U.S. Department of Justice
Federal Bureau of Prisons

Program Statement

OPI: HSD/HPB
NUMBER: P6370.01
DATE: 1/15/2005
SUBJECT: Laboratory Services

1. **PURPOSE AND SCOPE.** To ensure medical laboratory services will be regularly available to meet the needs of inmates at all Bureau institutions.

Laboratory services are classified into one of three categories; waived, moderate complexity, or high complexity.

- Each institution's category will reflect its mission and the inmate population.
- The Medical Director will make the initial laboratory category designation when an institution opens.

2. **PROGRAM OBJECTIVES.** The expected results of this program are:

a. Testing will be performed by qualified health care personnel.

b. Medical laboratory test reports will be accurate and timely.

c. Laboratory test results will be reported to inmates as necessary and incorporated into the inmate's health record.

d. Accurate records will be maintained.

e. Safety and quality control procedures will be enforced.

3. **DIRECTIVES REFERENCED**

P4100.04 BOP Acquisitions Manual (5/19/04)
P6010.02 Health Services Administration (1/15/05)
P6031.01 Patient Care (1/15/05)
P6090.01 Health Information Management (1/15/05)
P6360.01 Pharmacy Services (1/15/05)

Clinical Laboratory Improvement Act of 1988 (CLIA`88)

4. **STANDARDS REFERENCED**

a. American Correctional Association (ACA) 4th Edition Standards for Adult Correctional Institutions: 4-4378, 4-4384, 4-4424, and 4-4427

b. American Correctional Association (ACA) 3rd Edition Standards for Adult Local Detention Facilities: 3-ALDF-4E-04, 3-ALDF-4E-07, 3-ALDF-4E-9, and 3-ALDF-4E-17

5. **APPLICABILITY.** Institutions other than Medical Referral Centers (MRCs) will operate only Waived Category laboratories.

- Institutions currently operational may petition the Medical Director for review of the current classification.
- Only upon the Medical Director's approval will the category of laboratory services be increased or reduced.

6. **BUREAU LABORATORY SERVICES AND CLASSIFICATIONS.** Use of the Medical Reference Laboratories (MRL) is mandatory for all Bureau institutions for initial, routine, and non-emergency patient management testing.

- Commercial laboratories will be used only for those tests not available at the MRLs and for emergency laboratory services, or in extenuating circumstances if the Medical Director has approved a waiver.
- Current documentation will be maintained from the contract lab demonstrating certification and availability of services to include a copy of CLIA certification.
- Laboratory service contracts negotiated with commercial laboratories will require a provision that the contract vendor will send a copy of the monthly billing statements for review to the Bureau’s National Health Systems Administrator. This copy will be sent at the time the institution is billed.

Health Services Administrators (HSA) will ensure that all current national contracts for special laboratory studies, such as CD4 and viral load testing for HIV infection, are used for these studies.

Each of the regions will be assigned to one of the MRLs by the Medical Director.

The MRLs will provide collection and packing supplies. Failure to use MRL provided supplies will result in rejection of specimens.

- Specimens must be shipped on the day of collection and can only be shipped **Monday through Thursday** using the nationally contracted overnight service (i.e. Federal Express).

- Specimens should not be shipped the day before a Federal holiday.

7. **DEFINITIONS**

a. **Specimen Collection** procedures include:

- venipuncture using appropriate anticoagulant and/or additive for required analysis;
- capillary puncture;
- collection of urine specimens for urinalysis and chemistry analysis;
- collection of parasitology specimens (feces and blood); and
- collection of bacteriology specimens for culture for procedures referred to Reference Laboratories.

b. **Specimen Processing** procedures include:

- specimen preservation;
- specimen processing and separation; and
- preparation for transportation for procedures referred to appropriate Reference Laboratories.

8. **LABORATORY MANUALS.** The director of the laboratory must approve, sign, and date any policies and procedures manuals. All laboratory policy and procedures will be reviewed annually and revised as necessary. Local laboratory policy and procedure manuals will be negotiated in accordance with the Master Agreement.

a. **Laboratory Policy Manual.** There will be a written policy manual for laboratory services. This policy manual must be reviewed annually. Policy will include, but not be limited to:

- scheduling of tests;
- required records and reports;

- safety;
- infection control;
- chemical hygiene plan;
- OSHA Bloodborne Pathogen guidelines; and
- Quality Assurance.

b. **Laboratory Procedure Manual.** A written procedure manual for performing all analytical methods the laboratory uses must be readily available and followed by laboratory personnel. This manual will be reviewed annually.

- Textbooks may be used as supplements to these written descriptions, but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

- Manufacturers' package inserts or operator manuals may be used, when applicable, to meet the requirements of this section.

c. **Technical Reference Manual (TRM).** The TRM lists all tests available at the MRLs, the procedures for specimen collection and processing, packing and shipping instructions, and procedures for reporting test results. MRL supervisors will conduct an annual review of the TRM.

9. **LABORATORY FORMS.** MRLs will format their own laboratory report forms. Laboratory reports must be legible, accurate, timely, and results must be reported in clearly designated units of measurement. Reference values are to be provided with each laboratory test result.

All laboratory analyses must be ordered in writing (by electronic or manual methods) on the appropriate forms. Requests will include the following information, clearly and legibly typed, stamped, or printed:

- Inmate's full name and complete registration number;
- Name of the requesting individual;
- Full name and address of the institution;
- All tests required;
- Date the specimen was collected and the time of collection if relevant; and
- Source of the specimen (e.g., culture, site, etc.).

All MRLs will have compatible Laboratory Information Systems (LIS) approved by the Medical Director. MRLs with LIS may maintain some or all of this required information electronically.

10. **REPORTS.** Test reports will include all of the information on the request form listed above (Section 9). Information will be available regarding:

- Date and time received by the MRL; and
- Date and time analysis reported by the MRL.

Authenticated, dated reports of all examinations performed by the pathology and medical laboratory services will be made a part of the patient's health record.

- The name, address, and phone number of the laboratory performing the analysis will be included on each report.

Each institution will develop a local procedure for reviewing and acting upon abnormal laboratory values. Qualified health personnel will use good clinical judgement to determine the need to personally inform an inmate of an abnormal laboratory value.

Notations regarding significant laboratory or pathology abnormalities will be made in the Chronological Record of Medical Care (SF-600).

- A physician will review, initial, and date all laboratory reports prior to filing in the health record.

Each institution pathology and medical laboratory service will maintain a daily accession record of specimens collected, specimens processed, and an appropriate identification system for each. The accession record will include at least:

- Patient identification;
- Identification of the practitioner ordering the test; and
- Test or evaluation performed.

The daily accession record may be maintained electronically.

The performing laboratory will maintain duplicate copies of all pathology and medical laboratory services testing and examinations in a readily retrievable manner. Requirements for record retention are determined by Federal, state, and local regulations. All laboratory records and patient reports will be maintained according to the following table:

Record/Material	**Period of Retention**
Test requisitions	2 years
Test records	2 years
Immunohematology	5 years

Test reports	2 years
Pathology	10 years
Proficiency testing	2 years

11. **CLASSIFICATIONS.** In accordance with the CLIA`88, all Bureau institution laboratories must meet strict laboratory testing standards. The Bureau's laboratories are subject to inspection by surveyors from the College of American Pathology (CAP) and/or the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO).

Classifications are as follows:

- Waived
- Moderate Complexity
- High Complexity

The following indicates the Laboratory Services generally provided in each of the classification categories.

a. **Classification Category: Waived**

- Specimen Collection
- Specimen Processing for referral to MRLs or contract laboratories
- Waived Tests as defined by CLIA`88 as Classification Category Waived to meet the needs of the institution's health services program. Examples of waived tests include:
  - dipstick urinalysis;
  - finger stick glucose testing;
  - erythrocyte sedimentation rate (ESR) testing;
  - fecal occult blood testing;
  - spun hematocrit testing; and
  - Hgb Ac (if equipment is available).

b. **Classification Category: Moderate Complexity**

- Specimen Collection
- Specimen Processing for referral to MRLs or commercial laboratories.
- Waived tests as defined in Classification Category Waived

- Moderate Complexity tests as defined by CLIA `88 regulations and updates.

c. **Classification Category: High Complexity**

- Specimen Collection
- Specimen Processing for referral to MRLs or commercial laboratories
- Waived tests as defined in Classification Category Waived
- Moderate Complexity tests as defined by CLIA 88 regulations and updates.
- High Complexity tests as defined by CLIA 88 regulations and updates.
- Accredited by the College of American Pathologists (CAP).

12. **PERSONNEL REQUIREMENTS AND RESPONSIBILITIES**

a. **Category Waived.** There are no CLIA requirements for a Laboratory Director, Technical Consultant, or Clinical Consultant for Waived Category laboratories.

b. **Category Moderate Complexity**

(1) **Laboratory Director.** The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, but can direct no more than five laboratories.

Individuals with the following qualifications may be laboratory directors:

- Pathologist
- Other licensed Medical Doctor (MD) or Doctor of Osteopathic Medicine (DO) with:

  (1) one year experience directing/supervising non-waived tests; or
  (2) by August 1993, have at least 20 CME credit hours in laboratory practice commensurate with director responsibilities; or
  (3) laboratory training during residency equivalent to above (2), or certification in hematology or hematology/oncology.

- Doctor of Philosophy (PhD) in science with:

  (1) laboratory related board certification; or
  (2) one year full-time experience supervising non-waived testing.

- Master's in science with:

  (1) one year laboratory training or experience; and
  (2) one year supervisory experience.

- Bachelor's in science with:

  (1) two years laboratory training or experience; and
  (2) two years supervisory experience.

- On or before February 28, 1992, qualified or could have qualified as a laboratory director under March 14, 1990, Medicare/CLIA 67 rules; or

- On or before February 28, 1992, qualified under state law to direct a laboratory in the state.

(2) **Technical Consultant.** The technical consultant is responsible for the laboratory's technical and scientific oversight. Technical consultant requirements for laboratory training or experience may be acquired concurrently in more than one of the specialties (e.g., the pathologist or medical technologist with experience can consult in each specialty).

The technical consultant is not required to be on-site at all times, but must be available to the laboratory as needed. Individuals with the following qualifications may be technical consultants:

- Pathologist;

- Other MD or DO with one year of laboratory training or experience in the specialty or subspecialty for which they are responsible;

- PhD or Master's degree in science and one year laboratory training or experience in specialty for which they are responsible; or

- Bachelor's degree in science or medical technology with two years laboratory training or experience in the specialty for which they are responsible.

(3) **Clinical Consultant.** The clinical consultant provides consultation to the laboratory's clients concerning the diagnosis, treatment, and management of patient care including appropriateness of testing ordered. The clinical consultant must prepare a written report after each visit to the institution. Individuals with the following qualifications may be clinical consultants:

- MD, DO, or PhD who qualifies as a laboratory director; or
- Licensed MD or DO.

(4) **Testing Personnel.** Testing personnel must be at least a high school graduate or equivalent with "documented training" appropriate for the testing the laboratory performs. Knowledge about specimen collection, proper instrument use, and the assessment of validity of patient test results is required.

c. **Category High Complexity**

(1) **Laboratory Director.** Individuals with the following qualifications may be a laboratory director:

- Pathologist;

- Other MD or DO with:

  (1) one year laboratory training or residency (e.g., physicians with board certification in hematology); or
  (2) two years experience directing or supervising high complexity testing.

- PhD with:

  (1) certification in one of the laboratory specialties; or
  (2) until September 1994, have two years laboratory training or experience, and two years experience directing or supervising high complexity testing. By the end of two years must become board-certified; or
  (3) On or before February 28, 1992, be serving as a laboratory director and previously qualified or could have qualified under March 14, 1990, rules (Medicare/CLIA 67); or
  (4) On or before February 28, 1992, qualified under state law to direct a laboratory in the state.

(2) **Technical Supervisor.** The laboratory must employ one or more individuals qualified by education and either training or experience to provide technical supervision for each of the specialties and sub-specialties of service in which the laboratory performs high complexity testing. Requirements for laboratory training or experience in each of the specialties or sub-specialties may be acquired concurrently.

The technical supervisor is not required to be on-site at all times but must be available to laboratory as needed. Time in the laboratory must be adequate to supervise the technical operation.

If the pathologist director is not board certified (or eligible for certification) in both anatomic and clinical pathology and the laboratory performs tests in the specialties of Microbiology (bacteriology, mycobacteriology, mycology, parasitology, virology), Diagnostic Immunology, Chemistry, Hematology, and Radiobioassay, the qualifications for technical supervisor are:

- Pathologist, board certified or eligible for certification in clinical pathology; or
- Other MD or PhD in science with one year laboratory training or experience within the specialty (e.g. Microbiology), with at least six months of experience in the applicable subspeciality (e.g., bacteriology, mycology); or
- Master's degree in science with two years laboratory experience or training in the specialty and a minimum of six months spent acquiring proficiency in the applicable subspecialty; or
- Bachelor's degree in science with four years training or experience in the specialty, with a minimum of six months experience in the applicable subspecialty.

(3) **Clinical Consultant.** The clinical consultant provides consultation on appropriateness of tests ordered and interpretation of test results.

Individuals with the following qualifications may be clinical consultants:

- MD, DO, or PhD qualified as a laboratory director for high complexity testing or

- Licensed MD or DO.

(4) **General Supervisor.** The general supervisor must be accessible to testing personnel whenever testing is performed and provide on-site supervision of testing personnel and reporting of test results.

For blood gas analysis, the general supervisor must have at least a bachelor's degree in respiratory therapy and one year of training or experience; or have an associate degree related to pulmonary function and two years of training or experience. Individuals with the following qualifications may be a general supervisor:

- MD, DO, or PhD, master's, or bachelor's degree in science and with one year of laboratory training or experience in high complexity testing; or

- Associate degree in a laboratory science or medical laboratory technology and two years laboratory training or experience in high complexity testing; or

- Previously qualified or could have qualified as a general supervisor under March 14, 1990, rules (Medicare/CLIA 67) on or before February 28, 1992.

(5) **Testing Personnel.** Individuals with the following qualifications may be testing personnel:

- MD, DO, or PhD, master's degree or bachelor's degree in science;

- Associate degree in laboratory science;

- Previously qualified or could have qualified as a technologist under March 14, 1990, rules (Medicare/CLIA 67) on or before February 28, 1992;

- Until September 1, 1997, individuals with a high school diploma or equivalent and documented training appropriate for the testing performed are qualified;

- For blood gas analysis, within five years either be number one or number two (above) or bachelor's degree in respiratory therapy or associate degree related to pulmonary function;

- For histopathology, tissue examinations must be performed by an MD or DO certified in anatomic

pathology (or eligible for certification). For dermatopathology, an MD or DO certified in dermatopathology or dermatology can also perform examinations; and

- There must be sufficient qualified personnel with documented training and experience to conduct the work of the laboratory as specified by the current Classification Category.

13. **QUALITY CONTROL.** Quality control systems and measures of the pathology and medical laboratory services will be designed to ensure both the quality and appropriateness of the laboratory service. All categories of laboratories will adhere to the minimum guidelines as currently mandated by CLIA 88 regulations. The quality control program will include, but not be limited to, the following:

- Preventive maintenance, periodic inspection, and performance testing of all equipment and automated instruments will be performed with documentation maintained for the test equipment's life.

- Emergency power will be available to meet the needs of the medical services provided. The emergency power will be sufficient to maintain all essential refrigeration, equipment, and instruments required for emergency testing.

- Documented monitoring of temperature controlled instruments will be performed daily.

- Labeling of reagents and solutions will include:

  - identity;
  - strength;
  - precautions and special handling information;
  - preparation date;
  - expiration date; and
  - the initials of the person preparing the reagent.

- Written procedures will be established for the preparation of patients and for the collection, preservation, transportation, and receipt of specimens to ensure satisfactory specimens are available or used for the analysis to be performed.

14. **PROFICIENCY TESTING.** All MRLs are required to participate successfully in an approved proficiency testing (PT) program. Recommended source for proficiency testing material is the College of American Pathologists (CAP).

15. **LABORATORY STANDARDS.** There will be sufficient space, equipment, and supplies within the medical laboratory service to perform the required volume of work with optimal accuracy, precision, efficiency, and safety. Equipment and instruments will be appropriate for the services specified for each classification category.

Special precautions will be taken to avoid unnecessary physical, chemical, and biological hazards. The routine use of laboratory instruments, equipment and the performance of laboratory analysis must be evaluated frequently to ensure quality and appropriate laboratory support is provided to meet the needs of the institution medical service.

16. **BLOOD TRANSFUSION SERVICE.** MRCs that operate a blood transfusion service will comply with the following specific requirements:

- **Under no circumstances will facilities operate a blood bank service (donor collection, blood or blood components processing); services will be strictly limited to transfusion services.**

- Personnel in the transfusion service will have sufficient training and/or experience and demonstrate technical competence in the performance of immunohematologic procedures performed.

- Institutions performing blood transfusions will have written policies and procedures which conform to the American Association of Blood Banks, Standards for Blood Banks and Transfusion Services.

  These policies and procedures will be readily available to staff and will be reviewed at least annually by the Director of the Service and revised as necessary.

- Blood or blood components will be stored and handled in such a manner that they retain their maximum efficacy and safety. They will be properly processed, tested, and labeled.

- Refrigerators used for the routine storage of blood will conform to all specifications of the American Association of Blood Banks. The proper functioning of the refrigerator will be constantly monitored by a system of audible and visible alarms (including remote alarms for use when there is no one in attendance) that are either battery operated or are on a circuit powered by the institution's emergency generator.

- A written procedure will be established for obtaining necessary blood and blood components at all times. It will be documented that stored blood is inspected daily for evidence of hemolysis and for possible bacterial contamination.

- The blood center source where blood or blood components are obtained will be recommended by the Laboratory Director and approved by the medical and administrative staff. The blood center must be certified by the American Association of Blood Banks (AABB).

- **Required Bench Reference.** MRCs which operate a blood transfusion service will have the most recent edition of the AABB Standards and AABB Technical Manual for Blood Banks and Transfusion Services available for reference.

17. **INMATE WORKERS.** Due to the confidentiality and sensitivity of diagnostic test results, inmate workers **will not be allowed** to work in clinical laboratories, other than in orderly positions and then only under **direct supervision.**

18. **NEEDLES AND SYRINGES.** When needles and syringes are maintained in the laboratory, an accountability system will be established in accordance with the Program Statement on Pharmacy Services.

/s/
Harley G. Lappin
Director