County Health Department Name
Address

Appendix 11

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?

GENERAL LABORATORY

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 records 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:

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:

_____ Did the lab have electronic requests for all tests performed?
_____ Did test requisitions contain all necessary information as stated in the lab's policy?
_____ 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:

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?
_____ Is there a policy describing how to enter results in an electronic health record?

Comments:

ANALYTIC SYSTEMS

PROCEDURE MANUAL:

_____ Are lab procedures current and complete?
_____ Are all procedures saved electronically?
_____ 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, urinalysis, hgb A1c) 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:

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.)
_____ Were test results present?
_____ 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? Are copies of lab results 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: _____