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:

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:

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**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:

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**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:

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**MAINTENANCE & FUNCTION CHECKS:**

________ Was scheduled instrument/equipment maintenance properly performed and documented?

Comments:

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**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: ____________