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 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?
□ 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?

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: (This section should be applied to electronic health records.)

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:
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:
________ 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?
________ 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:
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?

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: ____________