U.S. DEPARTMENT OF JUSTICE
Federal Bureau of Prisons

PROGRAM STATEMENT
Laboratory Services

Approved by	William K. Marshall III Director, Federal Bureau of Prisons
DPI	HSD
Number	6370.02
Date	June 22, 2026

Summary of Changes

Program Statement Rescinded:

- 6370.01 Laboratory Services (1/15/2005)

Changes:

- Clarifies Clinical Laboratory Improvement Amendments (CLIA)
- Defines waived and nonwaived testing laboratories
- Delineates roles for Medical Referral Laboratories versus Medical Referral Center Laboratories
- Standardizes laboratory testing menus
- Updates information regarding the laboratory information system

1. PURPOSE AND SCOPE

To ensure medical laboratory services will be regularly available to meet the needs of inmates at all institutions without compromising public safety concerns inherent to the Bureau of Prison's (Bureau) overall mission.

a. Program Objectives.

- All laboratory testing will be performed in accordance with quality standards established by the Clinical Laboratory Improvement Amendments (CLIA).
- Laboratory services will be delivered in an accurate and reliable manner using efficient and cost-effective methods.

b. Institution Supplement. None.

2. DEFINITIONS

Advanced Practice Provider (APP). For the purpose of this program statement, an APP is a Nurse Practitioner or Physician Assistant.

American Society for Clinical Pathology (ASCP). A professional membership organization for pathologists and laboratory professionals that provides education and certification**.**

Clinical Laboratory Improvement Amendments (CLIA). Federal regulatory standards enacted in 1988 (with final rule published in 2003 and subsequent amendments) that apply to all facilities performing laboratory testing on human specimens for health purposes. All facilities performing even one test (including waived tests) on human specimens for diagnosis, prevention, or treatment are considered laboratories under CLIA.

Certificate of Accreditation. Issued by Centers for Medicare & Medicaid Services (CMS) to laboratories that perform nonwaived testing and are accredited by a CMS-approved accreditation organization (e.g., College of American Pathologists, The Joint Commission).

Certificate of Waiver. Issued by CMS to facilities that perform only waived tests. A Certificate of Waiver is the only CLIA certificate that line institutions in the Bureau are permitted to obtain.

Clinical Consultant. Provides expert medical guidance on test selection, result interpretation, and clinical implications. Required in moderate- and high-complexity laboratories.

College of American Pathologists (CAP). A CMS-approved accreditation organization for laboratories performing nonwaived testing. The accreditation program offered by the CAP examines all phases of testing in the quality management aspect in the laboratory.

Competency. The demonstrated ability of testing personnel to accurately perform laboratory testing and report results. Assessment of competency must be documented and performed according to applicable accrediting guidelines. All testing, no matter the complexity (waived/nonwaived) requires competency assessments.

Laboratory Accreditation. Formal recognition by a CMS-approved accreditation organization that a laboratory meets defined standards. All laboratories at Medical Referral Centers (MRCs) that perform nonwaived testing must maintain current accreditation from a CMS-approved organization.

Laboratory Director (LD). The individual responsible for the overall operation and administration of the laboratory, including ensuring timely, reliable, and clinically relevant test results and compliance with all applicable regulations per 42 C.F.R. §493.1405/1443 for nonwaived laboratories.

This individual will be listed on the laboratory's CLIA certificate and, for laboratories performing nonwaived testing, must meet the education, training, and experience requirements specified in 42 C.F.R. Part 493 Subpart M of the CLIA regulations. CLIA does not specify qualifications for the LD of a facility that performs only waived tests.

Laboratory Information System (LIS). A software-based system responsible for managing data within a working medical laboratory. System elements include workflow and data tracking support, data exchange interfaces, and Electronic Health Record (EHR) connectivity.

Laboratory Supervisor. Oversees day-to-day testing activities and staff performance in high-complexity settings. Steps in to manage test operations and result reporting when higher-level staff are absent.

Line Institution. A Bureau institution that is not designated as a Medical Referral Center (MRC). These facilities constitute the majority of Bureau institutions and include Federal Correctional Institutions (FCI), United States Penitentiaries (USP), Federal Prison Camps (FPC), etc.

Medical Referral Center (MRC). A Bureau institution designated to provide advanced medical and surgical care, including inpatient services and specialty consultations. Each MRC will seek and maintain laboratory accreditation from an appropriate accrediting agency as designated by Bureau policy.

Medical Referral Laboratory (MRL). A laboratory within an MRC that has obtained a CLIA Certificate of Accreditation to perform nonwaived tests. MRLs will serve as the primary source for routine and STAT testing for the local inmate population. These laboratories will also serve as the primary source for routine laboratory testing for other geographically appropriate assigned Bureau facilities.

MRC Laboratory. A laboratory within an MRC that has obtained a CLIA Certificate of Accreditation to perform nonwaived tests. These laboratories will serve as the primary source for routine and STAT testing for the local inmate population.

Nonwaived Tests. Tests classified by Federal Drug Administration (FDA) as moderate- or high-complexity under CLIA.

Point-of-Care Testing (POCT). Testing performed near or at the site of patient care. Please note that POCT can be waived or nonwaived complexity.

Quality Control. Indicates processes and procedures designed to confirm laboratory results are reliable, comparable, accurate, and within specified limits of acceptability.

Technical Consultant. Provides technical oversight for moderate-complexity testing. Responsibilities include method evaluation, validation, and troubleshooting.

Technical Supervisor. Required in high-complexity labs to supervise and troubleshoot testing. Ensures proper implementation of technical procedures.

Testing Personnel. Staff who perform laboratory tests. Required to have proper education, training, documented competency, and follow procedures. Competency assessments occur periodically (six months, 12 months, and annually afterward).

Waived Laboratory. A facility holding a CLIA Certificate of Waiver.

Waived Tests. Tests cleared by FDA for home use or classified by CMS as having insignificant risk of erroneous result, as defined by 42 C.F.R. § 493.15.

3. PROGRAM RESPONSIBILITY

As required by CLIA regulations, the LD is responsible for the overall operation and administration of the laboratory. The LD must meet all applicable federal, state, local, CLIA, and accrediting-body qualifications. Facilities are expected to consult with the National Laboratory Administrator (NLA) to determine whether the LD meets those minimum requirements.

The LD is required to work within applicable Bureau directives as outlined by policy and the NLA. Certain duties outlined by CLIA can be delegated in writing to an appropriately qualified Bureau staff member (i.e., laboratory manager, laboratory supervisor, or other qualified personnel).

4. WAIVED LABORATORIES

a. **Scope of Services.** Only waived testing will be authorized for use and oversight within these facilities. Each facility will be responsible for obtaining a CLIA Certificate of Waiver. These facilities will collaborate with the NLA to determine oversight responsibility of the waived testing program. The NLA will approve and publish a standardized set of waived tests that can be performed within Bureau facilities.

Bureau facilities who decide to perform waived tests will be designated as a waived laboratory. These facilities are required to only perform waived tests as defined by CLIA and approved for use in the Bureau by the NLA. The approved test menu will be reviewed annually by the NLA and published in the Laboratory Services section on the Bureau’s intranet site.

Waived testing laboratory leadership will include a qualified LD. Testing personnel can include a wide range of staff including, but not limited to, phlebotomists, health services assistants, nurses, and APPs.

b. **Waived Laboratory Requirements.** Institutions performing any waived test are required to meet the following guidelines:

- Enroll in the CLIA program by obtaining a Certificate of Waiver
- Pay the certificate fee and renew every two years
- Follow the manufacturers' instructions for the waived tests they are performing
- Update any changes in ownership, name, address, or LD within 30 days
- Permit inspections by a CMS agent, such as a surveyor from the state agency
- Follow all applicable accrediting body waived testing requirements, which will include:
  - Written policies and procedures
  - LD/staff responsibilities
  - Staff competency
  - Quality control
  - Recordkeeping
  - Cleaning, disinfection, sterilization of supplies
  - Compliance with laws and regulations

5. ACCREDITED (NONWAIVED) LABORATORIES

a. **Scope of Services.** A CLIA Certificate of Accreditation will be maintained in each of the Bureau MRCs. There will be two types of accredited laboratories. Each type will be assessed and assigned in collaboration between the Medical Director and NLA. The two accredited laboratory types will be labeled as follows:

- MRC Laboratories
- Medical Referral Laboratories (MRL)

Accreditation must be obtained through a nationally recognized accrediting body determined by the Medical Director and NLA. Only nonwaived testing will be authorized for use and/or oversight within the accredited laboratories.

MRCs may also obtain a separate CLIA Certificate of Waiver if oversight and testing are not included within the accredited laboratory. These facilities will collaborate with the NLA to determine oversight responsibility of the waived testing program.

- **MRC Laboratories.**
  - MRC Laboratories will serve as the primary source for routine and STAT testing for the local inmate population. The laboratory will only perform the tests approved by

the LD and NLA. The approved menu will be reviewed and published annually in the Laboratory Services section on the Bureau's intranet site.

- MRC Laboratories' leadership structure will include a qualified LD and laboratory supervisor. Testing personnel may include medical laboratory scientists and/or medical laboratory technicians. Other support personnel can include health services assistants and/or phlebotomists.

- **Medical Referral Laboratories.**
  - MRLs will serve as the primary source for routine and STAT testing for the local inmate population. These laboratories will also serve as the primary source for routine laboratory testing for other geographically-appropriate assigned Bureau facilities. The laboratory will only perform the tests approved by the LD and NLA. A specimen collection and processing manual will be provided by each MRL's assigned facilities.
  - MRL leadership structure will include a qualified LD, laboratory manager, and laboratory supervisors. Testing personnel will include medical laboratory scientists and/or medical laboratory technicians. Other support personnel can include health services assistants and/or phlebotomists.

b. **Laboratory Requirements.** Laboratories holding a CLIA Certificate of Accreditation will meet the following core requirements (in addition to Subpart M of all applicable CLIA Regulation Subparts). The following elaborations are provided to assist non-laboratory healthcare professionals in understanding the intent and application of each requirement. Regulatory citations reference 42 C.F.R. Part 493.

- **Laboratory Director qualifications.** Regulatory Reference: 42 C.F.R. § 493.1405; 42 C.F.R. § 493.1443; 42 C.F.R. Part 493, Subpart M
  - The laboratory must have a qualified LD who meets specific educational and experience requirements based on the complexity of testing performed. The director is ultimately responsible for all laboratory operations, including test quality, staff competency, and regulatory compliance. This person may not simply be an administrator – they must have demonstrated scientific and clinical expertise appropriate to the level of testing performed.
- **Proficiency testing.** Regulatory Reference: 42 C.F.R. Part 493, Subpart H; 42 C.F.R. § 493.1236
  - Laboratories must enroll in and participate in a Health & Human Services (HHS)-approved external Proficiency Testing (PT) program for each specialty and subspecialty for which they seek certification. PT involves receiving unknown samples from an outside organization, testing them in the same manner as patient specimens, and submitting results for graded comparison. Successful PT performance is required to maintain CLIA certification. Unsuccessful PT may trigger corrective action and, if persistent, can result in loss of testing privileges for the affected test. Intentional referral of PT samples to another laboratory for analysis may result in certificate revocation.

- **Quality management.** Regulatory Reference: 42 C.F.R. Part 493, Subpart K; 42 C.F.R. § 493.1239
  - The laboratory must maintain a comprehensive Quality Management (QM) system that monitors all phases of testing – before the sample is collected (pre-analytical), during testing (analytical), and after results (post-analytical) are reported. This includes tracking errors, monitoring turnaround times, reviewing complaints, and identifying opportunities for improvement. Laboratories must document all quality assessment activities, review the effectiveness of corrective actions, and discuss findings with appropriate staff. QM is an ongoing, systematic process – not a one-time effort.
- **General issues.** Regulatory Reference: 42 C.F.R. §§ 493.1231–493.1234; 42 C.F.R. Part 493, Subpart J
  - This category covers broad operational standards that apply across the laboratory, including appropriate test ordering, patient identification, confidentiality of results, and communication of critical values. Laboratories must have clear policies addressing how general day-to-day operations are conducted and how deviations from standard practice are identified and resolved. Laboratories must also document complaints and investigate problems arising from breakdowns in communication between the laboratory and ordering providers.
    - **Written Quality Management/Quality Control program.** Regulatory Reference: 42 C.F.R. § 493.1256; 42 C.F.R. Part 493, Subpart K
      - The laboratory must have a documented, written Quality Control (QC) program that defines how the accuracy and precision of test results are monitored every day. For each test system, control procedures must be performed using the number and frequency specified by the manufacturer, or as established by the laboratory when they meet or exceed regulatory requirements. At a minimum, control procedures must be performed, at least once, each day patient specimens are tested. This written program must specify acceptable QC ranges, corrective actions when QC fails, and documentation requirements.
    - **Unusual laboratory results.** Regulatory Reference: 42 C.F.R. §§ 493.1232–493.1233; 42 C.F.R. § 493.1291
      - Laboratories must have policies to identify, investigate, and communicate results that fall outside expected ranges or that are clinically unexpected. This includes delta checks (comparing a patient's current result to their previous result), critical value notification, and investigation of results that may indicate specimen integrity issues or instrument malfunction. Non-laboratory staff should understand that unusual results trigger a defined internal review process before being acted upon clinically. Laboratories must document all complaint investigations and problems identified.
    - **Supervisory result review.** Regulatory Reference: 42 C.F.R. § 493.1407; 42 C.F.R. § 493.1445; 42 C.F.R. Part 493, Subpart M

- Qualified laboratory supervisors must review test results before they are finalized and reported. This is particularly important for complex or high-risk tests. Supervisory review ensures results are accurate, complete, and clinically plausible. Supervisors are also responsible for reviewing QC data, flagging potential errors, and authorizing result release in accordance with laboratory policy. Personnel requirements for supervisors are defined separately based on testing complexity.

- **Instrument/equipment record review.** Regulatory Reference: 42 C.F.R. § 493.1252; 42 C.F.R. § 493.1254; 42 C.F.R. § 493.1255
  - Laboratories must maintain and regularly review complete records for all instruments and equipment used in testing. These records include maintenance logs, calibration records, function check records, and repair histories. Calibration and calibration verification procedures are required to confirm the continued accuracy of the test system throughout the laboratory's reportable range. Equipment that is out of service or malfunctioning must be clearly identified and removed from use until repairs are verified.
- **Comparability of instruments/methods.** Regulatory Reference: 42 C.F.R. § 493.1253; 42 C.F.R. § 493.1289
  - When a laboratory uses more than one instrument or method to perform the same test, it must demonstrate that the results produced are comparable, i.e., a patient would receive essentially the same result regardless of which instrument or method was used. This is critical in settings where multiple analyzers run the same test across shifts or locations. Laboratories must perform and document comparability studies whenever new instruments are added, or significant changes are made to existing methods.
- **Comparability criteria.** Regulatory Reference: 42 C.F.R. § 493.1253(b); 42 C.F.R. § 493.1289
  - Laboratories must define the specific, measurable criteria used to determine whether instruments or methods are producing comparable results. These criteria must be established in advance and must be clinically meaningful, i.e., any allowable difference between instruments must not be large enough to affect patient care decisions. Documentation of these criteria and the results of comparability testing must be maintained as part of the laboratory's quality records.
- **Specimen collection and handling.** Regulatory Reference: 42 C.F.R. § 493.1232; 42 C.F.R. § 493.1242
  - The laboratory must establish and follow written policies and procedures which ensure 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. Non-laboratory staff involved in specimen collection, such as nurses and phlebotomists, must follow laboratory-defined procedures,

including correct tube types, collection order, volume requirements, and temperature conditions for transport. Improper collection or handling is one of the most common sources of laboratory error and can result in inaccurate results.

- **Procedure manuals.** Regulatory Reference: 42 C.F.R. § 493.1251
  - A written procedure manual for all tests, assays, and examinations performed by the laboratory must be available to and followed by laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures. The procedure manual must include requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, and processing; step-by-step performance of the procedure; calibration and calibration verification procedures; the reportable range; and corrective actions when QC fails. Procedure manuals must be reviewed and approved annually by the LD.
- **Results reporting.** Regulatory Reference: 42 C.F.R. § 493.1291; 42 C.F.R. Part 493, Subpart K
  - Laboratory results must be reported in a clear, accurate, and timely manner to authorized individuals. Reports must include the patient's name and identifier, the test name, result, units of measurement, reference intervals, and the laboratory's name and address.
  - Critical values must be communicated immediately to the responsible clinician. Each facility will develop a local procedure for reviewing and acting upon abnormal laboratory values to ensure prompt and appropriate follow-up to abnormal lab results, including critical labs.
  - Laboratories must also have policies for amended reports when errors are corrected after initial release. Requests for corrected reports are forwarded to a health informatic specialist with the basis for correction.
- **Reagents.** Regulatory Reference: 42 C.F.R. § 493.1252
  - All test systems, equipment, instruments, reagents, materials, and supplies used in laboratory testing must be monitored to ensure they are acceptable for performing the type of testing required. Reagents must be labeled with lot numbers and expiration dates, and expired reagents must never be used for patient testing. Laboratories must document receipt, quality checks, and any issues with reagents. Reagent failure is a recognized cause of inaccurate results and must be addressed through the laboratory's corrective action process.
- **Instruments and equipment.** Regulatory Reference: 42 C.F.R. § 493.1252; 42 C.F.R. § 493.1254; 42 C.F.R. § 493.1255
  - The laboratory must maintain all instruments and equipment in proper working order through a defined preventive maintenance and function check program. Each instrument must be calibrated on a schedule that meets manufacturer and regulatory requirements. Records of all maintenance,

calibration, and corrective actions must be retained. Equipment that is out of service or malfunctioning must be clearly identified and removed from use until repairs are verified and documented.

- **Test method validation/verification.** Regulatory Reference: 42 C.F.R. § 493.1253
  - Before any new test is introduced into clinical use, the laboratory must establish or verify the performance specifications of the test system. For FDA-cleared or approved test systems, the laboratory must verify performance specifications are achievable. For laboratory-developed tests or modified FDA-cleared tests, the laboratory must establish performance specifications. This process includes evaluating accuracy, precision, and reportable range. Results must be reviewed and approved by the LD before patient testing begins.
- **Method Performance Specifications.** Regulatory Reference: 42 C.F.R. § 493.1253; 42 C.F.R. § 493.1251(b)(9)
  - Each test method must have clearly defined performance specifications, including the analytical measurement range (the range of values the test can accurately measure), precision (reproducibility of results), accuracy (closeness to the true value), and any known interferences or limitations in the methodology. These specifications guide clinical interpretation and help clinicians understand the limitations of any given test result. Limitations in test methodology, including interfering substances, must be documented in the procedure manual.
- **Reference intervals.** Regulatory Reference: 42 C.F.R. § 493.1253(b)(4); 42 C.F.R. § 493.1251
  - Reference intervals define the expected range of results for a healthy population. Laboratories must verify the reference intervals they use are appropriate for their patient population, taking into account factors such as age, sex, and specimen type. If a laboratory's patient population differs significantly from the population used to establish published reference intervals, the laboratory must establish its own reference intervals. Reference intervals must be included in the procedure manual and reviewed and updated as needed.
- **Personnel requirements.** Regulatory Reference: 42 C.F.R. Part 493, Subpart M; 42 C.F.R. § 493.1235
  - All laboratory personnel must meet minimum qualifications based on the complexity of the tests they perform. CLIA defines specific education, training, and experience requirements for testing personnel, technical supervisors, laboratory supervisors, and laboratory directors performing moderate and high complexity testing. Laboratories must establish and follow written policies and procedures to assess staff competency and must review

and evaluate the results of that assessment. Competency must be assessed at least annually for all testing personnel.

- **Physical Facilities.** Regulatory Reference: 42 C.F.R. Part 493, Subpart J
  - The laboratory must maintain a safe and functional physical environment that supports accurate testing. This includes adequate space, appropriate lighting, temperature and humidity control, proper ventilation, and safe storage of chemicals and biological materials. Facilities must be designed and maintained to prevent contamination, protect specimen integrity, and support the workflow necessary for the volume and complexity of testing performed. Laboratories must also comply with applicable federal, state, and local facility requirements.
- **Laboratory Safety.** Regulatory Reference: 42 C.F.R. Part 493, Subpart J; 29 C.F.R. Part 1910 – Occupational Safety and Health Standards
  - Laboratories must comply with all applicable safety regulations in addition to CLIA, including those established by the Occupational Safety and Health Administration (OSHA), the Centers for Disease Control and Prevention (CDC), and applicable state and local authorities. This includes programs for bloodborne pathogen exposure prevention, chemical hygiene, fire safety, and electrical safety. Laboratories must maintain Safety Data Sheets (SDS) for all hazardous chemicals, provide appropriate personal protective equipment (PPE), and train all personnel in safety practices. A safe laboratory environment protects not only laboratory staff, but also patients and other healthcare workers who interact with the laboratory.

c. **Laboratory Equipment and Supplies Standardization.** The Bureau will standardize specified laboratory-related equipment and supplies. National contracts will be attained to assist with standardization. Health Services Administrators and appropriate laboratory leadership are expected to work within all applicable laboratory national agreements. The NLA will assist facilities in obtaining laboratory equipment and supplies through these national agreements.

d. **Blood Transfusion Services.** Accredited laboratories have the option, depending on their mission, to have a blood transfusion service. Facilities opting to have a blood transfusion service will comply with the following specific requirements:

- Under no circumstances will Bureau laboratories perform donor collection or blood-component processing. Under this program statement, transfusion services are limited to storage, compatibility testing, and administration.
- Personnel in the transfusion service will have sufficient training and/or experience and demonstrate technical competence in the performance of immunohematology procedures performed.
- Institutions performing blood transfusions will have written policies and procedures which conform to all applicable accrediting standards.

- Any provider can order a transfusion, but orders for transfusion must be reviewed and co-signed by a physician before the lab can process the order and distribute units.

These policies and procedures will be readily available to staff and will be reviewed at least every two years by the LD 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 applicable accrediting blood banking standards. The proper functioning of the refrigerator will be constantly monitored as outlined by accrediting standards.
- A written procedure will be established for always obtaining necessary blood and blood components. It will be documented that stored blood is inspected daily for evidence of hemolysis and for possible bacterial contamination.
- Blood and blood components will be obtained only from FDA-licensed blood establishments. Selection of the supplier will be approved by the LD and institution leadership.

6. OPERATION OF MULTIPLE LABORATORIES AT SAME LOCATION

The CLIA regulations, 42 C.F.R. § 493.35(a), § 493.43(a) and § 493.55(a), require all laboratories performing waived and non-waived testing to file a separate application for each laboratory location. Multiple laboratories may operate at the same physical location (e.g., same building or suite, as applicable) with separate CLIA numbers, as long as each laboratory can demonstrate it is operating as a separate and distinct entity. Each CLIA certificate represents a laboratory, and each laboratory is responsible for complying with the applicable CLIA requirements.

In addition, multiple laboratories that operate at the same physical location and use the same testing personnel and equipment must meet the following conditions:

- All records (e.g., quality control, procedure manuals, personnel competency) must be kept separate and distinct for each laboratory and must clearly show each laboratory is operating independently.
- The hours of operation must be specified for each laboratory.
- The hours of operation for each laboratory must be separate and distinct. The times of testing cannot overlap and cannot be simultaneous.

7. TEST MENUS AND LABORATORY ORDERS

All test menus for non-waived and waived testing facilities will be reviewed and approved annually by the NLA. There will be a standardized test menu for all laboratory testing facilities.

Testing facilities are required to adhere to those approved menus to ensure testing is offered in the safest and most cost-efficient manner.

Any authorized Bureau prescriber (physician, dentist, advanced practice provider (APP), or pharmacist with prescribing authority) may order laboratory tests via the EHR. Electronic orders are required prior to patient testing in a Bureau or commercial laboratory. In the event of EHR downtime, facilities will utilize their local reference laboratory for all laboratory testing. Once the existing EHR comes back on-line, the requested facility will be responsible for placing the order electronically.

8. REFERENCE LABORATORIES

a. **Medical Referral Laboratories.** Bureau facilities are required to utilize Bureau MRLs for initial, routine, and non-emergency laboratory testing. An extensive standardized test menu will be available. The MRLs will provide collection and packaging supplies to each of the facilities utilizing their services. See your specific MRL instructions on specimen collection and processing requirements.

b. **Contracted Commercial Laboratories.** A commercial laboratory will be used only for those tests not available at the MRLs and for emergency laboratory services, or in extenuating circumstances (e.g. EHR downtime) as approved by the Medical Director. Health Services Administrators will ensure all current national contracts for commercial laboratory services will be utilized.

c. **Local/State Public Health Laboratories.** In the event of a public health emergency or outbreak investigation (influenza, varicella, etc.), institutions are encouraged to work with their local or state public health laboratory. These laboratories would be most equipped in dealing with public health emergencies or outbreak investigations. Contact the NLA for further information and guidance.

d. **Requirements.** Collecting facilities are expected to follow collection and processing procedures outlined by their MRL, contracted commercial laboratory, or local/state public health laboratory. Personnel responsible for the packaging and shipping of infectious substances (i.e., laboratory specimens) are required to satisfactorily complete applicable training. Recurrent training is required every two years. Facilities can contact the NLA for training resources.

Up to date accreditation and CLIA certificates will be maintained by the HSA from the MRLs and any contracted commercial laboratory utilized by the collecting facility.

9. LABORATORY INFORMATION SYSTEM (LIS)

The Bureau will utilize a standardized LIS at all sites that provides laboratory services, waived and nonwaived. The LIS interfaces with the EHR and results are electronically available for provider review.. Under no circumstances will local agreements be negotiated with other reference laboratories for interfaces.

Standardized reporting formats will be established and utilized within the LIS. All Bureau laboratories are required to follow each of the standardized elements..

10. INMATE WORKERS

Inmate workers are prohibited from performing or assisting with clinical laboratory testing or result handling. They may perform only non-clinical orderly duties under direct staff supervision.

11. NEEDLES AND SYRINGES

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

REFERENCES

Program Statements
Pharmacy Services

Federal Regulations
29 C.F.R. Part 1910
42 C.F.R. Part 493

ACA Standards
None

Records Retention Requirements
Requirements and retention guidance for records and information applicable to this program are available in the Records and Information Disposition Schedule (RIDS) on the Bureau's intranet site.