (e.g. timely, effective) of the monthly review process of quality control, temperature, and maintenance logs to identify problems

    b. Record any corrective action for patient results affected by the testing process failure.

    c. Evaluate the effectiveness of the corrective action taken.

- Have any changes been made to the five elements of the Risk Assessment (i.e. reagents, environment, specimen, testing personnel, or test system) requiring reevaluation of the Quality Control Plan?

- Have any changes been made to the Quality Control Plan?

    a. Specify any updates/modifications

- Have revisions to the Quality Control Plan been signed by the laboratory director (including signature and date)?

- Is the ICCP sufficient to mitigate risk in this laboratory? If no, explain actions to be taken.

Reviewed by:
Laboratory Director/Designee Click here to enter text. Date

Attachment C

Considerations for Developing an Individualized Quality Control Plan (IQCP)