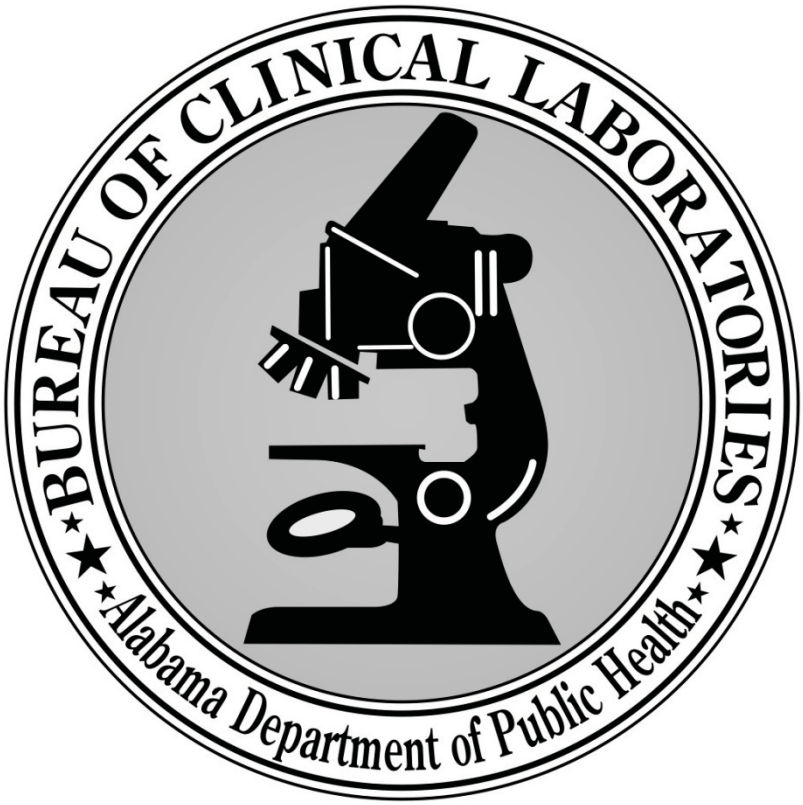
Bureau of Clinical Laboratories Quality Assessment Plan



THE ALABAMA DEPARTMENT OF PUBLIC HEALTH
BUREAU OF CLINICAL LABORATORIES

Alabama Department of Public Health

Bureau of Clinical Laboratories

Title: ***BCL Quality Assessment Plan***	Distribution: Lab-Wide
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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

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.

- **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.

- **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

Reference Manual.

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

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 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
      - 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.

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.

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**.**

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

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S-2 Quality Assessment Committee Members
S-3 Laboratory Personnel Qualifications
S-4 Employee Orientation Checklist
S-5 Employee Training Report
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S-8 Policy Acknowledgement Form
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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
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S-16 Proper Use of the Biological Safety Cabinet
S-17 Biological Safety Cabinet Record Sheet
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S-24 Proficiency Testing Performance Report
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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

Division _____ **Date** _____
Manager_____ **Supervisor** _____

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_____
   _____

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_____
   _____

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

_____
_____
_____
_____
_____
_____
_____

Bureau of Clinical Laboratories Quality Assessment Plan

S-2 Quality Assessment Committee Members

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

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.

Name Maiden Name (if applicable)

Mailing address

Work arrangements: Full time

Part time

EDUCATION

High School Graduate or Equivalent YES NO List College, University, or other schools attended

Name & Address of Institution	Major	Degree or Diploma (include month & year conferred)

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

CLINICAL LABORATORY TRAINING

Name & Address of Institution	Program Title	Degree or Diploma (include month & year conferred)

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

ADPH/QM/07-2012

LABORATORY PERSONNEL QUALIFICATIONS

CLINICAL LABORATORY EXPERIENCE

Name of Laboratory or Institution	Period Employed	Position(s) Held	Experience in the following Specialties						
			Histocompatibility	Microbiology	General Immunology	Chemistry	Hematology	Immunohematology	Pathology

LICENSE, CERTIFICATION, OR REGISTRATION

Name of Granting Agency	License/Certification or Registration Title	Year Granted	License #
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 Moderate Complexity

TS _____ GS _____ TP _____ 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)

Rev. Jan., 2010

ALABAMA DEPARTMENT OF PUBLIC HEALTH
EMPLOYEE ORIENTATION CHECKLIST

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

Employee Handbook	2010-002
Americans with Disabilities Act Employment Policy	2009-007
Discipline Policy	2006-014
Drug-Free Workplace Policy	2004-019
Equal Employment Opportunity/Affirmative Action Policy	2007-003
Family and Medical Leave Act Policy	2010-001
Grievance Policy	2007-014
HIPAA Privacy Policy	2006-008
Professional Conduct Policy	2006-023
Security Policy	2005-016
Sexual Harassment Policy	2003-016
Policy Against Workplace Threats and Violence	2008-002

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

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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.

Name:	SSN:			
Class Code:	Bureau/PHA:			
Classification:	Division/County:			
Position Number:	From:		To:	
	Check below only if applicable			
Title	Required to come off of probation	Required for supervisors	Required yearly	Passed Test

Rating Supervisor's Signature

Employee's Signature

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

Copy – Employee
Copy – Worksite

ADPH-PER-33/Rev. 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.

Pre-analytic Phase	**Evaluation Method**	**Status**	**Date**
Handling Specimens			
Information on form checked and compared to specimen			
Safety precautions followed			
Specimen numbered and dated*			
Processing Specimens			
Specimen processed according to Procedure Manual*			
Reagent/ Media Preparation			
Preparation accomplished according to Procedure Manual			
Analytic Phase			
Testing Procedure			
Procedure set up according to Procedure Manual*			
Procedure performed and interpreted according to Procedure Manual*			
Quality Control (QC)			
QC performed according to Procedure Manual*			
Internal Proficiency Testing			
Procedure performed on blind samples with accuracy and precision+			
External Proficiency Testing			
Procedure performed on PT sample with 80% accuracy			
Maintenance/Function Checks			
Performed according to manufacturer's instructions*			

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Bureau of Clinical Laboratories
Employee Competency Checklist

	Evaluation Method	Status	Date
Calibration			
Performed calibration procedure according to manufacturer's instructions			
Remedial Action			
Conducted according to Procedure Manual and documented			
Post-analytical Phase			
Recording Results			
Patient results recorded according to Procedure Manual			
QC results recorded according to Procedure Manual			
PT results recorded according to PT program instructions			
Notification of Panic Values			
Panic values identified, reported to Health Care Provider, and documented according to Procedure Manual			
Reporting Results			
Patient results are reported according to Procedure Manual and checked			
Referrals			
Referrals are sent according to Procedure Manual			
Records reviewed			
Worksheet			
Complaint/problem documentation			
Preventive maintenance records			

Bureau of Clinical Laboratories
Employee Competency Checklist

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

Employee
Signature: _____ Printed Name: _____

Supervisor
Signature: _____ Printed Name: _____

Date: _____

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Bureau of Clinical Laboratories Quality Assessment Plan

S-7 Employee Medical Information Card

Employee Medical Information Card

Employee Full Name_____ Phone: _____ Date / /
(PRINT)

Employee Address_____
(PRINT)

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

Name _____

Job Title _____

Division _____

Policy	Policy #	Signature	Date	Comments

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

ADPH/BCL/QM/08-12

Bureau of Clinical Laboratories Quality Assessment Plan

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.

S-10 Correction of Test Reports, Request Slips, and Laboratory Testing Quality Assurance Records Policy

Bureau of Clinical Laboratories

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.

ADPH/BCL/QM/08-12

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

Type of Record	Retention Time
Certification Files	6 years
Clinical Chemistry Test Reports	2 years
Environmental Chemistry (including lead)	2 years
Laboratory Testing Protocols	2 years post-retirement of protocol
Milk Reports	3 years
Newborn Screening Test Reports	21 years (send to Archives)
Proficiency Testing	2 years
Rabies Laboratory Reports	2 years
Respiratory Test Reports	2 years
Select Agents Reports	3 years
Testing Personnel Qualification and Competency Evaluations	2 years
Water and Shellfish Reports	5 years
Other Laboratory Test Reports (e.g. Microbiology, Mycology, STD, etc.)	2 years

ADPH/BCL/QM 08-12

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.

S-13 Department of Public Health Record Destruction Notice

DEPARTMENT OF PUBLIC HEALTH RECORD DESTRUCTION NOTICE

Office/Bureau _____

Office/Bureau Records Liaison _____

Phone _____ Date _____

Date Records Destroyed _____

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

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

Reference	Volume (Box, Roll, Book)	Name of Records	Date Span

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

S-14 Maintenance Repairs at BCL

Maintenance Repairs at Bureau of Clinical Laboratories

Mobile / Montgomery

Please circle branch name and record division name _____

Date	Time	Description of the Work Performed	Person(s) Performing the Work	Comments

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 #2005-016) 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

Bureau of Clinical Laboratories Quality Assessment Plan

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.

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 floor 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

BIOLOGICAL SAFETY CABINET RECORD SHEET

(Analyst performing and documenting checks must be competent in the protocol for the operation of the BSC.)

Division: **Month:**

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

Biological Safety Cabinet? (Class II or Fume Hood)	Location of Cabinet?	Yearly certification up-to-date? (yes or no)

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.

Initials of Analyst	Date	Visual Alarm	Sound Alarm	Airflow	*Smoke Test Wizard Stick	**UV Readings Cleanings	Other Detections	Pressure Gauge Reading

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

Date	Problem	Resolution	Initials

Replacement Part Information

Date	Problem	Resolution	Initials

*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℃ will remain constant throughout the usable life of the thermometer, and annual verification is not required.

Bureau of Clinical Laboratories Quality Assessment Plan

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

Bureau of Clinical Laboratories Quality Assessment Plan

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:

http://tf.nist.gov/general/pdf/1930.pdf

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

	TYPE	NUMBER		TYPE	NUMBER
Processing Phase	Broken/Leaked		Analytical Phase	Abraded	
	Expired filter paper			Clotted	
	Expired media/reagent			Contaminated	
	Expired tubes			Denatured	
	Improper collection			Hemolyzed	
	Incorrect specimen			Lab accident	
	No collection date			Lipemic	
	No provider			Mixed culture	
	Non-regulated container			Non-test day	
	No requisition			Nonviable	
	No signature			QNS (quantity not sufficient)	
	No specimen received			Specimen destroyed	
	Old specimen			Transfused	
	No specimen identification			Unevenly saturated	
	Total			**Total**	
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.)

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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.)

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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 Vesphene 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:

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Bureau of Clinical Laboratories Quality Assessment Plan

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.

S-24 Proficiency Testing Performance Report

PROFICIENCY TESTING PERFORMANCE REPORT

Receipt of PT Samples

Section _____ Event Number _____

PT Program (circle one) AAB CAP CDC WSLH OTHER _____

Date PT samples received _____

Condition of samples: 1-excellent 2-poor (if not excellent, explain)

CIRCLE ONE:

Lypholyzed	Slide	sample # 1 _____
Whole Blood	Urine	sample # 2 _____
Serum	Photo	sample # 3 _____
Swab	Formalized	sample # 4 _____
		sample # 5 _____

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

Date	Diluent	Amount	Initials
_____	_____	_____	_____

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) _____
(investigation studies on reverse)

Unsatisfactory performance (< 80%) _____

Date reviewed _____

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

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MISSED ANALYTE INVESTIGATION

Date _____

Analyte _____

Your Result _____

PT Program Mean and Range _____

Repeated Result _____

Investigative Study and Findings

_____

_____

_____

_____

_____

_____

_____

_____

_____

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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S-25 Documentation of Communication and /or Complaints

COMMUNICATION / COMPLAINT LOG

I. Description of communication or complaint

_____

_____

_____

_____

_____

Date of notification _____ Received by _____

Received from (name of caller) _____

(name of facility) _____

Caller's telephone #&/or e-mail address _____

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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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: _____

_____

_____

_____

_____

_____

_____

_____

_____

Cause or Effect of Problem: _____

_____

_____

_____

_____

_____

_____

_____

_____

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

Division / Section _____ Date _____

Name of person(s) performing wipes _____

Wipe#	Location Description	Results	Initials	Notes/Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

Notes: _____

_____

_____

_____

_____

Signature of Reviewer (Division Manager/Supervisor) _____

Comments by reviewer _____

_____

_____

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