

**County Health Department  
Address**

## LABORATORY QUALITY SYSTEMS ASSESSMENT CHECKLIST

**Select one or more sections under a system periodically and evaluate components or processes for compliance.**

- Write "Y" for Yes or "N" for No by an item to indicate the outcome of the assessed item.
- Write "N/A" if item is not applicable at the time of evaluation.
- In the "Comments" area, explain how the assessment was done. Were charts reviewed, requisitions examined, for what period of time? List all significant findings.
- Summarize overall findings in the "Discussion" area on the last page.

### GENERAL LABORATORY SYSTEMS

#### PATIENT CONFIDENTIALITY:

- \_\_\_\_\_ Patient information was kept confidential throughout all phases of testing under the laboratory's control.
- \_\_\_\_\_ Does the laboratory staff view the contents of the patient's chart at any point?

Comments:

#### PATIENT IDENTIFICATION & SPECIMEN INTEGRITY:

- \_\_\_\_\_ Were specimens collected by non-laboratory personnel labeled legibly and correctly?
- \_\_\_\_\_ Was proper paperwork submitted for the specimens received?
- \_\_\_\_\_ Were specimen rejection policies followed?
- \_\_\_\_\_ Were submitters notified when discrepancies were found?
- \_\_\_\_\_ Did the lab maintain optimum integrity of each specimen through completion of testing?

Comments:

#### COMPLAINT INVESTIGATIONS:

- \_\_\_\_\_ Have complaints been documented (on the Problem Log) and investigated according to policy?
- \_\_\_\_\_ If a complaint was investigated, was the problem and resolution documented (QA Study)?
- \_\_\_\_\_ Was the resolution followed up to ensure corrective action was appropriate (monitoring)?
- \_\_\_\_\_ Were policy and/or procedure revisions necessary to prevent reoccurrence of the complaint (corrective action)?

Comments:

#### COMMUNICATIONS:

##### Internal:

- \_\_\_\_\_ Did the lab manager receive information from health department administration that would be impact the efficiency and effectiveness of lab operations?
- \_\_\_\_\_ Did the lab manager share information received from administration with other lab personnel?
- \_\_\_\_\_ Did the lab manager share information received from the Technical Consultant with other lab personnel?
- \_\_\_\_\_ Did individuals with email check it regularly and leave appropriate "away" messages?

##### External:

- \_\_\_\_\_ Was proper telephone etiquette followed?
- \_\_\_\_\_ Were customers helped with a minimum of rerouting?
- \_\_\_\_\_ Were emails and/or voicemail from the Technical Consultant responded to in an appropriate amount of time or by the deadline?
- \_\_\_\_\_ Was the Technical Consultant contacted immediately when there was an unresolved instrument or QC failure?

Comments:

**PERSONNEL COMPETENCY ASSESSMENT:**

- \_\_\_\_\_ Has orientation and training been documented for all testing personnel?
- \_\_\_\_\_ Has proof of minimum education been provided to the lab manager for all testing personnel?
- \_\_\_\_\_ Has proof of education been forwarded to the Technical Consultant for new testing personnel?
- \_\_\_\_\_ Has the Lab Director reviewed and signed off on the assigned duties for testing personnel performing non-waived tests?
- \_\_\_\_\_ Has the Technical Consultant reviewed and signed off on the assigned duties for testing personnel performing only waived tests?
- \_\_\_\_\_ Have all testers performed QC on all approved tests at least once per quarter?
- \_\_\_\_\_ Did all testing personnel complete required annual continuing education in the previous calendar year?
- \_\_\_\_\_ Were competency assessments performed by appropriate personnel?
- \_\_\_\_\_ Were competency assessment results reviewed with appropriate personnel?
- \_\_\_\_\_ Were competency assessment failures investigated by the Technical Consultant and follow up shared with the lab manager?
- \_\_\_\_\_ Was competency assessed for personnel performing blood collections?

Comments:

**PROFICIENCY TESTING:**

**Only for laboratories that are performing at least one module of proficiency testing for Area D.**

- \_\_\_\_\_ Was proficiency testing rotated among testing personnel?
- \_\_\_\_\_ Were proficiency samples processed in a manner similar to patient samples?
- \_\_\_\_\_ Was the Proficiency Testing (PT) Performance form completed for each PT event?
- \_\_\_\_\_ Were copies of all submitted proficiency results retained?
- \_\_\_\_\_ Were incorrect results (graded and ungraded) investigated and corrective action taken (by TC)?

Comments:

**SAFETY:**

- \_\_\_\_\_ Was the Technical Consultant notified of any situation that could affect the lab's performance or the safety of employees?
- \_\_\_\_\_ Were Standard Precautions used when applicable?
- \_\_\_\_\_ Have lab personnel received annual safety training?
- \_\_\_\_\_ Have lab personnel documented annual review of safety manuals?
- \_\_\_\_\_ Have new lab personnel:
  1. Received safety training?
  2. Been offered the Hepatitis B vaccine?
  3. Other vaccine offered \_\_\_\_\_?

Comments:

**PREANALYTIC SYSTEMS**

**TEST REQUISITION:**

- \_\_\_\_\_ Did the lab have written requests for all tests performed?
- \_\_\_\_\_ Did test requisitions contain all necessary information as stated in the lab's policy?
  - Specimen source
  - Date and Time (when appropriate) of collection
  - Patient identification (2 )
  - Ordering clinic or provider
  - Test ordered
- \_\_\_\_\_ Was "received time" documented for all laboratory specimens tested?

Comments:

**POLICY MANUAL:**

- \_\_\_\_\_ Have lab personnel documented annual review of policies?
- \_\_\_\_\_ Are policies current?
- \_\_\_\_\_ Have normal and panic values been reviewed and approved by the Clinical Consultant this calendar year?

Comments:

**ANALYTIC SYSTEMS**

**PROCEDURE MANUAL:**

- \_\_\_\_\_ Were lab procedures current and complete?
- \_\_\_\_\_ Are all procedures saved electronically?
- \_\_\_\_\_ Were current package inserts in place with the corresponding procedure?
- \_\_\_\_\_ Have lab personnel documented annual review of procedures?
- \_\_\_\_\_ Has the Technical Consultant documented annual review of procedures?
- \_\_\_\_\_ Were discontinued procedures dated and kept for a two-year minimum?

Comments:

**QUALITY CONTROL:**

- \_\_\_\_\_ Were environmental controls (temperature, humidity, etc.) recorded and within acceptable limits prior to testing?
- \_\_\_\_\_ Were only in-date reagents, controls, kits, media, etc., used?
- \_\_\_\_\_ Were new lots of QC reagents (hemoglobin, glucose) verified before the current lot expired? Before being put into use?
- \_\_\_\_\_ Was new lot verification documented at the time of testing on the appropriate form?
- \_\_\_\_\_ Was procedural QC performed, documented, and within acceptable limits before patient test results were reported?
- \_\_\_\_\_ Was QC performed at the required frequency (per CLIA Contract description)?
- \_\_\_\_\_ Were appropriate Levy-Jennings charts plotted each day of testing and evaluated for trends or shifts?
- \_\_\_\_\_ Were QC failures (i.e., out-of-range results) documented, along with corrective action?
- \_\_\_\_\_ Was performance of QC rotated among testing personnel?

Comments:

**MAINTENANCE & FUNCTION CHECKS:**

- \_\_\_\_\_ Are scheduled instrument/equipment maintenance properly performed and documented?

Comments:

**COMPARISON OF TEST RESULTS:**

- \_\_\_\_\_ Were instrument comparisons conducted twice a year?
- \_\_\_\_\_ Was parallel testing documented twice each year by all testing personnel performing wet mounts?

Comments:

**TEST RECORDS:**

- \_\_\_\_\_ Were records of testing, including worksheets and instrument printouts, retained and complete?
- \_\_\_\_\_ Was the identity of testing personnel documented for each intermediate step in testing?

Comments:

## POSTANALYTIC SYSTEMS

### TEST REPORT:

- \_\_\_\_\_ Were test results present?
- \_\_\_\_\_ Did the tester initial the results?
- \_\_\_\_\_ Are reference values on the report or readily accessible?
- \_\_\_\_\_ Were panic values reported and documented according to lab policy?
- \_\_\_\_\_ Were corrected/amended reports issued according to lab policy?

Comments:

### DATA STORAGE & RETRIEVAL:

- \_\_\_\_\_ Were exact copies of in-house test reports maintained and accessible?
- \_\_\_\_\_ Was lab documentation (i.e., QC records, worksheets, package inserts, and instrument printouts) retained for a minimum of two years?

Comments:

DISCUSSION: Describe the outcome of the assessment. Were all areas evaluated satisfactory? If not, explain why and describe the corrective action plan. Will a QA Study be initiated as a result of this assessment?

COMPLETED BY: \_\_\_\_\_ DATE: \_\_\_\_\_

LAB MANAGER REVIEW: \_\_\_\_\_ DATE: \_\_\_\_\_

TECHNICAL CONSULTANT REVIEW: \_\_\_\_\_ DATE: \_\_\_\_\_