| CLINICAL LABORATORY INTERNAL AUDIT POLICY | |
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| Policy # | Prepared by: |
| Supersedes Policy: | Effective Date: |

**APPROVALS** *in this section*

**Approved by: _____ Date: _____**
Laboratory Director

**RECORD OF REVIEWS**

| Date | Signature | Title | Procedural Changes/Review |
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**VERSION HISTORY**

| Version # | Section #/Changes | Revision Date | Reason for Revision |
|---|---|---|---|
| 0 | | | |
| 1 | | | |
| 2 | | | |

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## PURPOSE

Laboratory internal auditing is a crucial component of an effective Quality Management System (QMS). Goals of the internal audit program at [Lab Name] include:

- Improving laboratory service, quality, productivity, and performance.
- Identifying inconsistencies among policies, processes, and procedures, and their implementation and/or practice.
- Serving as effectiveness checks for process improvements.
- Verifying conformance with regulatory and accreditation requirements.
- Ensuring the QMS is effectively implemented and maintained.

## POLICY

1. The Audit Program Coordinator (QA Manager) will conduct audits in the clinical units with assistance from the QA Consultant and other trained staff. Audits will rotate through all clinical laboratory units within two calendar years. Internal audits are announced and scheduled with the cooperation of the unit to be audited. Each January, the QA Manager will issue a proposed audit schedule for the coming year; however, workload and staffing priorities may necessitate schedule changes. Additional audits may be performed by laboratory staff as needed. The Environmental Laboratory QA Manager will oversee audits in the Environmental Sciences Unit.

2. Prior to conducting each audit, the Audit Program Coordinator will prepare a ***Laboratory Internal Audit Plan*** that lists the purpose of the audit, scope, activities to audit, sampling plan, documents required, etc. Information from the Audit Plan will be shared with the Auditee (Unit Manager/Supervisor) to assist them in preparing for the audit.

3. Audits will be performed as a full laboratory review (system audit), a focused (process) audit, or a service audit (e.g. reviewing requisitions for required information). The full laboratory review will be performed either as a mock inspection or using the tracer format in which the auditor follows and documents the path of a specimen throughout the laboratory area.

4. The ***[Lab Name] Clinical Laboratory Audit Tool*** checklist will be used for system audits, but adjusted for specific units and audit requirements as needed.

5. Staff will provide copies of requested procedures, documents, or files as needed to assist the auditor. The auditor will select the specimens to be used in a tracer audit. When feasible, the auditor will request materials (policies, procedures, package inserts etc.) ahead of time for a desk review prior to the onsite audit.

6. The audits will be numbered as:
    a. first four digits of the year (2017)
    b. the following digits will be sequential, beginning with 01.
    Example: 2017-02 – will be the second audit performed in 2017.

7. The ***Clinical Labs Audit Report*** form will be used to document system audits. Each finding will include the objective evidence and regulatory requirement. The report may also include observations which may require further investigation to determine if corrective action is necessary. The completed Audit Report will be sent to the Lab Director, Assistant Lab Director, Unit Manager, and Supervisor for their review. Each person reviewing the report will initial and date to indicate the review. If requested, a Word Version will be provided to the Unit Manager/Supervisor to facilitate a corrective action report. The audit report, records and supporting documentation will remain on file in the QA office for a minimum of 2 years.

8. When significant regulatory findings are identified, the unit manager and/or supervisor will respond to the QA Manager with a proposed plan of correction within **15** days of receipt of the report. Other findings that need correction, but do not directly affect patient testing must be corrected within **60** days unless an extension is granted. The QA Manager will work with the supervisor and manager to implement a corrective action plan and will lend support on interpretation of regulatory requirements. The supervisor will forward documentation of the corrected procedures or activities to the QA office to support the proposed corrections. If requested, a brief follow-up audit can be performed to confirm that corrections are in place.

**ATTACHMENTS:**

1. Laboratory Internal Audit Plan Template
2. Clinical Laboratory Audit Tool
3. Clinical Lab Tracer Audit Checklist
4. Clinical Labs Audit Report Template