NEW YORK STATE | **Department of Health**

WADSWORTH CENTER

CLINICAL LABORATORY EVALUATION PROGRAM

Guidance for completion of the Plan of Correction

This document provides guidance for completion of the Plan of Correction in response to the findings identified in your Laboratory Evaluation Report. The plan of correction is a three-step process to include the performance of a root cause analysis, corrective action or system change to prevent recurrence and, the quality system change made to monitor the effectiveness of the corrective action. **Failure to address all three steps will result in an unacceptable plan of correction and it will be returned for completion.**

I.   PERFORM A ROOT CAUSE ANALYSIS

A root cause analysis is a team process to identify the cause of a problem that resulted in a negative outcome. The root cause analysis provides an opportunity to identify why the problem occurred and the actions necessary to prevent similar issues in the future.

1. Investigate to determine what, who, how, why and when the event occurred. Identify the event, select key team member(s) who are knowledgeable about the relevant processes. These team members will collect the information in steps 2 - 4 below.

2. Review the elements of the **pre-examination** process, examples include but are not limited to:
    - **Human Resources:** Training and Competency Assessment
    - **Facility Design & Resource:** Reagent inventory control, Equipment maintenance, Safety
    - **Standard Operating Procedure(s):** Staff compliance, Version control and Bench excerpts
    - **Specimen**: Collection manual, Test requisition, Collection, Labeling, Transport, Accessioning, Order entry verification, Quality, Quantity

3. Review the elements of the **examination** process, examples include but are not limited to:
    - Method validations
    - Environmental controls
    - Calibration, Quality control
    - Analytical records (worksheets)
    - Instrument error
    - Testing delay, testing error

4. Review the elements of the **post-examination** process, examples include but are not limited to:
    - Process review to include data and results review
    - Reporting to include verification of accurate transmission and communication of results
    - Review of the Laboratory Information System (LIS)
    - Patient impact

II.   CREATE AND IMPLEMENT CORRECTIVE ACTION / SYSTEM CHANGE

The expectation is that all areas overseen by the laboratory and for which the laboratory is responsible have been reviewed for the same or similar nonconformity. Areas include, but are not limited to, transfusion medicine, point of care testing, patient service center, limited laboratory service, respiratory department, oncology unit, etc.

Examples of the questions to ask when creating your corrective action or system change include, but are not limited to, the following:

1. What change is necessary to ensure there will not be a repeat of this deficiency?

2. Do policies, procedures and/or processes need to be revised, amended, or created to ensure there will not be a repeat of this deficiency?

3. Is additional training and competency assessment needed?

4. Should control and feedback loops be created to ensure participants will complete an action?

5. Will simplifying or standardizing tasks improve the process?

6. Is increased supervisor oversight necessary?

7. Should staff increase or staff schedules be revised to provide better coverage for high volume times?

8. Will modification and/or verification of the laboratory information system (LIS) address the issue?

9. Are there distractions that can be reduced or eliminated?

10. Can the communication among laboratory, nursing and medical staff be improved?

III.   CREATE QUALITY ASSURANCE (QA) PROCESS(ES) TO FOLLOW THE EFFECTIVENESS OF THE CORRECTIVE ACTION / SYSTEM CHANGE

To ensure the effectiveness of the corrective action or system change, perform audits and/or put quality indicators in place to include the pre-examination, examination and post-examination processes. Examples of quality assurance processes include, but are not limited to, the following:

1. Increase the frequency of Quality Management System (QMS) meetings to provide timely feedback to management and staff

2. Create internal audits and quality indicators

3. Increase the frequency of internal audits and quality indicators

4. Assess specimen transport conditions

5. Assess result turn-around time

6. Increase the frequency of quality control and calibration review

7. Retrain and reassess competency

Root Cause

Review pre-examination process
- **Human Resources:** Training Competency Assessment
- **Facility Design & Resource:** Reagent Inventory Maintenance Safety
- **Standard Operating Procedure(s):** Compliance Version control Bench excerpts
- **Specimen:** Collection Manual Test requisition Collection/Labeling Transport Accessioning Verify Order Entry Quality/Quantity

Review examination process
- **Method Validation**
- **Environmental Controls**
- **Calibration, Quality control**
- **Analytical records (worksheets)**
- **Instrument error, Testing error, Testing delay**

Review post-examination process
- **Process review to include data and result review**
- **Reporting to include accurate transmission and communication of results**
- **Review of the Laboratory Information System (LIS)**
- **Patient Impact**

Corrective Action

- What change is necessary to ensure no repeat of deficiency?
- Do policies or processes need to be created or revised?
- Is training and competency assessment needed?
- Need to create control and feedback loops?
- Simplify or standardize tasks?
- Increase supervisor oversight?
- Increase staff or revise staff schedules during high volume times?
- Modifiy the LIS? Automate?
- Eliminate or reduce distractions?
- Improve communication with nursing and medical staff?

Quality Assurance Process

- **Increase frequency of Quality Management System meetings**
- **Create internal audits and quality indicators**
- **Increase the frequency of internal audits & quality indicators**
- **Assess specimen transport conditions**
- **Assess result turn-around-time**
- **Increase the frequency of QC & calibration review**
- **Retrain and reassess competency**

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