

GEORGIA DEPARTMENT OF CORRECTIONS



Standard Operating Procedures

Policy Name: Scope of Laboratory Services

Policy Number: 507.04.81

Effective Date: 02/10/2022

Page Number: 1 of 4

Authority:
Commissioner

Originating Division:
Health Services Division
(Physical Health)

Access Listing:
Level I: All Access

I. Introduction and Summary:

Laboratory services will be available for in-house diagnostic testing or through a Referral Laboratory and will operate under CLIA '88 guidelines. This procedure is applicable to all facilities that house Georgia Department of Corrections (GDC) offenders including county and private prisons.

II. Authority:

- A. NCCHC 2018 Adult Standard: P-D-04; and
- B. ACA Standards: 5-ACI-6B-12 and 5-ACI-6A-25.

III. Definitions:

- A. **Certificate for Provider Performed Microscopy** - Issued by HHS that allows limited testing under the CLIA '88 Section 353.
- B. **Certificate of Moderate Complexity** - Issued by HHS that allows Level I laboratory testing as specified by CLIA '88.
- C. **CLIA '88** - The Clinical Laboratory Improvement Amendment of 1988 (Public Law 100-578) is Federal Legislation that states laboratories may not perform tests on materials derived from the human body unless the laboratory has a certificate issued by the Department of Health and Human Services (HHS) applicable to the category of procedures performed by the laboratory.
- D. **Levels of Certificate** - Laboratory procedures that can be performed in-house according to the certificate level established by CLIA '88.
- E. **Referral Laboratory** - A laboratory currently in compliance with applicable CLIA '88 requirements that has had a record of satisfactory proficiency testing performance for all testing.
- F. **Panic Values** - Life threatening laboratory values outside the normal range as designated by the appointed laboratory.

GEORGIA DEPARTMENT OF CORRECTIONS



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Policy Name: Scope of Laboratory Services

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IV. Statement of Policy and Applicable Procedures:

A. Levels of Certificate:

1. Medical staff will not perform in-house laboratory tests on materials derived from the human body unless the laboratory has a Certificate issued by the Georgia Department of Human Resources (DHR) and Department of Health and Human Services (DHS) applicable to the complexity of procedures performed. Levels of Certificate available to Georgia Department of Corrections (GDC) laboratories:
 - a. Certificate of Waiver.
 - b. Certificate of Moderate Complexity.
 - c. Certificate for Provider Performed Microscopy.
2. The GDC laboratories Level of Certificate will be determined by the Office of Health Services' Administrator or designee. All laboratories will operate under an individual Certificate for Provider Performed Microscopy.
3. The Responsible Health Authority will submit the application for new requests or subsequent laboratory certificate renewals to the Department of Human Resources upon approval by OHS Administration on the User Remittance Form (HCFA - 35) for payment by the contractor. Renewals will be every two (2) years.

B. Certificate of Moderate Complexity:

1. Applications for Certificate of Moderate Complexity are subject to approval by the OHS Administrator.
2. Laboratories operating under a Certificate of Moderate Complexity will require renewal every two (2) years after passing the CLIA inspection conducted by DHR, Diagnostic Services Division.

GEORGIA DEPARTMENT OF CORRECTIONS



Standard Operating Procedures

Policy Name: Scope of Laboratory Services

Policy Number: 507.04.81

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Page Number: 3 of 4

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3. Certificate of Moderate Complexity will be displayed in the laboratory.
 4. The following facilities will operate under a separate Certificate of Moderate Complexity: ASMP in accordance with VH77-0002 [Moderate Complexity Labs].
- C. Certificate of Provider Performed Microscopy:
1. Applications for Certificate of Provider Performed Microscopy will be submitted to the OHS Administration. Upon approval, the application will be forwarded to DHR for review. Upon review and approval, a CLIA Identification Number will be assigned, and the certificate will be issued to identify the laboratory as a GDC Facility. The certification will be displayed in the Medical Unit.
 2. Certificates will be renewed every two (2) years and paid for by the Contract Vendor and placed in the designated laboratory area.
- D. Referral Laboratories:
1. Referral laboratory services will be available for all necessary tests not performed by the GDC. The Contract Vendor will select a Referral Laboratory that complies with all State and Federal Laws, subject to the approval of the Office of Health Services.
 2. Laboratory services will include a provision for STAT work with results within four (4) hours after the specimen is obtained. Routine laboratory work will have a turn-around period based on the guidelines established by the referenced laboratory on results.
 3. Callbacks must occur for all Panic Values with a log maintained for control and CQI purposes. The log will include the offender's name, ID number and test result.

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4. HIV antibody test(s) will be processed by the Laboratory Services selected by a Contract Vendor.

E. Data Collection:

1. Data will be maintained at the testing facility in accordance with CLIA '88 guidelines. Basic retention requirements include:
 - a. Immunohematology reports and data to be kept for five (5) years.
 - b. Pathology reports and data to be kept for ten (10) years.
 - c. All other reports and logbooks to be kept for at least two (2) years.
2. Data will be made available to the Office of Health Services upon request.

V. **Attachments:** None.

VI. **Record Retention of Forms Relevant to this Policy:** None.