Wake Forest Baptist Health	CAPA (Corrective Action/Preventative Action)	Document Control Number:	
		Effective Date:	11/13/18
		Revised Date:	July 2019
		Contact:	Laboratory Compliance, QA & Safety
Name and Title: Dr. Gregory Pomper, MD		Date Approved:	10/7/19

1) **General Policy Statement:**

It is the policy of Wake Forest Baptist Medical Center to perform all laboratory testing according to established and appropriate protocols and/or procedures. All members of the laboratory staff have been trained to identify nonconforming events that qualify for corrective action when deviation from these protocols or procedures occurs.

For appropriate laboratory management and patient safety, deviations from established procedures must be identified promptly and brought to the attention of leadership. The quality system within the laboratory requires that nonconformance events be recorded, investigated, and tracked so that corrective actions can be taken and necessary improvements made. In addition, CLIA and other regulatory bodies require recording and archiving of incidents (nonconforming events). These incidents and their corresponding corrective and preventive actions need to be recorded and distributed to the proper members of lab administration, to include the Safety Governance Committee, for resolution and archival to ensure proper laboratory function and overall effectiveness of the system.

The purpose of this procedure is to provide a process for identifying, preventing and eliminating the cause of actual or potential nonconformity, using risk management principles.

a) **Scope:**

All employees in the Laboratory Pathology Department of WFBMC including both AP and CP sections.

b) **Responsible Department/Party/Parties:**
   i. Policy Owner: Department of Laboratory Pathology
   ii. Procedure: Department of Laboratory Pathology
   iii. Supervision: Department of Laboratory Pathology
   iv. Implementation: Department of Laboratory Pathology

2) **Definitions:** For purposes of this procedure, the following terms and definitions apply:

a) **Corrective Action/Preventative Action (CAPA):** Structured problem-solving process that results in identifying the root cause of the problem, documents the immediate corrective actions and results in one or more preventative actions to minimize risk of recurrence.
b) **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
c) **Immediate Corrective Action:** Immediate actions taken to eliminate the cause(s) of an existing nonconformity, defect of other undesirable situation in order to prevent patient harm.
d) **Investigation:** A comprehensive review of the event to include: interviews, assessment of equipment failures, inappropriate acts (human errors) and external factors.

e) **Nonconformity:** Non-fulfillment of a specified policy and/or procedure. Deviation from the established policy and/or procedure.
f) **Preventive Action:** Actions taken to eliminate the cause(s) of a potential deviation, defect or other undesirable situation in order to prevent occurrence.
g) **Root Cause:** The most basic cause of a given behavior. Human error is not the root cause of an error; it is typically the starting point, a symptom of the system failure.
h) **Effectiveness:** For purposes of this policy, effectiveness will be achieved when the underlying causes of an incident have been identified, the preventative actions are appropriate solutions to the root cause and a plan for monitoring the success of the actions is in place when applicable.

3) **Roles and Responsibilities:**

Laboratory Testing Personnel

- Report any non-conforming events or deviations to the appropriate Supervisor/ Lab Manager in a timely manner.
- Participate in the Root Cause Analysis and Corrective and Preventative Action process/ discussions as necessary or requested by Lab Administration.

General Supervisor/ Lab Manager

- Initiate investigation per CAPA standard operating procedure.
- Make immediate corrective actions as necessary to prevent further nonconformance and potential patient harm.
- Develop a preventive action plan in collaboration with the Technical Supervisor or Section Director with the intent of minimizing the recurrence of the same type of event.
- Conduct or delegate audits as necessary to ensure the preventive actions are followed and are meeting the intent of minimizing a reoccurrence of the same event.
- Complete all documentation on CAPA form, including the signature of the Technical Supervisor or Section Director.
- Submit completed CAPA form to Quality Assurance.
- Present the CAPA to the Safety Governance Committee for feedback and approval.
- Complete any required follow-up for an event and report the follow-up to the Safety Governance Committee for approval.

Technical Supervisor or Section Director

- Develop a preventive action plan in collaboration with the General Supervisor/Lab Manager with the intent of minimizing the recurrence of the same type of event.
- Ensure that event information being submitted for their section is accurate and being appropriately classified and documented under the CAPA policy.
- Sign and date the completed CAPA form
- Present the CAPA to the Safety Governance Committee for feedback and approval when appropriate

Quality Assurance Personnel

- Log each event onto the CAPA Log for the Department of Pathology.
- Maintain all documents associated with the CAPA process in the Lab Compliance/QA Department.
- Track and trend the logged incidents for quality assurance purposes.

Safety Governance Committee

- Membership: Lab Pathology Department Chair, Administrative Director Pathology, CLIA Lab Director, Anatomical Pathology (AP) Pathologist, Associate Administrative Directors, QA Manager, Safety Manager, and Risk Management Consultant
- Review CAPAs with a focus on the root causes and preventative actions
- Make recommendations for revisions of the CAPA as deemed necessary to maintain compliance with all regulatory bodies and WFBH policies and procedures or approve the CAPA.
- When appropriate, review follow up documentation of the CAPA for effectiveness.
- Route CAPA to CLIA Lab Director

CLIA Laboratory Director

- Review each CAPA and when appropriate, review the follow up documentation and either suggest changes or approve it.
- Once approved, the decision made by the CLIA Lab Director is final.

4) Procedure:

A. Issue Identification

1. Any employee who learns of a nonconformity or potential nonconformity or deviation related to testing or a quality system shall immediately notify his/her manager.

2. The manager will determine if the event requires completion of a CAPA form by using the following guidelines:
    a) Was the event/incident planned?
    b) Was the event/incident predicted?
    c) Was event/incident included in the procedure?
    d) If the answer is no to any of these questions, a CAPA and/or a RL6 must be submitted.

3. CAPA must be completed for the following issues:
    a) Failed proficiency tests
    b) Issues that may affect the defensibility of quality test results (e.g. failure to run QC samples, running expired QC materials, failure to document QC QC failures that result in trends that require corrective action
    c) Any issue that affects the operational readiness of the laboratory (e.g. lack of reagent, expired reagent, equipment failure)
    d) Mislabeled/Missing or Lost specimens occurring between lab to lab transport
    e) QA tracking failures (TAT failures, Temperature/Humidity failures, Patient reporting errors, Failure to call critical values, etc.)
    f) Failure to follow Policy and/or Procedures; ie deviations from SOP
    g) Other incidents per lab manager's or director's discretion or at the recommendation from the QA Manager, Safety Manager or CLIA Lab Director.

4. RL6 must also (in addition to the CAPA) be completed for any deviation that involves a patient(s) or have the potential to involve a patient(s). Examples include but are not limited to: lost or misplaced specimens, accessioning errors, labeling errors, amended test values in the medical record that are amended from a normal value to an abnormal value or from an abnormal value to a normal value, delays in turnaround times and

equipment failures. Other incidents per lab manager's or director's discretion or at the recommendation from the QA Manager, Safety Manager, Risk Management or CLIA Lab Director.

a. All employees are encouraged to report all occurrences that cause harm or have the potential to cause harm through RL6. (Refer to Event Reporting Policy)

5. The manager will initiate the CAPA process by notifying the Lab Section Director. This notification should include a brief summary of the type of nonconforming event or deviation, the area in which it occurred, the date it occurred and the beginning date of the Root Cause Investigation.
    a. Lab managers may delegate the completion of a CAPA at their discretion

6. The QA staff will assign a reference number and log the CAPA in the CAPA Log for the Department of Pathology when the CAPA is submitted.

B. Completing the CAPA form (attachment A):

1. **Non-conformance/deviation description:** The nonconformity or deviation will be described to include:
    a) the date and time of the nonconformity/deviation
    b) where the nonconformity/deviation occurred
    c) description of the specific nonconformity/deviation
    d) if a patient(s) was harmed as a direct result of the nonconformity/deviation
    e) what was impacted and affected by the nonconformity, as applicable

2. **Root Cause Analysis:**
    a) Step 1: Investigate the nonconformity/deviation
        i. Interview those involved
        ii. Determine the overall sequence of events
        iii. Identify the *expected* outcome/action
        iv. Identify the *actual* outcome/action
        v. Identify the gap between the expected and actual outcome/action
        vi. Determine if this event or deviation has occurred in the past and if so at what frequency
    b) Step 2: Identify direct causes
        i. Consider equipment failures, inappropriate acts (human error) and external factors (tornadoes, snow storms)
        ii. Use the Taguchi method by asking 'why' five times
    c) Step 3: Identify the root cause
        i. There must be a cause and effect relationship
        ii. Human error is not the root cause of the failure; it is a symptom of the failure. While human error is often involved in nonconformities and deviations, the very occurrence of a human error implies that it can happen again

    d) If the investigation reveals that the scope or impact of a particular incident is severe or extreme, QA personnel may be brought in to assist the Section Manager with the analysis.

C. Immediate Corrective Action

1. Implement an immediate corrective action to contain and mitigate the nonconformance or deviation when applicable. For example, if something is spilled, the short term corrective action is to clean up the spill.
2. If the nonconformance or deviation was directly related to patient harm or reached the patient through a test value or pathology report in the medical record, the immediate corrective action must include the timeframe the ordering provider(s) was notified. Include the name of the provider that was notified and the date/time of the notification.
3. The date of implementation of the corrective action should be noted.

D. Preventive Action

1. Implement preventative actions that specifically address the root cause(s) with the goal to mitigate the risk of the same nonconformance or deviation from occurring again.
2. Each preventative action must be action oriented, assigned to a specific role and have an implementation date.
3. Preventative actions should be audited by the Section Manager or Section Director or their delegate to determine if the preventative actions are effective and if the lab section is compliant with the action plan. Generally a 4 month audit is acceptable to determine effectiveness and compliance; however, the timeframe for audits is at the discretion of the Lab Manager, the Medical Director and the Safety Governance Committee.
4. If the problem is judged to be a serious issue or risk by the QA department or CLIA Lab Director, then it may be necessary to perform additional audits or inspections to confirm the effectiveness of the corrective action.
    a) If no instances of the problem occur during the monitoring period and the corrective action is confirmed to be effective, the corrective action can be considered complete and the follow up can be completed.
    b) If follow-up audits, inspections or monitoring of the preventative actions indicate that the preventative action is not effective, the root cause analysis process should be repeated.
5. All CAPA audits should be submitted to Laboratory Compliance/QA Department and reported to Safety Governance Committee.

E. CAPA Approval

1. CAPAs will be reviewed and approved by the Safety Governance Committee before going to the CLIA director for final approval.
2. CAPAs are maintained in the Laboratory Compliance/QA Department for a minimum of 2 years.
3. The QA staff will log and classify each CAPA event for quality assurance purposes. The results of this process will be reviewed on a regular basis for trends that would need to be reported through the Laboratory's Quality Assurance Monthly meetings.

5) Staff Education and Competence:

1. All laboratory staff members are educated on CAPA and RL6 reporting upon hire and ongoing as necessary.
2. All personnel in the Pathology Department must read the CAPA procedure. Once successful understanding of CAPA is demonstrated, training documentation will be kept in the employee's personnel folder.

6) **Review/Revision/Implementation:**
   a) Review Cycle: Each 2 years
      i. All new policies/procedures/guidelines and those that have major revisions must be reviewed/signed by the CLIA Laboratory Director.
      ii. Review/sign-off can be completed by the designated section Medical Director or section manager in the following circumstances:
         - Biennial review
         - Minor document revisions
   b) Office of Record: Laboratory Compliance, QA & Safety

11) Related Policies: None

12) References:

42 CFR 493.1282 - Standard: Corrective actions. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_c_lab.pdf
Indiana Incident Management Program. August 2016. <<https://www.aphl.org/MRC/Documents/OS_2016Aug_Indiana-Incident-Management-Program.pdf#search=indiana%20incident%20management%20program>> accessed October 16, 2019

13) Attachments:

Attachment A: CAPA Form
Attachment B: Incident Management Workflow
Attachment C: Additional Follow-Up Workflow

14) Revisions:

Review/Revision Date	Review/Revision Description	Signature
04/03/2019	Added Additional Safety Governance Committee Review	
07/16/2019	CAPA Form Revised. Policy revised accordingly.	

Lab Section:	**Initial Date:**
CAPA Prepared by:	**Section Director:**
CAPA#:	Date Received:
Non-Conformance/Deviation Description:	**Completed by:**
Root Cause Analysis:	**Completed by:**
Immediate Corrective Actions:	**Completed by:**

Preventative Actions:	**By Whom:**	**Implementation Date:**
1.		
2.		

Did the identified nonconformity affect test/patient results?	**YES**	**NO**	**N/A**

RL6#	**Patient Harm Score:**	**MRN:**

1. Lab Manager Signature:	**Date:**
2. Lab Director Signature:	**Date:**
3. Send CAPA to Compliance	
4. Safety Governance Majority Approval Granted:	Date:

Audit Required:	YES	NO	Date to report audit:

5. CLIA Lab Director:	Date:

Non-Conformance/Deviation Description:

Immediate Corrective Actions:

Preventative Actions:	By Whom:	Implementation Date:
3.		
4.		

Additional Comments:

Safety Governance Recommendations:	
Preventative Actions:	**Date:**

Harm Score Guide

A. No Error
B1. No Harm, Did not reach patient by chance
B2. No Harm, Did not reach patient by staff action
C. No Harm, Did reach patient
D. No Harm, Did reach the patient, monitor
E. Harm, Temporary harm need intervention
F. Harm, Initial or prolonged hospitalization required
G. Harm, Permanent harm to patient
H. Harm, intervention necessary to sustain life

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Attachment B: Incident Management Workflow