Wake Forest Baptist Medical Center	**Department of Laboratory Medicine and Pathology Quality Assurance/Quality Improvement/Quality Management Plan**	**Dept:**	**Department of Laboratory Medicine and Pathology**
		Original Effective Date:	**July 1, 2016**
		Current (Revised) Date:	**February 2019**
		Contact:	**Laboratory Compliance, QA, Safety**
Approval Signature: GR		**Date of Signature:**	2/21/19
Title: CLIA Medical Director, Clinical Laboratories			

1) **General Policy Statement:**

In accordance with the Medical Center policy the Laboratories will maintain a planned, systematic, and ongoing departmental quality assurance quality improvement plan (QA/QI). These QA/QI activities augment the existing Laboratory Quality Control Program (QCP). While the QCP addresses technical issues relating to the accuracy and precision of work done, the QA/QI monitors laboratory performance at the interface between the laboratory and the patients or medical/nursing staff in terms of the availability, turn-around-time, cost effectiveness, and clinical utility of laboratory sections.

a) **Scope:** The Department of Laboratory Medicine and Pathology, hereafter referred to as the "Laboratories" are to be operated in full compliance with the requirements of the state and federal government and by the higher voluntary standards of the Clinical Laboratory Improvement Amendments (CLIA), College of American Pathology (CAP), and Joint Commission (TJC). All Laboratory employees, faculty and staff are responsible for complying with this policy. Meetings will be held on a monthly basis at 8:00AM on the last Wednesday of the meeting month.

The CLIA Laboratory Director is ultimately responsible for the overall development and execution of the QA/QI plan.

The CLIA Laboratory Director and the Manager, Laboratory Compliance, QA, Safety and POCT will co-chair the Laboratory QA/QI meeting. The other members of laboratory required to attend the meetings will be:

- The Department Chair of Pathology
- The Lab Administrative Director
- The Lab Associate Administrative Directors
- The Lab Section Medical Directors
- The Section Managers
- Members of the Laboratory Compliance and Quality Section
- Manager of Billing and Coding
- Representative of LIS Team
- Administrative Assistant to record minutes
- Laboratory Director and/or Manager for the HLA Laboratory
- Laboratory Director and/or Manager for the Medical Genetics Laboratories
- Transfusion Safety Officer
- Chief Residents

b) Responsible Department/Party/Parties:

- Policy Owner: Department of Laboratory Medicine and Pathology
- Procedure: Department of Laboratory Medicine and Pathology
- Supervision: Department of Laboratory Medicine and Pathology
- Implementation: Department of Laboratory Medicine and Pathology

2) **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) CAPA – Corrective Action/Preventative Action
   d) IQCP – Individual Quality Control Plan
   e) LEC – Laboratory Executive Committee
   f) MEC – Medical Executive Committee

3) **Policy Guidelines:**
   a) General Requirements for QA/QI Program/Meetings
   Each section of the medical laboratories [Central Processing, Phlebotomy (Inpatient and Outpatient), Laboratory Outreach, Microbiology, Core Lab (Hematology, Chemistry, and Referral Testing), Blood Bank, Bone Marrow Transplant, Transfusion Safety, Critical Care Lab, Autopsy, Cytology, Molecular Biology, Electron Microscopy, Histology, and Lab Compliance QA, Safety and POCT, Billing and Coding] will participate in the ongoing QA/QI program. The CLIA Laboratory Director will be responsible for the design and implementation of the department plan. Each section will follow the plan established for the department. The CLIA Lab Director will meet with each delegated Section Director and/or Manager at least once annually to discuss the QA/QI program and if necessary, adjust its design and implementation needs for the upcoming year to suit the needs of the individual sections.

   The QA/QI meetings will also serve to facilitate discussion of situations that may be deemed problematic or in need of improvement initiatives that should come to the attention of the CLIA Lab Director and Lab Administration. The representation should be sufficient at each meeting to escalate identified issues to higher Medical Center Administration as deemed appropriate. The Administrative Assistant present will document these discussions in the minutes of the meeting as well as include them on the Action Items Log to be followed at each meeting until a resolution can be reached. The minutes and the Action Items Log will be distributed along to all members of the QA/QI committee as well as the Medical Executive Committee (MEC).

   Agendas for each meeting will be prepared ahead of each meeting. Members will be given the opportunity to add new topics for discussion if they so choose by contacting the Administrative Assistant in Pathology.

   Prior to each meeting, the Section Manager will be responsible for pre-populating their section of the Minutes Template document with their planned talking points for each meeting and adding any new Action Items or updates to existing Action Items.

   The Laboratory QA/QI Committee will meet on a monthly basis unless otherwise deemed necessary by the CLIA Laboratory Director at which time the meetings will be called at his/her discretion. Minutes of each meeting will be prepared by the Pathology Administrative Assistant and forwarded to the MEC for further review and incorporation in to the hospital based quality plan. Reports will be prepared as required by the Hospital's Quality Council (quarterly summary of laboratory issues) and the Environment of Care Committee (annual Clinical Equipment report).

   b) The overall QA/QI program is required to address:

   - The quality indices that will be used to reflect the quality of services rendered by the sections, paying particular attention to processes that are high-risk, high-volume or problem prone.
   - The performance criteria for these indices above.
   - The method of documenting and reviewing corrective action followed when an index indicates

unacceptable performance. Corrective action and plans (CAPA) for monitoring/auditing to ensure continued compliance are expected to be included as part of the QA reporting process. The CLIA Laboratory Director will review corrective actions to ensure that they are appropriate for the situation and if necessary recommend disciplinary action.

- Those proactive efforts being made to identify and implement new services/procedures or service improvements.
- For those sections where IQCP applies, at least annually these sections should report on their review and overall compliance with any non-waived tests applicable to the IQCP process.
- Results of Proficiency Testing Participation (to include appropriate enrollment, failures and review process)
- Significant Quality Control failures (Calibration errors, maintenance problems/failures, missed function checks, failed temperatures/humidity, incomplete logs, procedure manual review, etc.) Included in CAPA reports.
- Any indices required under CAP, CLIA or AABB regulations.

In addition all sections will report any incidents for the items below. This part of the report will also include assessment, analysis and resolution of concerns related to:

- Employee concerns related to test quality or laboratory safety (using CAPA form).
- Clinical Care Team concerns with laboratory service.
- Device related adverse patient events.
- Product recalls or ECRI alerts
- Relevant RL6 reported events
- Staffing Issues (including but not limited to FTE assessment, CAPA form, and/or RL6)
- Missing Information/Documentation on New and Existing Employee Files (using CAPA form)
- New Test or Equipment Validations (using CAPA form)
- Deviation from or failure to follow standard operating procedures.

c) When the reports are due
By the third week of the meeting month, individuals responsible for preparing specific quality monitors will place their section reports in the QA folder on the laboratory shared drive. (G drive>Lab Shared> QA Reports Clinical Labs Combined AP CP QA Meetings). Prior to placing the information in this file the Section Medical Director must have reviewed and provided indication of signature approval. At this time the reports are ready to be reviewed and signed electronically by the CLIA Laboratory Director prior the QA/QI meeting. During the meeting, the Section Director or Section Manager will be expected to present on their data. They are only required to report verbally on specific quality monitors or issues that reflect unacceptable performance or need to be brought to the attention of lab administration.

d) Additional reports produced from QA/QI data:
   - Annually - The CLIA Laboratory Director will prepare a report from the combined QA/QI minutes and report to the Enterprise Safety Committee and the Department Chairman of Pathology on the following topics:

     - CAP proficiency testing summary results on CMS reportable analytes from each clinical section.
     - Charted critical values NOT called.
     - Validation analysis of lab reports in Beaker/Wake One/CareEvolve/Wake One Patient Portals annually.

   - Annually - Manager, Laboratory Compliance, QA, Safety and POCT will report to the Environment of Care Committee an incident/accident that evaluates the effectiveness of the lab safety program.

   - Information concerning employee file documentation pertaining to training/competency

documents, education, ect. will be accessible to all Managers and members of the Lab Administrative Team at any time by reviewing the online QA Report for Missing Documents under the lab shared folder on the G: drive. It will also be reviewed at each QA/QI meeting. Data will be reviewed by the CLIA Laboratory Director, Lab Administration and Laboratory Compliance, QA, Safety and POCT and included in the minutes of the meeting.

- CAPA event summaries and breakdown of event types, prepared by Laboratory Compliance and Quality Section.

e) QA/QI Reporting Points by Section:

- Anatomic Pathology Section (as a group)
  - Quarterly participation in CAP Sponsored Virtual Slide Program (all faculty)
    - This is conducted in a group setting; questions have immediate feedback so errors are immediately corrected with appropriate educative material.
- Autopsy
  - Autopsy Case Discrepancies WFBMC/OCME
  - TAT's for Hospital Autopsy PADs (Target 90% within 2 working days)
  - Hospital autopsy cases signed out within 60 working days (Target 90% within 60 working days)
  - Morgue Cooler Temperature
  - Autopsy Case breakdown:
    - Medical Examiner Autopsies
    - Medical Examiner Externals
    - Hospital Autopsies
    - Decedent Affairs (No autopsy)
- Cytology
  - TAT for Medical, PAPs, Outreach PAPs
  - FNA onsite vs Final Diagnosis
  - Specimen Collection Errors
  - Educational Challenges
  - Lab Test Volumes – Medicals (including FNA's), PAPs
  - Significant errors for routine Cyto-Surgical correlation
  - Cytology Diagnostic Summary (CAP requirement)
  - HPV Results of PAP Diagnosis
  - Daily slide QC compliance from all sites (Target 100%)
  - Cross Contamination Filtration Compliance (Target 100%)
  - CAPA non-conformances
- Histology
  - Total # of Blocks
  - Total # of H&E Slides
  - Total # of Unstained Slides
  - Total # of Special Stains (including Neuro Path Lab), Renals and Muscles
  - Block Labeling Errors per location
  - Slide labeling Errors
  - Workload Statistics: OR, NOR, Outreach, Bone Marrow, Cytology/Cell Blocks, Adds&Decals, Recuts, Autopsy, Lexington
- Electron Microscopy
  - TAT – Cilia, Muscle, Nerve, Renal
  - Number of Cases Inside vs. Outside
  - Clinical Thick and Thin Section Acceptability
- Central Processing
  - RL6's by category
  - Total Inbound Calls, Total Missed Inbound Calls, % Missed Calls Threshold (new TBD)
  - Percentage of Registration Errors (new TBD)

- Laboratory Outreach
    - Mislabeled Specimens Threshold monthly 3-5 specimens Goal 0
    - Specimen Issues Threshold monthly 5-10 specimens Goal 0
    - Courier TAT STAT <20 miles = Threshold and Goal 85 mins
    - Courier TAT STAT >20 miles = Threshold and Goal 125 mins
    - Courier TAT STAT >40 miles = Threshold and Goal 165 mins
- Microbiology
    - TAT – ER Gram Stains Threshold average 35 mins
    - Blood Culture Contamination – Threshold = 3.0%
    - Baseline Positive AFB Results
    - Baseline Positive Chlamydia (Threshold 10%) and GC (Threshold 3%) Results
    - Critical Values
- Inpatient Phlebotomy
    - Hand Hygiene Compliance goal 100%
    - Specimens inpatient phlebotomy unable to collect
- Outpatient Phlebotomy
    - Missed tests/Incorrectly collected tests
    - Cancer Center wait times Threshold <15 minutes
    - DHP Calling critical values Goal 100%
- Critical Care
    - Critical Values Called = Goal 100%
    - Hemolysis Grade on K >5.0 = Goal 100%
    - QC Performance = Goal 100%
    - BGAS TAT = 90% within 15 minutes
    - Proficiency Testing = Goal 100%
    - Number of floor mislabeled specimens
    - Number of instances of >3 attempts to call a critical value
- Core Lab
    - Chemistry
        - TAT's for Troponin, Glucose, CSF Glucose
            STAT =Threshold 60mins Target <20% under previous month
            ER TAT = Threshold 60 mins Target <20% under previous month
            Routine TAT = 90 mins Target
            Cancer Center Glucose = Target 60 mins
    - Hematology
        - TAT's for HGB, PT, UA
            STAT = Threshold 60 mins Target <20% under previous month
            ER TAT = Threshold 60mins Target <20% under previous month
            Routine TAT = 90 mins Target
            Cancer Center HB = 45 min Target
    - Critical Value Call Times for Core Lab Threshold 30 minutes
    - Error documentation
    - Specimen Rejections for ER, NICU, Other IP Ped Units
    - Referral Testing
        - Tests not performed by Quest
- Anatomic Quality Assurance
    - Total Accessions for the month
    - Amended Reports breakdown
    - TAT- Accession to pathologist sign out (Goal 100%)
    - Biopsies (2 days) Threshold=75% Target = 80%
    - OR (3 days) Threshold = 75% Target = 80%
    - Total Consults (Intradepartmental reviews)
    - Total Send outs
    - Conferences with Cases presented breakdown of discrepancies
    - Transcription Productivity

    - Second Read New Malignancy Audits (Pink Sheet Reviews)
- Point of Care Testing
    - QC rates for Hemochron/Medtronic/Avox = Expected performance 100%, unacceptable <95%
    - iSTAT star out rate = Acceptable <2%
    - iSTAT Quality Check Code rate = Acceptable <5%
    - iSTAT misidentification = Expected performance 0% unacceptable =0.2%
    - Glucometer improper use = Expected performance 0%, unacceptable threshold 1 occurrence
- Quality and Compliance
    - CAPA reports metrics
- Molecular Biology
    - TATs for Non-HPV, PCR, KRAS, EGFR, BRAF (Goals for KRAS, EGFR, BRAF = within 10 days)
    - Specimen/Requisition/Computer Errors
    - IHC/IMFL, PCR Test Volumes and % Repeats
- Billing and Coding
    - Audit – verification of referring physician's order to pathology report
    - Procedure and diagnosis coding per audit/per Wake One/CoPath
    - Attending Signature
- Blood Bank
    - Mislabeled Blood Specimens – Goal <1%
    - TAT (TAT in WHON) – Receive to Complete <60 mins
    - Computer- Billing Wake One Issues
    - Wastage Goal <2% (except Cryo <20%)
- Bone Marrow Transplant
    - Positive cultures #
    - Micro cultures sent #
    - % of total Positive cultures
    - # of infusions
    - # of reactions
    - Reaction type breakdown
    - Number of transplants
    - Days to ANC (average days to)
    - Platelet Engraftment (average days to)
    - Research Samples
    - Number of Quality Exceptions
    - FDA reportables
    - LIS Charges
- Blood Transfusion Safety Report – quarterly submission
- LIS will provide summary of:
    - New tests validated Beaker/EPIC/Patient Portal
    - New software or major upgrade validation and testing.
    - LIS Downtime reports
    - Physician/Employee Incidents from HELP tickets

HLA and Medical Genetics participate in the QA/QI meetings for the Department of Pathology and their reports are included in the summary of our minutes. However, each of these laboratories hold separate CLIA/CAP/ASHI accreditation certificates and are ultimately responsible for their own individual QA/QI plans as deemed appropriate by their Laboratory Directors for CLIA purposes.

4) **Laboratory Executive Committee, LEC:**
    a) The LEC meets monthly to discuss the strategic planning and research and development appropriate to the clinical needs of the laboratory. The processes of implementing and evaluating improvements and/or solutions will also be discussed.
    b) Minutes of these monthly meetings will be reviewed by the CLIA laboratory director.

5) **Review/Revision/Implementation**

a) Review Cycle: This policy shall be reviewed by The CLIA Laboratory Director at least annually from the effective date.

b) Office of Record: Laboratory Compliance Section of the Department of Laboratory Medicine and Pathology.

6) **Related Policies N/A**

7) **Governing Law or Regulations**

CAP Standards
CLIA Standards
AABB Standards
TJC Standards

8) **Attachments: QA/QI Annual Assessment Form**

9) **Revision Dates:**

Review/Revision Date	Review/Revision Description	Signature
July 1, 2016, March 15, 2018. November 17, 2018	Biennial Reviews;	
February 21, 2019	Added Information on LEC and staffing requirements; added review/revision chart at end	

Wake Forest Baptist Health
Department of Pathology
QA/QI Annual Section Assessment Form

Section:_____ **Completed by:** _____ **Date:** _____

	Yes	No	Comments
1. Does the QA/QI report follow the QA/QI Plan?			
2. Are monitored elements objective and measurable with goals/thresholds clearly defined?			
3. Are monitored elements appropriate based on CLIA/CAP guidelines for your section?			
4. Are appropriate data collection methods used?			
5. Do indicators relate to both quality and appropriateness?			
6. Are patterns/trends identified on a timely basis?			
7. Are corrective action plans developed when patterns or trends are identified?			
8. Are reports detailed enough to be useful? Are corrective actions that may have been implemented addressed in the report?			
9. Has any process resulted in improved patient care? What/How?			
10. Should all monitors be continued? If NO, which ones, why?			
11. Are revisions or addition of new monitors needed for the QA/QI plan? If, yes, please identify the changes.			
12. Are all staff aware of (involved in) QA/QI activities?			
Additional Comments:			
Manager Signature:			
Section Medical Director Signature:			
CLIA Lab Director Signature:			

Department of Pathology QA/QM/QI Plan Form Revision 3/11/2019