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

1) **General Policy Statement:**

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

For good laboratory management, it is important that deviations from these established procedures are promptly brought to the attention of leadership so they can be addressed appropriately. The quality system within the laboratory must make it mandatory that such incidents 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 member of lab administration, for resolution and archival to ensure proper laboratory function.

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:** Roles and Responsibilities of personnel in the Department of Pathology pertaining to discovery of or investigation of nonconforming incidences or deviations from established procedure.

CLIA Laboratory Director

- Review the submitted documentation for each incident and either suggest changes or approve it.
- If required, review the follow up documentation for each incident and either suggest changes or approve it.
- Once approved, the decision made by the CLIA Lab Director is final.

Technical Supervisor or Section Director

- Review the incidents, investigations, corrective actions, and follow-ups that involve his/her particular section providing guidance and making suggestions as necessary.
- Ensure that event information being submitted for their section is accurate and being appropriately classified and documented under the CAPA policy.

General Supervisor/Manager

- Initiates investigation per CAPA standard operating procedure.
- Opens the incident, by notifying the Section Director and Quality Assurance (QA).
- Recommend the incident for closure through the QA staff.

- Suggest any corrective actions that may be useful in preventing recurrence of this type of incident and record that in on the CAPA form.
- Complete any required follow-up for an incident and route the follow-up for approval.

Testing Personnel

- Understand the types of events that require Corrective Actions
- Report any non-conforming events to the appropriate Supervisor/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.

Quality Assurance Personnel

- Open and log each incident in to the Nonconforming Events Excel Log for the Department of Pathology.
- Review every incident reported for accuracy, completeness, and appropriateness.
- Route the incident CAPA forms to the appropriate individuals for the approval process.
- Review any follow up information, routing the follow up to the CLIA Lab Director for final approval.
- Maintain all documents associated with the CAPA process in the Lab Compliance/QA Department.
- Track and trend the logged incidents for quality assurance purposes.

b) **Responsible Department/Party/Parties:**

i. Procedure Owner: Laboratory Compliance, Quality Assurance (QA), Safety and Point-of-Care Testing Department. It is the responsibility of this department to review all CAPA(s) submitted.

ii. Procedure: All personnel in the Pathology department who are educated and qualified to investigate nonconformities are responsible for following the processes outlined in this document.

iii. Supervision: The Medical Director and/or laboratory director, as indicated on covering CLIA certificate, shall supervise the person(s) performing activities outlined in this document.

iv. Implementation: Each employee in the Pathology department is responsible for ensuring compliance with processes/procedures and identifying when nonconformance has occurred. All investigations must be brought to the attention of the Laboratory Compliance, Quality Assurance (QA), Safety Office.

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

a) **Corrective Action:** Actions taken to eliminate the cause(s) of an existing nonconformity, defect of other undesirable situation in order to prevent recurrence.
b) **CAPA:** A form that documents an existing or potential non-conformity and subsequent corrective and/or preventative action.
c) **Clinical Laboratory Improvement Amendments (CLIA):** United States federal regulatory standards that apply to all laboratory testing performed on humans.
d) **Investigation:** A comprehensive review of real or alleged issues related to nonconformance.
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:** A fundamental nonconformity that results in a deviation and must be correct to prevent recurrence of the same or similar nonconformity.

3) Procedure:

A. Issue Identification

1. Any employee who learns of a nonconformity or potential nonconformity related to testing or a quality system shall immediately notify his/her manager and review the situation.
2. The manager is to determine whether the event requires completion of a CAPA form by using the following guidelines:
    a) Was it planned?
    b) Was it predicted?
    c) Was it included in the procedure?
    d) If the answer is no to all of these questions, the event should be investigated and documented.
3. Formal Corrective Actions must be implemented and recorded for the following types of 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) Any other incidents of concern per manager's discretion.

    NOTE:** The manager has the discretion to investigate any event or situation they deem necessary but unless they are classified above, they are not required to be formally documented by a full root cause analysis. Other occurrences may only be documented using the problem logs in the lab section where a brief description of the event, the corrective action can be recorded.

4. The manager shall initiate the formal corrective action process by bringing the issue to the attention of their Section Director and the Laboratory Compliance/QA Department. This notification should include a brief summary of the type of nonconforming event, the area in which it occurred, the date it occurred and the beginning date of the Root Cause Investigation.
5. The QA staff will review the initial information and if appropriate for the corrective action process, will assign the newly established CAPA with a reference number,(i.e. CAPA_yearmonth_01) and log it in the Nonconforming Events Log for the Department of Pathology.
6. The QA staff will respond back to the Section Manager with a newly assigned CAPA number to be included on the CAPA form when submitted.

B. Root Cause Analysis

1. The nonconformity identified should be described on the CAPA form by the Section Manager in as much detail as possible. This includes the date and time of the nonconformity, where the nonconformity occurred, why and how the nonconformity occurred, who identified the nonconformity, and who/what was impacted and affected by the nonconformity. The level of effort associated with the investigation should be commensurate with the extent of the problem.
2. Several effective principles associated with root cause investigation include the following:
    a) Thorough investigation includes reviewing records to determine what happened, why it happened, when it happened, what else was happening, who was involved, what areas were affected, what the impact was, and where other information may be found.
    b) The investigation should include a determination of whether or not the problem has occurred in the past, and if so, at what frequency.
    c) Investigators should systematically analyze the problem and its associated data and facts to narrow down the potential root causes to the most likely one(s).
    d) Most root causes are not ultimately found to be due to personnel issues, so be sure to initially examine processes, training, equipment, maintenance, and facilities instead of relying on analyst error.
    e) When 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. Corrective Action

1. It may be necessary in some situations to first implement a simple, immediate corrective measure (aka short term corrective action) to contain and mitigate the immediate problem. For example, if something is spilled, the short term corrective action is to clean up the spill.

    NOTE:** While frequently necessary, these should not be confused with long-term corrective actions designed to prevent future occurrences of the problem.

2. All steps within the corrective action plan should be described in as much detail as possible. The actions taken should be commensurate with the magnitude and potential implications and risks of the problem and should be documents.
3. The date of implementation of the corrective action should be noted.
4. Once the corrective actions have been decided upon, the Section Manager will complete the CAPA form, attach the appropriate supporting documentation and deliver it to the Lab Compliance QA staff. The QA staff will review the action plan for completeness.

D. Preventive Action

1. Regardless of the corrective action chosen, its effectiveness must be monitored by the Section Manager or Section Director for a period of time determined in the incident investigation or corrective action. 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 or inspections or monitoring of the corrective action indicates that the corrective action was not effective, then it is necessary to go back through the process of considering root causes and corrective actions. It may be that the root cause was incorrectly identified, or it may be that the corrective action chosen from among the potential corrective actions was not appropriate.

2. All steps within the preventive action plan are described in as much detail as possible.
3. The date of implementation of the preventive action should be noted as well as the identity of the personnel responsible for it implementation.

E. CAPA Approval

1. Once the CAPA form and investigation has been completed, it must be reviewed, approved and signed off by the CLIA Laboratory Director.
2. Documentation is filed and help for two years in the Laboratory Compliance/QA Department.
3. The QA staff will number, log, and classify each CAPA, in accordance with the events listed above in 3.A.3, 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.

4) Staff Education and Competence:

1. Every staff member must have been trained to recognize the events that require initiation of CAPA investigations.
2. All personnel in the Pathology Department must read the procedure. Once successful understanding of CAPA is demonstrated, training documentation will be kept in the employee's personnel folder.

5) 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 and Point-of-Care Testing

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/QS_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) Revision Dates:
Effective Date:

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Reviewed: _____ Date: _____

Attachment A: CAPA Form

Corrective Action / Preventive Action Plan

Area/Department:	Initial Date:
Lab Manager:	Section Director:
CAPA Number (To be completed by QA):	

Non-Conformance Description:

Root Cause Analysis:

Corrective Action:
Date of Implementation:

Preventive Action:
Date of Implementation:

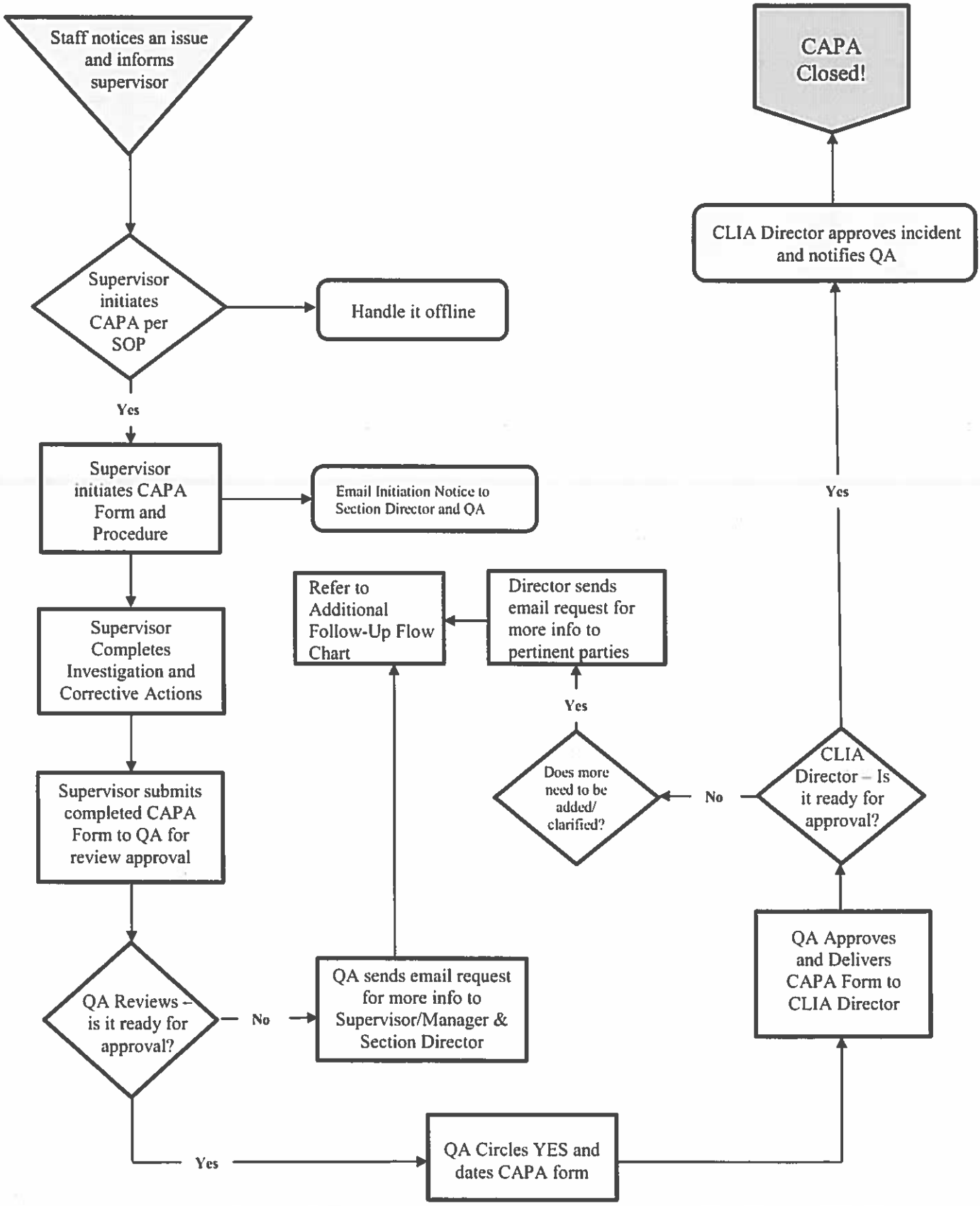
CAPA Reviewed:	Date:
Section Medical Director Signature:	Date:

CAPA Approved:	YES	NO
QA Manager Signature:		Date:

CAPA Approved:	YES	NO
CLIA Director Signature:		Date:

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

Attachment B: Incident Management Workflow



Attachment C: Additional Follow-Up Workflow