

**Laboratory Name**  
**Laboratory Address**

**Quality Assessment Plan**

**Purpose:** This Quality Assessment Plan (QAP) consists of the written policies and procedures for our laboratory to monitor, assess and, when indicated, correct problems identified in the laboratory systems of preanalytic, analytic, postanalytic as well as general laboratory systems. The QAP exists to ensure the highest possible quality of laboratory services. The plan provides a mechanism for identification of problems, implementation of corrective action, monitoring for desired outcome, and documentation of all QAP activities.

**Responsibility:** The Laboratory Director is primarily responsible for the development and administration of the QAP. Certain tasks may be delegated in writing to appropriate personnel but the ultimate responsibility and oversight rests with the Laboratory Director. The entire staff participates in, is empowered by, and gains knowledge of improved quality systems.

**General Laboratory Systems**

**Confidentiality-** the staff is trained in HIPAA, we document all incidents of results being sent to the wrong location, results are only available on the chart and given to the patient with a signed release. We will monitor the number of incidents of inappropriate PHI release.

**Complaint investigation** – all complaints are documented and investigated for validity; corrective action(s) are taken regarding that complaint as needed, and preventive action(s) are put in place so it does not occur again. We will monitor the number of complaints and evaluate any trends.

**Communication** –the QA Plan and any remedial action is communicated to the staff during lab meetings. The lab director reviews all remedial actions and signs documentation. We will monitor that incidents are documented on the form designed to capture issues in the laboratory, that they are reviewed and evaluated by the lab director, and complete.

**Personnel competency-** The Technical Consultant/Technical Supervisor will evaluate the competency of all testing personnel and ensure that the staff maintains their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to:

- (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
  - (ii) Monitoring the recording and reporting of test results;
  - (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
  - (iv) Direct observation of performance of instrument maintenance and function checks;
  - (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and
  - (vi) Assessment of problem solving skills; and
- (9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results the individual's performance must be re-evaluated to include the use of the new test methodology or instrumentation.

We will monitor that the competency of all testing personnel is documented at appropriate intervals and that remedial training for areas of concern is completed.

**Proficiency testing-** will be performed three times per year on regulated analytes and twice per year on unregulated analytes. The samples are entered in the patient log and/or computer system and documented the same as a patient, using the same method and testing personnel. The instrument printouts or patient logs and any interim worksheets are maintained with the other patients for at least 2 years, and a copy is filed with the PT results forms for ease of review. The results are submitted to the PT provider within the acceptable timeframe noted. The testing personnel review the data entry on the results form and sign the attestation statement along with the lab director. When the evaluation is returned to the laboratory, the laboratory director will review the results for acceptability and any trends in instrumentation, and sign the evaluation. Any unsatisfactory results will be investigated and documented.

We will monitor for timely submission of all proficiency testing, as well as the acceptability of scores, investigation of failures and any preventive action taken for acceptable results maintenance. Accuracy verification will be performed twice each year on non-regulated analytes and for all tests that have no commercial PT available. Accuracy verification will be performed once following a PT result that is unsatisfactory or has non-consensus to verify the lab's methodology is accurate. The lab will monitor that this is documented appropriately.

**Specimen identification and integrity-** the lab will use two unique identifiers (patient name and date of birth) on requisitions, specimens, documentation of testing, and test reports to ensure appropriate identity of results. Specimen collection criteria is defined and followed to ensure the quality of the sample, and therefore the results of our patients.

We will monitor the number of specimens rejected, number of requisitions with incomplete information, and will note improvements. We will do this using a specimen rejection log, an audit comparing lab records to charted results, and a review of incident report forms.

### Preanalytical Laboratory Systems

The **test request** is made by an authorized person and documented in the computer, on the chart, or on the superbill. It will include the patient name, date of birth, sex, and test(s) ordered. The source, date and time of collection, (LMP for PAP), is also included as appropriate for the test ordered.

The **specimen** will be collected and transported according to our procedures (or that of our reference laboratories) including proper patient preparation, labeling, storage, processing, rejection criteria, and referral instructions. The date and time of receipt in lab can be based on the appointment schedule.

We will monitor to ensure that our reference laboratories are CLIA licensed.

We will monitor the appropriate turn-around-time for reference lab results, track incomplete requisitions, rejected samples, reference lab errors and subsequent documentation of follow-up.

### Analytical Laboratory Systems

Our procedure manual is written according to the CLIA regulations. (493.1251)

We will **establish and verify method performance** by testing precision, accuracy, reportable range and reference range (for high complexity tests, must also verify sensitivity and specificity). The documentation will be maintained for 2 years after we discontinue a test method.

We will ensure that the **test systems**, equipment, instruments, reagents, materials and supplies function according to manufacturer's specifications.

We will ensure that **reagents** have appropriate labels including, strength, storage conditions and expiration date. We will not use any reagent beyond the expiration date or open-vial stability date. We will not mix vials of different lot numbers unless approved by the manufacturer. We will monitor and record environmental conditions required for specimen and reagent stability.

Our **test records**, including the patient analytic log and instrument printouts, will include the date & time, test performed, testing personnel performing, as well as 2 forms of specimen identification.

We will perform **calibration** on our instruments according to the manufacturer's instructions, as well as perform calibration verification (3 levels q 6 months minimum) as appropriate.

We will use at least 2 levels of **quality control (QC)** material per test each day. For test systems that include internal (on-board) controls, an **Equivalent Quality Control (EQC)** study can be performed to reduce the frequency of testing external (liquid) controls.

We will use **Option 1** for internal controls that check the entire analytic process. The evaluation process will test external controls for 10 consecutive days of testing, and if acceptable according to the manufacturer and the laboratory director, the external controls can be reduced to two levels once per calendar month and with each new lot or shipment, and the results of internal controls will be documented daily.

We will use **Option 2** for internal controls that check only part of the analytic process. The evaluation process will test external controls for 30 consecutive days of testing, and if acceptable according to the manufacturer and the laboratory director, the external controls can be reduced to two levels once per calendar week and with each new lot or shipment, and the results of internal controls will be documented daily. We will follow the Centers for Medicare and Medicaid Services (CMS) guidelines for when an EQC study needs to be repeated. All quality control activities will be documented and retained for at least 2 years.

We will document the **calculations of statistical acceptability** of quantifiable controls such as mean, standard deviation, and percent coefficient of variation. We will verify the acceptability of controls before reporting patients.

Our **remedial actions** for all test methods are to ensure the instrument/reagent is working according to manufacturer's instructions. If the quality control fails, the test must be repeated. If the QC fails again, then a new control vial should be run. If it fails again, the reagent should be replaced. The technical services should be contacted for help with troubleshooting the problem. They may have you check certain items or re-calibrate. If that does not correct the problem, the service representative should make a service call. If a test method is out of service, contact the provider to see if the samples can be held until after the service call (if it will be in the same day and the samples will still be acceptable), or if the samples need to be referred to an outside laboratory until the problem is resolved. In some situations, the patient may have to be contacted and the sample collected on a different day.

We will record and monitor the **preventive maintenance and function checks** as defined by the manufacturer. If the manufacturer's instructions have no guidelines to follow, then the lab director will determine the level and frequency of maintenance to be completed and documented. If an increased level of maintenance will ensure the proper functioning of our equipment, then we will document the maintenance and monitor the equipment/instrument as specified by the lab director.

We will ensure **quality of patient results** by clinical correlation done by physicians, and by periodic audit of test results from lab data to charted results to ensure appropriate data entry.

We will document all **corrective actions** including environmental monitoring, instrument troubleshooting, equipment maintenance and function checks not meeting specified intervals; test methods not meeting performance specifications; unacceptable QC, calibration or calibration verification or if we're not meeting appropriate time interval for these activities; inappropriate reporting of sample results that are outside of reportable range for an instrument (should be reported as > xx); any determination that the lab reportable range is inappropriate for the patient population; or improper storage of reagents or samples (left out at room temperature or refrigerator failure).

All **test records will be retained** for at least 2 years, including sample identification, date and time of receipt, condition of sample, test records, identity of person performing test, and all instrument printouts.

We will monitor to ensure that all **procedures, and changes to procedures**, are reviewed and signed by lab director; all new test methods are verified; all reagents are labeled properly; environmental and storage conditions are monitored daily; all test records are reviewed and initialed; calibration is done per manufacturer's instructions; calibration verification is done

at least every 6 months; quality control is reviewed monthly for trends, shifts and meeting acceptability criteria; preventive maintenance and function checks are reviewed monthly for completeness and appropriate intervals; data entry and clinical correlation are performed for accuracy periodically and documented; and that corrective actions are reviewed for effective outcome.

### **Postanalytical Laboratory Systems**

The **test report** will have 2 forms of patient ID, the performing laboratory's name & address, units of measure or interpretation of results, report date, test(s) performed, the specimen source, if appropriate, reference interval, comments on the condition of the sample or disposition if a rejected sample, and the test results.

Information concerning the **test method** must be available to those that use the laboratory results, such as performance specifications, interfering substances, and any changes as they occur.

We will notify the ordering provider of any **panic or alert values** immediately. (Called to Dr. Smith on *date at time by testing person.*)

We will **notify** our providers of any delay in testing.

All **reference lab reports** are placed in the appropriate chart without modification.

All reports must be **retrievable** (original and corrected, preliminary and final) for 2 yrs. If any **result must be corrected**, the provider is notified with a hardcopy result indicating the corrected report with "previously reported as \_\_\_\_\_". Document the provider was notified, fill out an incident report, and investigate the cause of the error.

We will **monitor quality** by periodic review of test results, to include test report forms for appropriateness, retrievability of interim reports, proper documentation of corrected reports, and verifying that panic/alert values are communicated and documented appropriately. We will verify the accuracy and reliability of data, from the lab to the final destination (medical record) in a timely manner, by performing a periodic chart audit.

### **QA Review**

Periodic review of monitors for each topic above are documented and signed by the lab director.

Review of the effectiveness of corrective action(s) taken to resolve problem is documented.

Revision of policies and procedures to prevent recurrence of problems is documented.

Discussion of QA reviews with appropriate staff is documented.

### **Documentation**

Incident Report Form

Periodic QA Checklist

Chart Audit Form

Personnel Competency Form

QC/Maintenance/Temperature Logs

Approved

Date \_\_\_\_\_

\_\_\_\_\_  
Signature Laboratory Director