Bureau of Clinical Laboratories
Quality Assessment Plan

THE ALABAMA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF CLINICAL LABORATORIES
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Bureau of Clinical Laboratories Quality Assessment Plan

I. Quality Assessment Plan
   A. The objective of the Alabama Department of Public Health, Bureau of Clinical Laboratories (BCL) Quality Assessment Plan is to provide high quality analytical data which is accurate, reliable, and appropriate for its intended purpose. The Quality Assessment Plan will enable personnel to establish written procedures to be followed for a comprehensive program of quality assurance as required by the Clinical Laboratory Improvement Amendments (CLIA) (formerly NCCLS). See the ADPH website, “See All Sites”, “Bureau of Clinical Laboratories”, “Quality Management” for the CLIA Regulations.
   B. This document supersedes all previous Quality Assurance Plans. Any preceding ones are to be archived.

II. Goals of the Quality Assessment Plan
   A. To improve the overall quality and efficiency of the laboratory service
   B. To evaluate the effectiveness of the laboratory's policies and procedures
   C. To allow a means of identification of problems and corrections
   D. To assure the accurate, reliable, and prompt reporting of test results
   E. To assure the adequacy and competency of staff.

III. Quality Assessment Committee Chair (Quality Management Manager)
   A. Conducts reviews of quality control records for each division at least annually. A sampling of patient test records/quality control records will be retrieved and checked for:
      a. accuracy of laboratory-supplied information
      b. the efficiency of storage of reports
      c. the time it takes to retrieve the reports.
   B. Utilizes the Outcome-Oriented Survey (Appendix S-1) to assess overall quality assurance of each division.

IV. Quality Assessment Committee (Appendix S-2)
   A. Will consist of one to two persons from each of the following areas:
      Administration / Clerical
      Administrative Support
      Clinical Services / Chemical Terrorism Lab
      Microbiology / Biological Terrorism Lab
      Mobile Division
      Newborn Screening
      Quality Management
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Respiratory Diseases
Sanitary Bacteriology
Sexually Transmitted Diseases

B. Members will be elected by their section personnel or appointed by their division managers.

C. Duties of the committee:
   1. Advisory in nature.
   2. Attends meetings. A majority must be present to vote or take any action.

D. The QA Committee meeting minutes will be reviewed by all employees. The division managers will disseminate to each employee the information regarding any QA activity.

V. Managers
   A. Responsible for ensuring the overall quality assurance of their divisions, including:
      1. reviewing data and identifying problems
      2. recommending corrective action
      3. prioritizing identified areas of concern
      4. implementing a monitoring plan
      5. implementing alternative corrective action if the solution identified for problems is ineffective
      6. documenting all quality assessment activities.

VI. Terminology
   • **Acceptance Criteria/Limits:** specified limits placed on characteristics of a quality control item as defined in required methods. These limits are either statistically defined by historical method performance or by specific method requirements.
   • **Accuracy:** degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components due to sampling and analytical operations
   • **Analyst:** designated individual who performs the analytical methods and associated techniques and who is responsible for applying required laboratory practices and other pertinent quality controls to meet the required level of quality.
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- **Assessment**: evaluation process used to measure or establish the performance, effectiveness, and conformance of an organization and/or its systems to defined criteria.
- **Audit**: systematic evaluation to determine the conformance to quantitative and qualitative specifications of some operational function or activity.
- **Blank**: sample that has not been exposed to the analyzed sample stream in order to monitor contamination during sampling, transport, storage or analysis. The blank is subjected to the usual analytical and measurement process to establish a zero baseline or background value.
- **Blind Sample**: sample for analysis with a composition known to the submitter. The analyst/laboratory may know the identity of the sample but not its composition. It is used to test the analyst’s or laboratory’s proficiency in the execution of the measurement process.
- **Calibration**: determination, by measurement or comparison with a standard, of the correct value of each scale reading on a meter, instrument, or other device. The levels of the applied calibration standard should bracket the range of planned or expected sample measurements.
- **Confirmation**: verification of the identity of a component through the use of an approach with a different scientific principle from the original method.
- **Corrective Action**: action taken to eliminate the causes of an existing nonconformity, defect or other undesirable situation in order to prevent recurrence.
- **Deficiency**: unauthorized deviation from acceptable procedures or practices, or a defect in an item.
- **Document Control**: act of ensuring that documents (and revisions thereto) are proposed, reviewed for accuracy, approved for release by authorized personnel, distributed properly and controlled to ensure use of the correct version at the location where the prescribed activity is performed.
- **Precision**: degree to which a set of observations or measurements of the same property, obtained under similar conditions, conform to themselves.
- **Proficiency Test (PT) Sample**: a sample, the composition of which is unknown to the analyst and is provided to test whether the analyst/laboratory can produce analytical results within specified acceptance criteria.
- **Quality Control Sample**: sample used to assess the performance of all or a portion of the measurement system.
- **Reference Material**: material or substance, one or more properties of which are sufficiently well established, to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials.
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- **Sensitivity**: capability of a method or instrument to discriminate between measurement responses representing different levels (e.g., concentrations) of a variable of interest.

**VII. Personnel Assessment**
A. Job descriptions are reviewed annually and revised as needed.
B. A signed copy of the "Position Classification Questionnaire" (Form 40) must be maintained at the Bureau level and the original sent to Health Personnel either upon assumption of a position or modification of an existing position description.
C. A copy of the employee's credentials (i.e., diploma or transcripts) indicating degree obtained, certificate, license or other documentation relevant to the position must be maintained at the Bureau level (*Appendix S-3*).
D. The BCL will follow established programs for orientation of new employees. The "Employee Orientation Checklist" (*Appendix S-4*) is found in each Employment Handbook and covers department policies as well as other requirements. It must be signed by the employee and the immediate supervisor and returned to Health Personnel.
E. Personnel must meet or exceed CLIA regulations. The division managers will ensure that personnel are supervised and competent (*Appendices S-5*).
   1. All employees are evaluated twice within the first year of employment and annually thereafter.
   2. The first employee competency assessment must occur before the employee is allowed to report patient results.
   3. The second assessment may be done at the employee's six month evaluation.
   4. If an employee needs assistance or improvement, corrective actions are documented, and the employee is re-assessed within six months.
F. Division directors are responsible for initial training, the three-month, six-month and annual competency for all personnel who perform laboratory testing. This is recorded on the "Employee Competency Checklist" and is maintained in each division (*Appendix S-6*).
G. Performance appraisals, including mid-appraisals, are done in an orderly fashion in a time frame prescribed by Health Personnel.
H. Records of medical contact information, health exposures, incidents or accidents are maintained by the laboratory safety officer and stored in the office of the administrative assistant. These are reviewed annually or as needed to ensure that records are current (*Appendix S-7*).
I. The laboratory Safety Officer conducts mandatory training to all personnel.
J. Additional training and continuing education for Bureau employees is available from external agencies, e.g., National Laboratory Training Network, Centers for Disease Control and Prevention and others.

VIII. Records
A. Each employee must read and understand the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and sign a policy acknowledgment form (Appendix S-8) to this regard.
B. Sample/specimen information is recorded in a written or typed log or a computer-based laboratory information system (Appendix S-9).
C. All quality assessment (QA) activities are documented.
D. Each section supervisor will review test requisitions, worksheets, patient logs, or other records to ensure the following information is included.
   1. Suitable identifiers of the authorized person requesting the test or the name and address of the laboratory submitting the specimen and, if applicable, a contact person to enable the reporting of imminent life threatening laboratory results
   2. Patient's name or other identifier and mechanism/number that links the specimen to that patient
   3. Gender and age (or date of birth) of the patient
   4. Test(s) requested (They should be pertinent to the diagnosis and/or treatment of the patient.)
   5. Specimen source
   6. Date of collection and, if applicable, the time of specimen collection
   7. Date and time the specimen was received into the laboratory
   8. Identity of the laboratory personnel who performed the test(s) and date results are reported
   9. Condition and disposition of unsatisfactory specimens.
E. Lack of pertinent information and/or inconsistencies on the form or patient specimen are verified by the health care provider via phone or fax or reported unsatisfactory. If the specimen can be tested, it will not be reported until all required information is provided by the client/submitter of the specimen and record.
F. Employees must ensure:
   1. the test results are consistent with related data (age, sex, diagnosis, and other tests ordered).
   2. the test reports are legible, error free, and reported within the established time as reflected in the turn-around-times recorded in the Laboratory
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3. That alert (panic) values are reported and there is documentation of reported alert values.

G. There is a policy governing the process of properly correcting records (Appendix S-10).

H. Records retention (see Appendix S-11 for a more detailed list)
   Most records are maintained for a minimum of two years to include:
   • analytic systems records
   • test requisitions and authorizations
   • maintenance and function checks
   • calibration and calibration verification procedures
   • proficiency testing records
   • quality control/assessment records
   • test procedures for at least 2 years after a procedure has been discontinued and must include the dates of initial use and discontinuance
   • patient test records including instrument printouts if applicable
   • test reports - retain or be able to retrieve a copy of the original report (including preliminary, final, and corrected reports)
   • employee competency records
   NOTE: If the laboratory ceases operation, it must make provisions to ensure that all records are maintained and available for at least 2 years.

I. Records destruction (Appendix S-12 and S-13)
   • Records may be appropriately destroyed once they have exceeded the retention time for the specific records.
   • Destruction of records is to be documented on the appropriate form.

IX. Laboratory Equipment and Instrumentation
   A. Laboratory equipment, standard devices/materials of known accuracy, computer hardware and software, instruments and test system status are monitored as preventive maintenance (see Appendices S-14 thru S-21 for some of the maintenance policies).
      1. Maintenance and function checks as specified by the manufacturer, as well as frequency, are documented for each test system within each section.
      2. Calibration verification must be performed at least with the frequency recommended by the manufacturer or at least once every six months and when any of the following occur:
         a. A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot number
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does not affect the range used to report patient test results and control values are not adversely affected by reagent lot number changes.

b. When controls begin to reflect an unusual trend or are outside acceptable limits and other means of assessing and correcting unacceptable control values fail to identify and correct the problem.

c. There is major preventive maintenance or replacement of critical parts that may influence test performance.

d. The laboratory’s established schedule for verifying the reportable range for patient test results requires more frequent calibrations.

3. All records of preventive maintenance are documented in the equipment maintenance logbook provided by the manufacture or a suitable ledger that is maintained by the section personnel. It will contain:
   a. the identity of the piece of equipment (and its software, if applicable),
   b. manufacturer’s name, type ID, and serial number or other unique identification,
   c. manufacturer's instructions, if available,
   d. the dates, results and copies of reports and certificates or all calibrations, adjustments, and acceptance criteria,
   e. the maintenance plan, where appropriate, and maintenance performed to date,
   f. documentation of any damage, malfunction, modification or repair to the equipment.

4. All records of corrective action taken or minor troubleshooting and repair performed must be documented in the individual unit’s equipment maintenance log or a suitable ledger maintained by the section personnel.

5. Equipment preventive maintenance, records of corrective action taken, and function checks documented in the previously mentioned maintenance log or ledger will be reviewed by the technical supervisor or personnel designated as responsible for this task by the technical supervisor or Division Director.

B. Tachometers are maintained in the Quality Management division. They are used to check centrifuge revolutions per minute (RPM’s) annually (Appendix S-15).

C. Biological Safety Cabinets (Appendices S-16 & S-17)
   Certification and routine maintenance with the vendor is scheduled annually by the safety officer. Certifications are performed on new cabinets prior to use, a cabinet that has been moved, filter has been changed, and if certain repairs have been performed by the vendor. Additional maintenance will be scheduled with the safety officer. Certification is documented by labeling
the equipment with the date of certification and the date when certification is
due. This task is performed by the vendor and visually checked by the
safety officer.

X. Laboratory Reagents
A. Reagents are defined as any chemical substance used to dissolve, digest,
extract, react with or otherwise interact with any sample or analytical
component of the sample.
B. Reagents used in the laboratory will be of the appropriate quality for their
intended use.
C. All reagents prepared by laboratory shall be marked with date of preparation
and expiration date.
D. All reagents purchased from a commercial vendor will be marked with the
date of receipt.
E. All reagents will be marked with date opened.
F. All reagents will be labeled with the expiration date.
G. All reagents shall be stored according to manufacturer’s instructions.
H. All reagents shall be labeled to indicate content, and when appropriate titer
or concentration.
I. Reagent shelf life will be observed and must not be used when they have
exceeded their expiration date, have deteriorated, or are of substandard
quality.
J. Components of reagent kits of different lot number are not interchangeable
unless specified by the manufacturer.

XI. Specimen Criteria and Reporting
A. Submission and handling
1. All specimens submitted for testing must be done according to the BCL
Laboratory Reference Manual. All specimens must have a written or
electronic request for patient testing from an authorized person or
agency/client.
2. All samples/specimens are stored according to established methods.
Unsatisfactory/ unacceptable specimens will be reviewed by the section
supervisors by way of the monthly report. The division manager will
review the section's unsatisfactory specimen criteria to determine whether
the criteria have been compromised.
B. Specimen rejection
The Laboratory Director has established criteria for the rejection of
specimens in the laboratory. The division manager will inform employees
of these criteria which can be found in the Laboratory Reference Manual.
The use and appropriateness of the criteria will be reviewed as problems are identified by personnel.

C. Referral of specimens
   1. Each division manager will establish and outline in the division’s procedure manual the criteria for the referring specimens to another section or laboratory. These criteria will be reviewed by the division manager and the section supervisor if problems are identified by section personnel.
   2. The laboratory must refer a specimen for further testing or confirmation only to a Centers for Medicare and Medicaid Services certified laboratory or a laboratory meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services.
   3. If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified for specimen acceptance which is outlined in the Bureau of Clinical Laboratories’ Laboratory Reference Manual.

D. Turn-around-time for reporting test results
   Each division manager will establish turn-around-times (TATs) for the respective test procedures. A list of these TAT's can be found in the Laboratory Reference Manual. Section supervisors will verify that results were reported within the established time frames and such is indicated on the Monthly QA Audit Form (Appendix S-22).

XII. Procedures
   A written procedure manual selected and/or developed and optimized for all specimen processing, tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel in advance of performing testing. Procedures will be equivalent to or exceed requirements recognized by regulating agencies, state, and/or federal regulations and will follow the CLIA Approved Guideline. The “New Method Validation” policy will be followed (Appendix S-23). Procedure manuals are maintained in each division and include the criteria listed below as applicable.

A. Requirements for the following are found in the Laboratory Reference Manual and division procedure manuals for each test performed.
   1. patient preparation
   2. specimen:
      • collection
      • labeling
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- storage
- preservation
- transportation
- processing
- referral
- acceptance and rejection

3. Step-by-step performance of testing procedures (analytical methodology/principles) including limitations of procedures, reagents, and calculation explanations and interpretation of results.

4. Referral of specimens, including procedures for specimen submission, handling, and positive identification and optimum integrity of a patient’s specimen from the time of collection or receipt through completion of testing and reporting of results.

5. Procedures for microscopic examination, including the detection of inadequately prepared slides.

6. Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing.

7. Handling procedures including reportable ranges, tests outside of reportable ranges, and criteria or panic values.

8. Calibration and calibration verification procedures.

9. Reportable range for test results.

10. Control procedures.

11. Corrective action guidelines when calibration, control results or test systems fail to meet the laboratory’s criteria for acceptability.

12. Limitations in the test methodology, including interfering substances.

13. Reference intervals (normal values).

14. Protocol for entering results in the patient record and reporting results including reporting imminent life-threatening test results or panic/alert values.

15. Pertinent literature references.

B. These procedures must be approved, dated and signed at least annually by the laboratory director, and any changes in the procedures must be approved, signed and dated by the laboratory director or designated technical supervisor before use. Procedures must be re-approved, signed and dated if the directorship of the laboratory changes.

C. The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance for a period of two years for clinical procedures and five years for environmental procedures.
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XIII. Corrective Actions
A. Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.
B. The laboratory must document all corrective actions taken, including actions taken when any of the following occur:
   1. Test systems do not meet the laboratory’s verified or established performance specifications, which include but are not limited to
      a. Equipment or methodologies that perform outside of established operating parameters or performance specifications;
      b. Patient test values that are outside of the laboratory's reportable range of test results for the test system; and
      c. When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.
   2. Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action(s) necessary to ensure the reporting of accurate and reliable patient test results.
   3. The criteria for proper storage of reagents and specimens are not met.

XIV. Quality Control (QC) Assessment
A. QC is performed and documented for each procedure as recommended by the manufacturer and as described by the division procedure manual.
B. QC is evaluated with each patient run to determine if the patient run is acceptable.
C. QC data is charted each day of business or monthly, depending on the manufacturers’ directions, and observed for accuracy and precision of test procedures.
   1. When problems occur, corrective action is taken and documented on the Monthly QA Audit Form (Appendix S-22).
D. Calibrations are performed according to manufacturer's recommendations. Instruments that are internally calibrated by the manufacturer have their calibrations verified at least every six months.
E. Preventive maintenance is performed according to manufacturer's recommendations for all instruments and equipment.
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F. Temperatures of room, refrigerators, incubators, and other temperature dependent equipment are recorded each day of business. Humidity checks, where applicable, are also recorded.

G. Parallel (comparison) studies will be done on all analytes or tests performed on different instruments (ex: back-up systems) or performed by different methodologies, where applicable, and reviewed by the technical supervisor and division manager. The comparison studies are performed twice annually to verify the accuracy and reliability of those tests not included in an approved PT program.

H. Remedial actions are taken when:
   1. test methods fail,
   2. test equipment fails,
   3. media/reagents fail,
   4. patient results are outside the reportable range,
   5. a population reference range is inappropriate,
   6. controls are out of range,
   7. calibration is unacceptable,
   8. established time frames cannot be met,
   9. reported results are incorrect.

Remedial actions are outlined in the divisions’ Procedure Manuals. When any of the above situations occur, any staff discussion(s) and remedial action(s) will be documented on the Remedial Action Logs. These logs are reviewed monthly by the technical supervisors and include any review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems assessment reviews with the appropriate staff. This review is recorded and monitored via the Monthly QA Audit Form (Appendix S-22).

XV. Proficiency Testing (PT) Assessment

A. Active, successful participation in approved external PT programs that cover all analyses/procedures performed is required for testing for which certification is maintained. All testing personnel must participate in PT on a regular rotation within their respective areas of responsibility. The BCL is enrolled in a PT program in order to:
   1. ensure the competency of employees in their areas of testing and includes direct supervisory observation.
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a. The retesting of previously analyzed specimens, internal blind samples, reference proficiency test samples or external PT samples that have already been reported to approved PT programs may be used to assess the performance levels of each staff member responsible for performing and supervising testing.

2. ensure an ongoing mechanism to monitor, assess, and correct any problem identified in the testing procedure.

B. If no external PT is available, a mechanism to semi-annually document and determine accuracy and reliability of analytic results on patient samples is required.

C. A PT program shall be defined for each specialty and subspecialty evaluated in the laboratory.

D. PT is performed for all regulated analytes, and the reports are signed and submitted to the PT agency within the allotted time frame.

E. Participation in a particular PT program must be continued for one year before changing to a new one.

F. Release is authorized of all necessary data from PT programs to certifying agencies.

G. PT samples are handled like patient specimens.

H. PT results are not discussed between inter-laboratory personnel or with personnel at the branch labs until after the date the laboratory must report the PT results to the program provider.

I. PT samples (or portions) are not sent to any other laboratory for analysis.

J. All steps of proficiency testing are documented.

K. Receipt of PT results
   1. Each division manager must:
      a. have each analyst (as necessary) review, sign and date the results.
      b. have the laboratory director review, sign and date the results.
      c. retain these signed PT results in their divisions to be available for CLIA inspections.

   2. In the event that the PT performance indicates:
      a. an unacceptable response for an analyte
      b. an unsatisfactory response for a specialty/subspecialty
      c. any Exception Reason Code,
         the Missed Analyte Investigation section of the Proficiency Testing Performance Report (Appendix S-24) must be completed by the division supervisor within ten working days. Copies must be submitted to the Quality Management Division and the laboratory director who both review all PT results.
XVI. Communication Problems and Complaints

A. Communication problems
   1. An assessment of any problem occurring due to a breakdown in communication between the laboratory and the health care provider is investigated and documented.
   2. Remedial action is documented.
   3. The QA Committee will review the complaints, corrective actions and documents.

B. Complaints
   1. Complaints/problems received by any employee from staff, patients, or health care providers are documented in telephone logs, complaint logs, the "Documentation of Communication Breakdown or Complaints" form (Appendix S-25), or the "Problem/Complaint/Remedial Action Form" (Appendix S-26).
   2. The remedial action is documented for all valid complaints.
   3. When corrective actions are necessary to decrease problems with a procedure (pre-analytical, analytical, or post-analytical), the effectiveness of them are reviewed by the division manager.

XVII. Facilities and Safety

A. The Bureau of Clinical Laboratories consists of two control-accessed facilities.
   1. Nine divisions are housed in the State Laboratory in Montgomery:
      • Administration / Clerical
      • Administrative Support
      • Clinical Services / Chemical Terrorism Lab
      • Microbiology / Biological Terrorism Lab
      • Newborn Screening
      • Quality Management
      • Respiratory Diseases
      • Sanitary Bacteriology
      • Sexually Transmitted Diseases
   2. The Mobile Division Laboratory houses a Clinical Branch and an Environmental Branch.

B. To assist in assuring quality testing and results, each division must keep work areas clean using appropriate disinfectants (i.e., 10% bleach solution, vesphene, etc.) and chemical spill kits when necessary.

C. The wipe test procedure should be performed by any section where amplification of DNA is conducted (Appendix S-27 and S-28).
D. Refer to the “Bureau of Clinical Laboratories Safety Policies” for safety information.

XVIII. Appendices

- S-1 Outcome-Oriented Survey
- S-2 Quality Assessment Committee Members
- S-3 Laboratory Personnel Qualifications
- S-4 Employee Orientation Checklist
- S-5 Employee Training Report
- S-6 Employee Competency Checklist
- S-7 Employee Medical Information Card
- S-8 Policy Acknowledgement Form
- S-9 Policy on the Operation of Computer Work Stations
- S-10 Correction of Test Reports, Request Slips, and Laboratory Testing Quality Assurance Records Policy
- S-11 Department of Public Health Record Retention Times
- S-12 Instructions for Completing ADPH Record Destruction Notice
- S-13 Department of Public Health Record Destruction Notice
- S-14 Maintenance Repairs at BCL
- S-15 Policy on Centrifuge Checks
- S-16 Proper Use of the Biological Safety Cabinet
- S-17 Biological Safety Cabinet Record Sheet
- S-18 National Bureau of Standards Thermometers Recertification
- S-19 Procedure for the Calibration of Thermometers
- S-20 Pipette Calibration
- S-21 Timer Checks
- S-22 Monthly QA Audit Form
- S-23 New Method Validation
- S-24 Proficiency Testing Performance Report
- S-25 Documentation of Communication Breakdown or Complaints
- S-26 Problem/Complaint/Remedial Action Form
- S-27 Wipe Test Procedure
- S-28 Area Wipe Test Check
### S-1 Outcome-Oriented Survey

**Outcome-Oriented Survey**

**Conducted by Quality Management Staff**

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The principal focus of the outcome-oriented survey is the effect (outcome) of the laboratory’s practices on patient test results and/or patient care. Quality Management has designed this survey to mimic the survey conducted by the CLIA inspectors.

#### Standard operating procedure manual with all test procedures (e.g., package inserts and supplemental information, as necessary):

1. Completed with all signatures (Dr. Massingale, Dr. Davis, and Division Director)?
   - Yes________ No________
   - a. If not, what is the problem?

2. Documentation that staff has reviewed manual? Yes______ No______
   - a. If no, why not?

3. Does staff know where all testing information is kept (e.g., procedures, function checks, complaint logs) and how to navigate the information?

4. Comments__________________________

#### Reference laboratories’ client services manual, if applicable:

1. Current copy available? Yes______ No______
   - a. If no, why not?

2. Do you have a copy of reference lab’s CLIA certificate? Yes______ No______

3. Comments__________________________

#### Records of tests referred to other laboratories, if applicable:

1. Reports on all tests sent (tracking system)? Yes______ No______

2. Do you have a copy of lab’s CLIA certificate? Yes______ No______

3. Comments__________________________

#### Personnel records (testing staff) - please have available: (Circle number after reviewing stated documents.)

1. Diplomas, certificates, degrees (new personnel since last inspection)

2. Training and experience

3. Continuing education, if applicable

4. Competency assessment

5. Duties/responsibilities

6. Personnel changes, if applicable

7. Comments__________________________

ADPH/BCL/QM – Internal CLIA Survey Form

August 2012/Page 1 of 3
Outcome-Oriented Survey
Conducted by Quality Management Staff

Quality control records - please have available: (Circle number after reviewing stated documents.)
1. Remedial action information
2. Calibration and calibration verification records (e.g., parallel studies, linearity)
3. Statistical limits
4. Instrument maintenance and function checks records (e.g., centrifuges, biological safety cabinets, microscopes, temperature logs)
5. Comments

Proficiency testing (PT) reports, including: (Circle number after reviewing stated documents.)
1. Test runs with PT results
2. Direct printouts
3. Attestation statements
4. Remedial actions for unsatisfactory results
5. Comments

Quality system assessment plan and documentation:
1. Current copy available? Yes____ No____
   a. If no, why not?
2. Documentation that staff has reviewed manual? Yes____ No____
   a. If no, why not?
3. Documentation of complaints / problems? Yes____ No____
   a. If no, why not?
4. Comments

For each of the systems, documentation of ongoing assessment activities: (Circle number after reviewing stated documents.)
1. Review of corrective actions taken • Monthly QA Audits
2. Complaint documents
3. Revision of policies and procedures to prevent recurrence of problems
4. Discussion of assessment reviews with staff
5. Thermometer calibration documentation, if applicable
6. Pipette calibration, if applicable
7. Timer calibration, if applicable
8. Wipe test, if applicable
9. Comments

ADPH/BCL/QM – Internal CLIA Survey Form
August 2012/Page 2 of 3
Bureau of Clinical Laboratories Quality Assessment Plan

Outcome-Oriented Survey
Conducted by Quality Management Staff

Safety Information:
1. Copy of Safety Manual available? Yes______ No______
   a. If no, why not? 
2. Documentation that staff has reviewed manual (See Safety Training Records)?
   Yes______ No______
   a. If no, why not? 
3. Safety equipment function checks up to date? Yes_____ No______
   a. If no, why not? 
4. Copies of Material Safety Data Sheets? Yes______ No______
   a. If no, why not? 
5. Comments

Patient testing records: (Circle number after reviewing stated documents.)
1. Requisition
2. Work records (direct printouts)
3. Patient test reports
Note: Requisition, work records and patient test reports should be consistent with like demographics.

Documentation of ongoing testing record assessments:
1. Is there an unsatisfactory specimen log? Yes______ No______
   a. If no, why not? 
2. Comments

Technical Consultants (initial)
Charlene Thomas ___________ Aretha Williams ___________

Signature of Reviewer (Bureau Chief/Designee) ____________________________

Comments by Reviewer
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

ADPH/BCL/QM – Internal CLIA Survey Form August 2012/Page 3 of 3
# Bureau of Clinical Laboratories Quality Assessment Plan

## S-2 Quality Assessment Committee Members

<table>
<thead>
<tr>
<th>Division</th>
<th>Members</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laboratory Director</td>
<td>Sharon Massingale, Ph.D.</td>
</tr>
<tr>
<td>Assistant Laboratory Director</td>
<td>Michael Davis, Ph.D.</td>
</tr>
<tr>
<td>QA Committee Chair</td>
<td>Charlene Thomas</td>
</tr>
<tr>
<td>Administration / Clerical</td>
<td>Courtney Jones</td>
</tr>
<tr>
<td>Administrative Support</td>
<td>Marian Woodman</td>
</tr>
<tr>
<td>Clinical Chemistry / CT Lab</td>
<td>David Sherrod</td>
</tr>
<tr>
<td>Microbiology (downstairs)</td>
<td>Evelyn Franklin</td>
</tr>
<tr>
<td>Microbiology (upstairs)</td>
<td>Pat Morrow</td>
</tr>
<tr>
<td>Mobile</td>
<td>Curtis Andrews</td>
</tr>
<tr>
<td>Newborn Screening</td>
<td>Russ Majors</td>
</tr>
<tr>
<td>Quality Management</td>
<td>Aretha Williams</td>
</tr>
<tr>
<td>Respiratory Disease</td>
<td>Becky Giles</td>
</tr>
<tr>
<td>Sanitary Bacteriology</td>
<td>Shahla Taki</td>
</tr>
<tr>
<td>STD</td>
<td>Elaine Whetstone</td>
</tr>
</tbody>
</table>
Bureau of Clinical Laboratories Quality Assessment Plan

S-3 Laboratory Personnel Qualifications

LABORATORY PERSONNEL QUALIFICATIONS

Persons employed by the Bureau of Clinical Laboratories must verify their qualifications according to the Clinical Laboratory Improvement Amendments of 1988. The Health Care Financing Administration needs the following information to determine whether the Bureau meets the requirements for qualified personnel. Please complete this form and return it to the Quality Management Division of the Central Laboratory within two weeks of your first day of employment.

<table>
<thead>
<tr>
<th>Name</th>
<th>Maiden Name (if applicable)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Mailing address

Work arrangements: Full time

Part time

<table>
<thead>
<tr>
<th>High School Graduate or Equivalent</th>
<th>YES</th>
<th>NO</th>
<th>List College, University, or other schools attended</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name &amp; Address of Institution</td>
<td></td>
<td></td>
<td>Major</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Degree or Diploma</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(include month &amp; year conferred)</td>
</tr>
</tbody>
</table>

A copy of your diploma should be returned with this form.

<table>
<thead>
<tr>
<th>CLINICAL LABORATORY TRAINING</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name &amp; Address of Institution</td>
</tr>
<tr>
<td>Program Title</td>
</tr>
<tr>
<td>Degree or Diploma</td>
</tr>
<tr>
<td>(include month &amp; year conferred)</td>
</tr>
</tbody>
</table>

A copy of your diploma should be returned with this form.
## LABORATORY PERSONNEL QUALIFICATIONS

### CLINICAL LABORATORY EXPERIENCE

<table>
<thead>
<tr>
<th>Name of Laboratory or Institution</th>
<th>Period Employed</th>
<th>Position(s) Held</th>
<th>Experience in the following Specialties</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Histocompatibility</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Microbiology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>General Immunology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Chemistry</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Hematology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Immunohematology</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Pathology</td>
</tr>
</tbody>
</table>

### LICENSE, CERTIFICATION, OR REGISTRATION

<table>
<thead>
<tr>
<th>Name of Granting Agency</th>
<th>License/Certification or Registration Title</th>
<th>Year Granted</th>
<th>License #</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A copy of your certification should be returned with this form.

**CERTIFICATION:** I certify that all of the information provided on this form is true and complete to the best of my knowledge.

Signature ____________________ Date __________

---

**For Office Use Only**

Provide the Qualification Code that matches this employee’s qualifications for the following positions.

- **High Complexity**
  - TS ______
  - GS ______
  - TP ______

- **Moderate Complexity**
  - TC ______
  - TP ______

ADPH/QM/07-2012
S-4 Employee Orientation Checklist

ALABAMA DEPARTMENT OF PUBLIC HEALTH
EMPLOYEE ORIENTATION CHECKLIST

Human Resources / Finance forms must be returned to the appropriate office within three (3) working days after employee begins work.

Checklist (all pages) must be completed and returned to the Office of Human Resources within two (2) weeks after employee begins work.

Name __________________________ Last 4 digits of SS# __________________________
Classification __________________________ Area/Co./Bureau/Office __________________________

I. Arrival of New Employee

Welcome employee to Department
Explain Department’s mission and structure
Explain organization of your office
Explain supervisory structure as it relates to employee

II. Introduction to Work Unit and Job

Introduce employee to coworkers
Tour of facility
Discuss dress code & other office procedures
Discuss hours of work, lunch, breaks
Discuss procedures for requesting leave
Discuss check-in procedures for illness, other unexpected absence
Discuss the Employee Preappraisal form
Discuss probationary period
Discuss training plans
Discuss security measures and emergency guidelines

III. Human Resources/Finance Forms - Submit forms to appropriate offices as noted.
(* Return to Human Resources; ** Return to Health Finance)

* Total Service Date for Annual Leave Accumulation Form
* Form I-9, Employment Eligibility Verification Form
* Selective Service Registration Form (if applicable)
* Compensatory Time Agreement Form (non-exempt employees)
* New Hire Reporting Form (NH-1) (fax to HR)
SEICTF Employee Instruction Card (employee keeps)
** Health Insurance Enrollment Form
** Non-Tobacco User Discount Application
** Dependent Premium Conversion Plan Form
** Retirement Enrollment Form
** Federal Tax Withholding Form
** State Tax Withholding Form
** Direct Deposit Form
Discuss Employee Weekly Leave Documentation Form
Mediation Pamphlet (employee keeps)
ALPHA Brochure (employee keeps)

1 of 2

Rev. Jan., 2010
ALABAMA DEPARTMENT OF PUBLIC HEALTH
EMPLOYEE ORIENTATION CHECKLIST

IV. Departmental Policies
(Available on employee web site and/or in
Lotus Notes Workspace, ADPH Policy Library)

<table>
<thead>
<tr>
<th>Policy ID#</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010-002</td>
<td>Employee Handbook</td>
</tr>
<tr>
<td>2009-007</td>
<td>Americans with Disabilities Act Employment Policy</td>
</tr>
<tr>
<td>2006-014</td>
<td>Discipline Policy</td>
</tr>
<tr>
<td>2004-019</td>
<td>Drug-Free Workplace Policy</td>
</tr>
<tr>
<td>2010-001</td>
<td>Family and Medical Leave Act Policy</td>
</tr>
<tr>
<td>2007-014</td>
<td>Grievance Policy</td>
</tr>
<tr>
<td>2006-008</td>
<td>HIPAA Privacy Policy</td>
</tr>
<tr>
<td>2006-023</td>
<td>Professional Conduct Policy</td>
</tr>
<tr>
<td>2005-016</td>
<td>Security Policy</td>
</tr>
<tr>
<td>2003-016</td>
<td>Sexual Harassment Policy</td>
</tr>
<tr>
<td>2008-002</td>
<td>Policy Against Workplace Threats and Violence</td>
</tr>
</tbody>
</table>

V. Videos / Slide Shows to be viewed within first two weeks of employment [available through the Learning Content Management System (LCMS), On-Demand Webcasts; link on employee web site]:

- General Orientation for New Employees
- Orientation to the Essentials of Public Health – Introductory Level
- Employee Orientation to Performance Appraisal
- HIPAA Privacy Training
- Application of HIPAA to ADPH Employees and Our Patients
- Electronic Cost Accounting (e-CATS) - Time Sheets
- Violence in the Workplace: Policy & Prevention

By signing below, I certify that all information listed on pages 1 & 2 of this Employee Orientation Checklist has been presented to and/or discussed with me and that I have been provided an opportunity to ask questions about any information that was unclear to me.

Employee’s Signature __________________________ Date __________

Immediate Supervisor’s Signature __________________________ Date __________

Immediate Supervisor’s Name (printed) __________________________

EMPLOYEE and SUPERVISOR MUST SIGN

REMEMBER to RETURN
EMPLOYEE ORIENTATION CHECKLIST
to the OFFICE of HUMAN RESOURCES

2 of 2

Rev. Jan., 2010
# Bureau of Clinical Laboratories Quality Assessment Plan

## S-5 Employee Training Report

### EMPLOYEE TRAINING REPORT

**Purpose:** This form is a tool to be used to ensure that employees receive appropriate orientation, education and training for job performance. It provides a summary of orientation, education and training, which the employee has received during this evaluation period.

**Instructions:** Complete each section. List all orientation, education and training the employee has successfully completed during this evaluation period. Place check marks in the appropriate columns to indicate if required before employee can come off of probation, or is required for supervisors, or is required yearly (such as OSHA, CPR, etc.). Also place a check mark to indicate employee has passed applicable tests.

Give a copy to employee. Place a copy in employee’s personnel file.

<table>
<thead>
<tr>
<th>Name:</th>
<th>SSN:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Class Code:</td>
<td>Bureau/PHA:</td>
</tr>
<tr>
<td>Classification:</td>
<td>Division/County:</td>
</tr>
<tr>
<td>Position Number:</td>
<td>From:</td>
</tr>
</tbody>
</table>

Check below only if applicable

<table>
<thead>
<tr>
<th>Title</th>
<th>Required to come off of probation</th>
<th>Required for supervisors</th>
<th>Required yearly</th>
<th>Passed Test</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Rating Supervisor’s Signature

Employee’s Signature

By signing, employee states that he or she did attend classes listed above.

Copy – Employee
Copy – Worksicte

ADPH-PER-33Rev. April 2007
Bureau of Clinical Laboratories Quality Assessment Plan

S-6 Employee Competency Checklist

Bureau of Clinical Laboratories
Employee Competency Checklist

Employee: ______________________________
Division/Section: ______________________________

Please evaluate employee’s competency by using the following assessment methods:
1. Direct observation of test performance
2. Monitor recording and reporting of results
3. Review intermediate test results, worksheets, Quality Control (QC), proficiency testing (PT), preventative maintenance (PM) records
4. Direct observation of instrument maintenance/function checks
5. Assessment of test performance thru testing previously analyzed specimens, internal blind testing samples or external PT
6. Assessment of problem solving (can be oral)
7. Not applicable (NA).

Status = (A) Acceptable, (U) Unacceptable, (NA) Not Applicable

* Must be by direct observation
+ Documentation of target value/range of blind samples and employee’s results should be attached. Target value/range is to be established by the section supervisor or division director.

<table>
<thead>
<tr>
<th>Pre-analytic Phase</th>
<th>Evaluation Method</th>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Handling Specimens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information on form checked and compared to specimen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Safety precautions followed</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen numbered and dated*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processing Specimens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specimen processed according to Procedure Manual*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reagent/Media Preparation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preparation accomplished according to Procedure Manual</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Analytic Phase</th>
<th>Evaluation Method</th>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Testing Procedure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure set up according to Procedure Manual*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure performed and interpreted according to Procedure Manual*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quality Control (QC)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QC performed according to Procedure Manual*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Internal Proficiency Testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure performed on blind samples with accuracy and precision+</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Proficiency Testing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure performed on PT sample with 80% accuracy</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintenance/Function Checks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performed according to manufacturer’s instructions*</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ADPH/BCL/QM/08-12 1 of 3
### Bureau of Clinical Laboratories

**Employee Competency Checklist**

<table>
<thead>
<tr>
<th>Evaluation Method</th>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Calibration</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performed calibration procedure according to manufacturer’s instructions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Remedial Action</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conducted according to Procedure Manual and documented</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Post-analytical Phase</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Recording Results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient results recorded according to Procedure Manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>QC results recorded according to Procedure Manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PT results recorded according to PT program instructions</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Notification of Panic Values</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Panic values identified, reported to Health Care Provider, and documented according to Procedure Manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reporting Results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient results are reported according to Procedure Manual and checked</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Referrals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Referrals are sent according to Procedure Manual</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Records reviewed</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Worksheet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complaint/problem documentation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preventive maintenance records</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
# Bureau of Clinical Laboratories Quality Assessment Plan

## Bureau of Clinical Laboratories
Employee Competency Checklist

<table>
<thead>
<tr>
<th>Laboratory Safety</th>
<th>Evaluation Method</th>
<th>Status</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facility Safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working knowledge of BCL Safety Policies Manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knowledge of the following safety measures:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material Safety Data Sheet (MSDS)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency evacuation routes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Equipment Safety</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Knows the location and manner of operation of the following items:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BCL Safety Policies Manual</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Accident/Illness Report Form</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biosafety Cabinet</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chemical fume hood</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donning and doffing of PPE</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency eyewash</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emergency shower</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire alarms</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire blanket</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fire extinguisher</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First aid kit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spill kit</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action(s) taken to correct any deficiencies</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Comments</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Observations</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Employee
Signature: ____________________________  Printed Name: ____________________________

Supervisor
Signature: ____________________________  Printed Name: ____________________________

Date: ____________________________

ADPH/BCL/QM/08-12  3 of 3
Bureau of Clinical Laboratories Quality Assessment Plan

S-7 Employee Medical Information Card

Employee Medical Information Card

Employee Full Name: ______________________ Phone: ______________________ Date: / / 
Employee Address: ______________________

IN CASE OF EMERGENCY, CONTACT:

Name: ________________________________ Relationship: ____________________ 
Phone: ________________________________

Name: ________________________________ Relationship: ____________________ 
Phone: ________________________________

Personal Physician: Name: ______________________ Phone: ______________________

Other Medical Specialist: Name: ______________________ Phone: ______________________
Other Medical Specialist: Name: ______________________ Phone: ______________________
Other Medical Specialist: Name: ______________________ Phone: ______________________

Allergies:

__________________________________________________________

Medications:

__________________________________________________________
__________________________________________________________

Other Pertinent Information:

__________________________________________________________
__________________________________________________________

Employee Signature/Date: ______________________ Manager Signature/Date: ______________________
Employee Signature/Date: ______________________ Manager Signature/Date: ______________________
Employee Signature/Date: ______________________ Manager Signature/Date: ______________________
Employee Signature/Date: ______________________ Manager Signature/Date: ______________________

ADPH-BCL-Medical (12/2011)
Bureau of Clinical Laboratories Quality Assessment Plan

S-8 Policy Acknowledgement Form

Policy Acknowledgement Form  
Bureau of Clinical Laboratories

<table>
<thead>
<tr>
<th>Name</th>
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<tbody>
<tr>
<td>Job Title</td>
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<tr>
<td>Division</td>
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</table>

<table>
<thead>
<tr>
<th>Policy</th>
<th>Policy #</th>
<th>Signature</th>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

This form is to be signed and dated upon receipt and understanding of each policy reviewed.

ADPH/BCL/QM/08-12
S-9 Policy on the Operation of Computer Work Stations

There are procedures that must be performed and applied to the laboratory computer system that the laboratory uses in everyday operations. These procedures include, but are not limited to, Microsoft updates, virus scans, and antivirus updates. To help facilitate these actions, it is the policy of the Bureau of Clinical Laboratories that all user work stations are to be left on at all times, being sure to log out overnight. Further, these work stations are to be rebooted at least once weekly.
Correction of Test Reports, Request Slips, and Laboratory Testing Quality Assurance Records Policy

Purpose

The purpose of this policy is to establish guidelines for appropriate corrective actions (i.e. corrections, amendments, addendums) to test reports, request slips, and laboratory testing quality assurance records.

Philosophy

All test reports, request slips, and laboratory testing quality assurance records are maintained in a manner that ensures correct information and permits ready identification and timely accessibility. When errors occur, corrective actions are documented and appropriate persons are notified.

Corrective actions are monitored by the management staff per division to ensure appropriate training for staff is done and appropriate changes to the policy have been approved by the laboratory director if necessary.

Standards

1. For correction of test reports placed in LIMS (Laboratory Information Management System), to include Horizon, Neometrics MSDS, and Perkin Elmer Specimen Gate, refer to the appropriate LIMS procedure.

2. For corrections of request slips, circle the area on the slip needing correction with a red pen/marker. Document the correct information in another location on the slip using red pen/marker. Initials of person making the correction and date of correction will also be documented.

3. For correction of laboratory testing quality assurance records, ensure that white correction fluid or tape is not used. A single line is drawn through the incorrect information, and the correct information is written adjacent to it. Initials of person making the correction and date of correction will also be documented.
Bureau of Clinical Laboratories Quality Assessment Plan

S-11 Department of Public Health Record Retention Times

RECORD RETENTION TIMES

Record retention times are determined by the following regulatory agencies:
- CLIA – Clinical Laboratory Improvement Amendments
- CDC – Centers for Disease Control and Prevention
- EPA – Environmental Protection Agency
- FDA – Food and Drug Administration

<table>
<thead>
<tr>
<th>Type of Record</th>
<th>Retention Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Certification Files</td>
<td>6 years</td>
</tr>
<tr>
<td>Clinical Chemistry Test Reports</td>
<td>2 years</td>
</tr>
<tr>
<td>Environmental Chemistry (including lead)</td>
<td>2 years</td>
</tr>
<tr>
<td>Laboratory Testing Protocols</td>
<td>2 years post-retirement of protocol</td>
</tr>
<tr>
<td>Milk Reports</td>
<td>3 years</td>
</tr>
<tr>
<td>Newborn Screening Test Reports</td>
<td>21 years (send to Archives)</td>
</tr>
<tr>
<td>Proficiency Testing</td>
<td>2 years</td>
</tr>
<tr>
<td>Rabies Laboratory Reports</td>
<td>2 years</td>
</tr>
<tr>
<td>Respiratory Test Reports</td>
<td>2 years</td>
</tr>
<tr>
<td>Select Agents Reports</td>
<td>3 years</td>
</tr>
<tr>
<td>Testing Personnel Qualification and Competency Evaluations</td>
<td>2 years</td>
</tr>
<tr>
<td>Water and Shellfish Reports</td>
<td>5 years</td>
</tr>
<tr>
<td>Other Laboratory Test Reports (e.g. Microbiology, Mycology, STD, etc.)</td>
<td>2 years</td>
</tr>
</tbody>
</table>
S-12 Instructions for Completing ADPH Record Destruction Notice

1. Office/Bureau - Bureau of Clinical Laboratories (including Division)
2. Office/Bureau Records Liaison - Leave blank
3. Phone - Self explanatory
4. Date - Self explanatory
5. Date Records Destroyed - Self explanatory
6. Method of Destruction - Self explanatory
7. Are the records being replaced electronically? - Self explanatory
8. Reference - Leave blank
9. Volume - The amount of information being destroyed
10. Name of Records - Specific name(s) of documents being destroyed. i.e., GC worksheets, Milk incubator temperature charts, etc.
11. Date Span - Dates of documents being destroyed
12. Custodian - Person in possession of the records
13. Authorized Personnel - Leave blank

Provide a copy of the Record Destruction Notice to Administrative Support and retain a copy for your records.
Bureau of Clinical Laboratories Quality Assessment Plan

S-13 Department of Public Health Record Destruction Notice

DEPARTMENT OF PUBLIC HEALTH RECORD DESTRUCTION NOTICE

<table>
<thead>
<tr>
<th>Office/Bureau Records Liaison</th>
<th>Phone</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

Date Records Destroyed

Method of Destruction: ( ) Shredding ( ) Landfill ( ) Recycling ( ) Other

Are the records being replaced electronically? ( ) Yes ( ) No

<table>
<thead>
<tr>
<th>Reference (Box, Roll, Book)</th>
<th>Name of Records</th>
<th>Date Span</th>
</tr>
</thead>
<tbody>
<tr>
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</table>

I hereby certify that the records disposed of are represented correctly above, that any audit requirements for the records have been fulfilled, and that further retention is not required for any pending or imminent litigation. The records have been destroyed in the manner shown above.

Printed Name/Custodian

Signature/Custodian

Printed Name/Authorized Personnel

Signature/Authorized Personnel

ADPH/BCL/QM 08-12
Bureau of Clinical Laboratories Quality Assessment Plan

S-14 Maintenance Repairs at BCL

Maintenance Repairs at Bureau of Clinical Laboratories

Mobile / Montgomery

Please circle branch name and record division name

<table>
<thead>
<tr>
<th>Date</th>
<th>Time</th>
<th>Description of the Work Performed</th>
<th>Person(s) Performing the Work</th>
<th>Comments</th>
</tr>
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<tbody>
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It is the policy of the Alabama Department of Public Health that facilities’ managers maintain records of all maintenance performed at their facilities. For BCL this includes any maintenance related to testing instrumentation and/or general building repair. This policy (ADPH Security Manual Policy #2003-016) is found in the document library under the category of ADPH HIPPA Privacy & Security. Please refer to section III.B.4. Maintenance Records, page 73.

ADPH/QM/07-2012
S-15 Policy on Centrifuge Checks

Proper operation of test system equipment is essential for accurate and reliable test results. It is the policy of the Bureau of Clinical Laboratories that the revolutions per minute (RPMs) of the centrifuges are checked at least annually. In any testing area where the time of centrifugation is critical to the reliable production of accurate test results, the built-in timer will also be checked.
Bureau of Clinical Laboratories Quality Assessment Plan

S-16 Proper Use of the Biological Safety Cabinet

PROPER USE OF THE BIOLOGICAL SAFETY CABINET

I. PURPOSE
This document serves as a guideline for the operation of the Biological Safety Cabinet (BSC) which will be used to provide containment of potential and possible pathogens and to reduce exposure of these potential and possible pathogens to laboratory personnel.

II. PRINCIPLE

Class I BSC
Containment is provided by unfiltered room air being drawn across the work surface. Personal protection is provided by this inward airflow as long as minimum velocity of 75 linear feet per minute is maintained through the front opening. This type of BSC provides personnel and environmental protection, but no product protection. However, in many cases, they are used specifically to enclose equipment or procedures that may generate aerosols.

Class II BSC
Containment is accomplished by balanced directional airflow and filtration. During operation, room air is drawn through the grille. The unfiltered room air and the filtered air flowing down through the work area are combined under the work surface. After being pressurized by the blower, approximately 70% of the air is forced through the supply High Efficiency Particulate Air (HEPA) filter. The filtered sterile air flows down over the work area. The down flow air stream splits (smoke splits) with some air flowing through the front grille and the remainder flowing through the rear grille. The remaining 30% of the air is forced through the exhaust HEPA filter, and the sterile air is exhausted to the room.

The front opening, where the room air is drawn into the BSC, is known as the air curtain. This air curtain is easily compromised and should have minimal disruption (i.e. room traffic or entry into the room).

Laminar Flow “Clean Bench”
This is not considered a BSC; however, it discharges HEPA-filtered air from the back of the cabinet across the work surface and toward the user. These devices only provide product protection. They can be used for certain clean activities such as the dust-free assembly of sterile equipment or electronic devices. Clean benches should never be used when handling cell culture materials, drug formulations, or when manipulating potentially infectious materials. “Clean benches” must never be used as a substitute for a biological safety cabinet. Users must be aware of the differences between these two devices.

Class III BSC
This type of BSC was designed for work with highly infectious microbiological agents and for conducting hazardous operations. It provides maximum protection for the environment and the worker. It is a gas-tight enclosure with a non-opening view window. Access for passage of materials into the cabinet is through a dunk tank that is accessible through the cabinet door or a double-door pass-through box that can be decontaminated between uses. Reversing that process allows materials to be removed from the cabinet safely. Both supply and exhaust air are HEPA filtered. Airflow is maintained by a dedicated, independent exhaust system exterior to the cabinet, which keeps the cabinet under negative pressure.

Long, heavy-duty rubber gloves are attached in a gas-tight manner to ports in the cabinet and allow direct manipulation of the materials isolated inside. Although these gloves restrict movement, they prevent the user’s direct contact with the hazardous materials.
PROPER USE OF THE BIOLOGICAL SAFETY CABINET

III. OPERATION

The following procedure takes into account all cabinets discussed. Perform all steps and safety checks based on your safety cabinet.

A. Planning
1. Try to schedule uninterrupted work time
2. Turn off UV light if it is on
   NOTE: If UV light is used, ensure that a weekly cleaning procedure is in place with appropriate documentation on the “Biological Safety Cabinet Record Sheet”.
3. Assemble materials
4. Keep laboratory door closed

B. Start Up
1. Ensure the sash is in the appropriate position.
2. Turn on fluorescent light and blower and allow to operate unobstructed for 4-5 minutes.
3. Ensure the air grilles are unobstructed.
4. Note and record the pressure gauge reading.
5. Disinfect the interior surfaces of the cabinet, and allow to dry.
6. Appropriate PPE (personal protective equipment) per test procedure performed must be worn by analyst.
   NOTE: BCS checks are to be performed and documented each day of use, weekly and monthly as necessary on the “Biological Safety Cabinet Record Sheet”.

C. Loading Materials and Equipment
1. Load only the materials required for the procedure. Do not overload the cabinet.
2. Do not obstruct the air grilles.
3. Large objects should not be placed together.
4. After loading, wait 2-3 minutes prior to using to purge airborne contaminants from the work area.

D. Work Techniques
1. Keep all materials at least 4 inches inside of the sash, and perform all contaminated operations as far to the rear of the work area as possible.
2. Segregate all clean and contaminated materials in the work area, keeping the contaminated materials to the rear.
3. Avoid using techniques or procedures that disrupt the airflow patterns of the cabinet, such as side to side motion.
4. If there is a spill or splatter during use, all objects in the cabinet will be surface decontaminated with appropriate disinfectant before removal.
5. Upon completion of work, the cabinet will be allowed to operate 2-3 minutes undisturbed to purge airborne contaminants from the work area.

E. Unloading Materials and Equipment
1. Objects in contact with contaminated material will be surface decontaminated with appropriate disinfectant before removal from the cabinet.
2. All open trays or containers will be covered before being removed from the cabinet.

F. Shut Down
1. Disinfect interior surfaces with appropriate disinfectant and allow to dry.
2. Turn off the fluorescent light. Allow unit 2-3 minutes of undisturbed operation time before shutting down blower. Turn on the UV light if desired and appropriate.
PROPER USE OF THE BIOLOGICAL SAFETY CABINET

NOTE: PERSONNEL SHOULD NOT WORK IN OR NEAR THE BSC WHILE THE UV LAMP IS IN USE. ALSO, SOME BSC MAY NOT HAVE UV LAMPS.

IV. PROCEDURAL NOTES
A. Pressure Differential Gauge (measures pressure drop across HEPA filter)
   1. Before use and after any power fluctuation, the gauge will be observed for changes.
   2. Look for a significant change from previous reading.
   3. An increase in gauge reading would suggest filter loads or blockage (resistance up).
   4. A decrease in gauge reading would suggest a hole or tear in the filter (resistance down).
B. HEPA filters do not filter gases and vapors - only particulates. Chemicals can compromise the integrity of the filter. Do not place or store any chemicals in BSC.
C. UV lamps have limited penetrating power (surface or air only) and therefore have limited decontamination ability.
D. Maintenance and Certification
   1. Inspect condition of unit and electrical cord/plug to ensure safe operation.
   2. Equipment determined to be unsafe will be removed from service immediately.
   3. Certification and routine maintenance with vendor is scheduled annually by Safety Officer.
   
   NOTE: Certifications are performed on new cabinets before use, a cabinet that has been moved and/or filter has been changed, and if certain repairs have been performed by vendor.
   4. Any additional maintenance/service is to be scheduled with the Safety Officer.
   5. A decontamination / disinfection procedure may be required before certain maintenance/service is scheduled. Refer to the “Procedure for Fumigating Hoods” which is found in the Respiratory Disease Division. Consult Safety Officer for help if needed.
   6. Certification is documented by labeling the equipment with the date of certification and the date when certification is due. This task is performed by the vendor and visually checked by Safety Officer.
Bureau of Clinical Laboratories Quality Assessment Plan

S-17 Biological Safety Cabinet Record Sheet

<table>
<thead>
<tr>
<th>Division:</th>
<th>Month:</th>
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</table>

SAFETY CHECKS MUST BE COMPLETED EACH DAY OF USE. Records are to be retained for two years.

<table>
<thead>
<tr>
<th>Biological Safety Cabinet? (Class II or Fume Hood)</th>
<th>Location of Cabinet?</th>
<th>Yearly certification up-to-date? (yes or no)</th>
</tr>
</thead>
</table>

Note: If certification is not current, the BSC cannot be used. Contact safety officer immediately.

Document all appropriate indicators before use with an “A” acceptable, “UA” unacceptable, or “NA” non-applicable.

Note: If “UA” is documented, appropriate corrective action must be done and documented before use of the BSC.

<table>
<thead>
<tr>
<th>Initials of Analyst</th>
<th>Date</th>
<th>Visual Alarm</th>
<th>Sound Alarm</th>
<th>Airflow</th>
<th>*Smoke Test - Wizard Stick</th>
<th>**UV Readings - Cleanings</th>
<th>Other Detections</th>
<th>Pressure Gauge Reading</th>
</tr>
</thead>
</table>

VISUAL ALARM......Air flow indicator green / SOUND ALARM......Short “beep” at start / AIRFLOW..............Paper indicator

Corrective Action Log

Note: Include maintenance or repair done by professional company and BCL staff below

<table>
<thead>
<tr>
<th>Date</th>
<th>Problem</th>
<th>Resolution</th>
<th>Initials</th>
</tr>
</thead>
</table>

Replacement Part Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Problem</th>
<th>Resolution</th>
<th>Initials</th>
</tr>
</thead>
</table>

*Denotes monthly checks
**Denotes weekly checks of UV light and appropriate cleaning of the UV light.
Bureau of Clinical Laboratories Quality Assessment Plan

S-18 National Bureau of Standards Thermometers Recertification

There are conditions that must be monitored and documented to ensure the proper testing environment. The in-house thermometers are checked at least annually using the National Bureau of Standards (NBS) thermometers which meet the requirements of the ISO 9001 series of quality standards. It is the policy of the Bureau of Clinical Laboratories that the NBS thermometers be recertified every three (3) years.
Bureau of Clinical Laboratories Quality Assessment Plan

S-19 Procedure for the Calibration of Thermometers

1. The National Bureau of Standards (NBS) thermometers are retained in the Quality Management Division. Select the thermometer with the range closest to the temperature being checked. If the thermometer is to be used at multiple temperatures, it should be standardized at each of the temperatures.

   a. For incubators and refrigerators:
      i. Place the thermometer to be tested and the NBS thermometer in a beaker of water inside the equipment.
      ii. Allow the temperature to stabilize.

   b. For freezers:
      i. Place the thermometer to be tested and the NBS thermometer in glycerin before placing in the freezer.
      ii. Allow the temperature to stabilize.

2. Read the temperatures of both thermometers and record the values.

3. Subtract the temperature of the working thermometer from the temperature of the NBS thermometer to obtain the correction factor (CF), and record the value.

   a. All temperature measurements using the working thermometer shall have the CF and the calibration date applied to the thermometer.

4. A permanent record of the standardizations will be maintained and contain the following:
   a. NBS serial number
   b. date of standardization
   c. thermometer identification number and location
   d. NBS reading estimated to 0.1°C
   e. thermometer reading of thermometer being standardized estimated to 0.1°C
   f. correction factor of thermometer being standardized

5. If a thermometer is out of calibration, corrective action shall be performed and documented.

NOTE: The Streck “Temp-Chex” thermometers used for some refrigerators and freezers, when used as intended, are not subject to the types of extreme conditions that can
compromise thermometer accuracy. Each thermometer is hermetically sealed and the volume of internal liquid can only be altered by breakage. The type of glass and annealing procedures used in the manufacturing of these thermometers resist change in the capillary stem and bulb. Under normal conditions, the accuracy of the National Institute of Standards and Technology (NIST) and DKD traceable “Temp-Chex” thermometers with scale divisions of 0.5°C will remain constant throughout the usable life of the thermometer, and annual verification is not required.
S-20 Pipette Calibration

Verification procedures are required to substantiate and ensure the accuracy of the test system. The policy of the Bureau of Clinical Laboratories is that all pipettes used in any test system be calibrated at least annually. The following methods may be used:

1. Spectrophotometric
2. Gravimetric
3. Contract service for pipette validations
S-21 Timer Checks

As part of the ongoing mechanism to monitor and assess the accuracy of test systems, test results and result reporting, it is the policy of the Bureau of Clinical Laboratories that all timers, clocks or stopwatches used in the performance of any testing be checked for accuracy at least annually. Any timing device that is a part of an instrument can be checked according to the manufacturer's direction. Other timers may be checked by using the procedure found in the National Institute of Standards and Technology (NIST) Recommended Practice Guide, special publication 960-12, or referring to the following website:

Bureau of Clinical Laboratories Quality Assessment Plan

S-22 Monthly QA Audit Form

MONTHLY QUALITY ASSESSMENT (QA) AUDIT FORM

Reporting Month/Year:
Division: Select... Section:

PRE-ANALYTICAL

**Unsatisfactory Specimens Types**

<table>
<thead>
<tr>
<th>Processing Phase</th>
<th>Type</th>
<th>Number</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Broken/Leaked</td>
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<tr>
<td></td>
<td>Expired filter paper</td>
<td></td>
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<td></td>
<td>Expired media/reagent</td>
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<td></td>
<td>Expired tubes</td>
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<td></td>
<td>Improper collection</td>
<td></td>
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<td></td>
<td>Incorrect specimen</td>
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<td></td>
<td>No collection date</td>
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<td></td>
<td>No provider</td>
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<tr>
<td></td>
<td>Non-regulated container</td>
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<td>No requisition</td>
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<td></td>
<td>No signature</td>
<td></td>
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<tr>
<td></td>
<td>No specimen received</td>
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<td></td>
<td>Old specimen</td>
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<td>No specimen identification</td>
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<td></td>
<td>Total</td>
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</table>

<table>
<thead>
<tr>
<th>Analytical Phase</th>
<th>Type</th>
<th>Number</th>
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<tr>
<td></td>
<td>Abraded</td>
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<td></td>
<td>Clotted</td>
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<td></td>
<td>Contaminated</td>
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<td></td>
<td>Denatured</td>
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<tr>
<td></td>
<td>Hemolyzed</td>
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<tr>
<td></td>
<td>Lab accident</td>
<td></td>
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<tr>
<td></td>
<td>Lipemic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mixed culture</td>
<td></td>
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<tr>
<td></td>
<td>Non-test day</td>
<td></td>
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<tr>
<td></td>
<td>Nonviable</td>
<td></td>
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<tr>
<td></td>
<td>QNS (quantity not sufficient)</td>
<td></td>
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<tr>
<td></td>
<td>Specimen destroyed</td>
<td></td>
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<tr>
<td></td>
<td>Transfused</td>
<td></td>
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<tr>
<td></td>
<td>Unevenly saturated</td>
<td></td>
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<tr>
<td></td>
<td>Total</td>
<td></td>
</tr>
</tbody>
</table>

Other:

GRAND TOTAL =

- Were unsatisfactory specimens tested? [ ] Yes [ ] No [ ] NA
  - Were results reported? [ ] Yes [ ] No (If yes, explain.)

- Were patterns detected that constituted a majority of these unsatisfactories? [ ] Yes [ ] No [ ] NA (If yes, explain.)

ANALYTICAL

Quality Control

- Have there been significant deviations from the expected range in control data? [ ] Yes [ ] No [ ] NA (If yes, explain.)

- List the remedial action taken to correct any out-of-control occurrences. (You may attach a copy of your "Remedial Action Log.")

Maintenance

- Has maintenance been documented and reviewed by the supervisor? [ ] Yes [ ] No [ ] NA (If no, explain.)
MONTHLY QUALITY ASSESSMENT (QA) AUDIT FORM

❖ List any problems that caused an instrument to be out of service for more than 24 hours or caused a delay in reporting specimen results.

➤ What remedial action was taken to resolve this problem? (You may attach a copy of your “Remedial Action Log.”)

➤ What is the status of the instrument?

➤ Has the resolution been documented and reviewed by the supervisor?
  ☐ Yes  ☐ No  (If no, explain.)

Reagents/Media
❖ Have problems with reagents/test kits/lab supplies and media been documented?
  ☐ Yes  ☐ No  ☐ NA  (If yes, attach a copy of the “Problem Report Form.”)

❖ Have reagents, test kits, lab supplies and media expiration dates been checked?
  ☐ Yes  ☐ No  ☐ NA

❖ Have expired reagents, test kits, lab supplies and media been discarded?
  ☐ Yes  ☐ No  ☐ NA  (If no, explain.)

Proficiency Testing (PT)
❖ Have PT samples been received?  ☐ Yes  ☐ No  Date

❖ Have PT results been received?  ☐ Yes  ☐ No  Date
  ➤ If yes, submit a copy of the completed “PT Performance Form”.

POST ANALYTICAL

Turn-Around-Times (TATs)
❖ How many times did reporting not meet established TATs?
  ➤ How many patient specimens were involved?
  ➤ What counties or private providers were affected by the delay?
  ➤ What remedial actions were taken to correct the problem?

Panic/Notification Values
❖ Were supervisory reviews of called panic/notification values performed?
  ☐ Yes  ☐ No  ☐ NA  (If no, explain.)

Corrected/Amended Reports
❖ Number of corrected reports issued:
  (Attach explanation if corrected report(s) issued.
  Corrected reports = incorrect result sent and had to be changed to correct the result.)

❖ Number of amended reports issued:
  (Amended reports = patient demographics that needed to be amended.)

❖ METABOLIC ONLY
  Number of metabolic amended reports issued:
  (Amended reports = had additional tests requested.)
MONTHLY QUALITY ASSESSMENT (QA) AUDIT FORM

- RESPIRATORY DISEASE ONLY
  Number of respiratory disease addendum reports:
  (Addendum reports = organisms in addition to the primary test isolate were found.)

Problems/Complaints
- Has the division received a complaint? ☐ Yes ☐ No
  (If yes, a “Problem Complaint Form” must be submitted.)

- Have problems been identified through record review or meetings that required an investigation? ☐ Yes ☐ No (If yes, attach a copy of your investigation study.)

Safety
- Have all safety documentations/observations been completed for the month (e.g. check first aid kits for expired supplies, eyewash station check, bleach or Vespheine solution checks, biosafety cabinet checks, etc.)? ☐ Yes ☐ No (If no, explain.)

(This Safety section is to be completed by the manager/supervisor only.)
- Have any accidents occurred during this month? ☐ Yes ☐ No
  ➢ If so, who had the accident?
  ➢ Has a copy of the report been included in the employee’s medical record file?
    ☐ Yes ☐ No (If no, explain.)

NOTE: Remind employees to update their Medical Information forms as necessary.

Employee Training
- Did employees participate in training events, seminars, conferences, etc.? ☐ Yes ☐ No
  ➢ If so, what type of training? Select...
    ➢ If other, specify
    ➢ Attendee(s) of the training:
    ➢ Name of training:
    ➢ Date of training:
    ➢ Did employees document training? ☐ Yes ☐ No (If no, explain.)

Additional Comments:

Form completed by:
Name: Title: Date:

Form reviewed by:
Name: Title: Date:
S-23 New Method Validation

For new procedures being incorporated, the instructions for performing the test(s) are placed in the procedure manual. The appropriate accuracy and precision studies have been performed and documented as required. Quality control is established. Documentation is made that training has been completed for appropriate testing personnel. Personnel are documented as competent before testing is performed and patient results are reported.
**PROFICIENCY TESTING PERFORMANCE REPORT**

**Receipt of PT Samples**

<table>
<thead>
<tr>
<th>Section</th>
<th>Event Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT Program (circle one)</td>
<td>AAB CAP CDC WSLH OTHER</td>
</tr>
<tr>
<td>Date PT samples received</td>
<td></td>
</tr>
<tr>
<td>Condition of samples: 1-excellent 2-poor (if not excellent, explain)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CIRCLE ONE:</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lypholyzed</td>
<td>Slide</td>
<td>sample # 1</td>
</tr>
<tr>
<td>Whole Blood</td>
<td>Urine</td>
<td>sample # 2</td>
</tr>
<tr>
<td>Serum</td>
<td>Photo</td>
<td>sample # 3</td>
</tr>
<tr>
<td>Swab</td>
<td>Formalized</td>
<td>sample # 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>sample # 5</td>
</tr>
</tbody>
</table>

If reconstitution required, record date, diluent and amount used:

<table>
<thead>
<tr>
<th>Date</th>
<th>Diluent</th>
<th>Amount</th>
<th>Initials</th>
</tr>
</thead>
</table>

Date specimens tested | |

Were specimens handled, processed, and tested in same manner as patients? | |

Results recorded to PT report forms by: | |

Results on PT report form checked by: | |

Attestation statement signed by analyst(s) and technical supervisor/director? | |

Method of submission to PT provider (circle one): E-mail On-line Fax U.S. Mail

Initials of person submitting: Date Confirmation received? (yes or no) |

**Review of PT Results**

Date received in Division | |

Reviewed by: | |

Any missed analytes Ungraded (or other exception reason codes) | |

Unsatisfactory performance (< 80%) | |

Date reviewed | |

Date PT reports/results submitted to Laboratory Director for signing | |

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Bureau of Clinical Laboratories Quality Assessment Plan

MISSED ANALYTE INVESTIGATION

Date ____________________________

Analyte ____________________________

Your Result ____________________________

PT Program Mean and Range ____________________________

Repeated Result ____________________________

Investigative Study and Findings

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

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Corrective Action

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

This form is to be completed within ten (10) working days and submitted to the Laboratory Director (or designee) for signing if a missed analyte investigation occurs.

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Bureau of Clinical Laboratories Quality Assessment Plan

S-25 Documentation of Communication and/or Complaints

COMMUNICATION / COMPLAINT LOG

I. Description of communication or complaint

II. Patient Demographics
   Name_________________________________________ Age/DOB______ Sex______ Race______
   Facility name_____________________________________
   Facility address___________________________________
   Physician ________________________________________ Telephone____
   Diagnosis_________________________________________
   Known medication(s) that may affect test results___________

III. Specimen Information
   Test(s) requested__________________________
   Date collected__________________ Type of specimen received____________
   Date received____________________ Type of specimen required___________
   Date reported_______________________
   Result in question_____________________
   Normal values________________________

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Bureau of Clinical Laboratories Quality Assessment Plan

Did the specimen meet the laboratory’s established criteria for acceptability? ___Yes ___No
If not, explain:

Is specimen available for repeat analysis? _____Yes _____No

If so, will the test be repeated? _____Yes _____No

IV. Problem Investigation

What was done?

How was the investigation conducted?

When was the problem investigated?

What was determined to be the cause(s) of the problem and why?

Who investigated?

V. Did the analyst verify the correctness of the report? _____Yes _____No
If not, explain:

VI. Are the results entered consistent per protocol? _____Yes _____No
If not, explain:

VII. What corrective action was taken?

When was it taken?

Who performed it?

VIII. Will remedial action necessitate re-training and documentation of training?

IX. Was there follow-up communication between the lab and the facility concerning the complaint? _____Yes _____No  If yes, explain
Bureau of Clinical Laboratories Quality Assessment Plan

S-26 Problem/Complaint/Remedial Action Form

Problem/Complaint/Remedial Action Form

Date of Occurrence: _______________________

Problem:__________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

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_________________________________________________________________

_________________________________________________________________

Cause or Effect of Problem:__________________________________________

_________________________________________________________________

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_________________________________________________________________

Corrective Action:___________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

_________________________________________________________________

Signature of person completing form: ________________________________ Date ____________

This report reviewed by: __________________________________________ Date ____________

(Attach any other relevant information)

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S-27 Wipe Test Procedure

Wipe Test Procedure

Objective: A wipe test is an evaluation of work areas, instruments/apparatus, floors, drawer fronts, doorknobs, telephones/computers, light switches, refrigerators, etc. for contamination. Laboratories make use of highly sensitive methods, and it is essential to take precautions to avoid contamination of the test and personnel.

Frequency: Wipe tests should be performed at least once monthly, if there is a spill, dropped glove, etc. or any suspicion that specimens/equipment has been mishandled.

Materials
- Sterile plastic applicator swabs/cotton wipes
- Personal protective equipment (PPE)
- Proper medium/container for sterile plastic applicator swabs/cotton wipes

Equipment
Instruments needed for testing

Controls
Appropriate positive and negative controls for analyte

Sample Collection
1. Select instruments/areas in lab to be tested. Label these items on your “Area Wipe Test Check” log.
2. Collect samples. Swab the designated areas using a circular motion.
3. Perform testing per instrument instructions.
4. Record results on your “Area Wipe Test Check” log.

Interpretation
1. Control results should be as expected.
2. Test samples should show no evidence of contamination. Any wipe test sample displaying a reading indicates possible contamination.
3. Document all results.

Action
1. If any area has a positive wipe test, notify the manager/supervisor immediately.
2. Stop testing until instructed to resume testing.
3. Any area suspicious of contamination must be thoroughly cleaned with appropriate cleaner and retested.
4. The supervisor should initiate a thorough investigation to identify the source of contamination.
5. The investigation may warrant additional wipe tests of laboratory surfaces to identify the source of contamination.
6. Once the supervisor or designee reviews all test results up to the last negative wipe test and is satisfied that the testing area is not contaminated, testing can resume.
7. Laboratory procedures and policies should be reviewed and modified as needed to prevent future incidences of contamination.

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# Bureau of Clinical Laboratories Quality Assessment Plan

## S-28 Area Wipe Test Check

### Area Wipe Test Check

<table>
<thead>
<tr>
<th>Wipe#</th>
<th>Location Description</th>
<th>Results</th>
<th>Initials</th>
<th>Notes/Comments</th>
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Notes: 

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Signature of Reviewer (Division Manager/Supervisor) ________________________

Comments by reviewer ________________________

________________________

________________________

________________________

ADPH/BCL/7-2012