

## 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. Were the findings satisfactory or unsatisfactory?

<b>GENERAL LABORATORY SYSTEMS</b>
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**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?  
\_\_\_\_\_ Was the resolution followed up to ensure corrective action was appropriate?  
\_\_\_\_\_ Were policy and/or procedure revisions necessary to prevent reoccurrence of the complaint?

Comments:

**COMMUNICATIONS:**

**Internal:**

- \_\_\_\_\_ 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?

**External:**

- \_\_\_\_\_ 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?  
\_\_\_\_\_ Were changes in lab testing or paperwork relayed appropriately to clinic personnel?

Comments:

**County Health Department Name**  
**Address**

**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 all appropriate competency assessment sets performed by qualifying 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.**

- \_\_\_\_\_ Was proficiency testing rotated among testing personnel, *if applicable?*
- \_\_\_\_\_ 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?

Comments:

**SAFETY:**

- \_\_\_\_\_ Was the Technical Consultant notified of any situation that could affect the lab's performance or the safety of employees?
- \_\_\_\_\_ Has the Safety Manual been updated in the last 5 years?
- \_\_\_\_\_ Have lab personnel received annual safety training?
- \_\_\_\_\_ Have lab personnel documented annual review of safety manuals?
- \_\_\_\_\_ Has a sharps evaluation been done this calendar year? The previous calendar year?

Comments:

**PREANALYTIC SYSTEMS**

**TEST REQUISITION: (This section should be applied to electronic health records, if applicable.)**

- \_\_\_\_\_ Did the lab have written (**or electronic**) 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?

\_\_\_\_\_ Is there a "back-up" system in place for receiving test requests when an electronic system is unavailable?

Comments:

**County Health Department Name  
Address**

**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:

<b>ANALYTIC SYSTEMS</b>
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**PROCEDURE MANUAL:**

- \_\_\_\_\_ Are lab procedures current and complete?
- \_\_\_\_\_ Are all procedures saved electronically?
- \_\_\_\_\_ Is there a procedure describing how to enter results in an electronic health record, if applicable?
- \_\_\_\_\_ Are 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?
- \_\_\_\_\_ Are 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:**

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

Comments:

**COMPARISON OF TEST RESULTS:**

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

Comments:

**County Health Department Name**  
**Address**

**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: (This section should be applied to electronic health records, if applicable.)**

- \_\_\_\_\_ Were test results present?
- \_\_\_\_\_ Did the tester initial the results? Is the tester readily identified in an electronic report?
- \_\_\_\_\_ Are reference values on the test 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? If patient logs are used, are they accessible and retained for a minimum of two years?
- \_\_\_\_\_ 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: \_\_\_\_\_