GEORGIA DEPARTMENT OF CORRECTIONS **Standard Operating Procedures**		
Policy Name: Waivered Laboratories/Provider Performed Microscopy		
Policy Number: 507.04.82	**Effective Date:** 01/19/2022	**Page Number:** 1 of 5
Authority: Commissioner	**Originating Division:** Health Services Division (Physical Health)	**Access Listing:** Level I: All Access

I. Introduction and Summary:

Laboratories operating under a Certificate of Waiver or Certificate for Provider Performed Microscopy will be certified to perform limited laboratory tests using the guidelines established by the United States Department of Health and Human Services (HHS) as mandated in the Clinical Laboratory Improvement Amendment (CLIA) 1988. This procedure is applicable to all facilities that house Georgia Department of Corrections (GDC) offenders including county and private prisons that have qualified and received a Certificate of Waiver.

II. Authority:

A. NCCHC 2018 Adult Standard: P-D-04;

B. 42 U.S.C. 262a; and

C. 42 C.F.R. Part 493.

III. Definitions:

A. **Certificate of Waiver** - Issued by HHS that allows limited laboratory testing under the CLIA 1988, Section 353.

B. **Certificate for Provider Performed Microscopy** - Issued by HHS that allows limited testing under the CLIA 1988, Section 353 to be performed by a physician, dentist, or midlevel practitioner (nurse practitioner or physician assistant).

C. **Clinical Laboratory Improvement Amendment (CLIA) 1988** - The CLIA 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.

IV. Statement of Policy and Applicable Procedures:

A. Waivered laboratories will perform test(s) that do not involve complicated instrumentation, calibration, extensive quality control, reagent preparation, multiple steps, or environmental control. In addition, the test must require minimal or no calculations, require a minimal or no patient or specimen preparation, and minimal training and experience.

B. Laboratories operating under a Certificate of Waiver may only perform CLIA Waived tests (e.g. urine dipstick, urine pregnancy tests, fecal occult blood, blood glucose, etc.). Please refer to CLIA guidelines for a complete list of waived tests.

C. Waivered laboratories must follow manufacturer's specifications of all test(s) performed.

D. Controls on waivered tests must be performed and documented daily or per manufacturer guidelines if a test is performed or as recommended by manufacture:

1. Follow manufacturer's recommendation for level(s) of controls.

2. Documentation of controls from each waivered test performed by the laboratory will be kept for two (2) years.

E. Documentation and results of all tests ordered by a physician will be kept in the medical record. Documentation will include the following:

1. Name of patient;

2. Name of physician ordering test;

3. Name of health care provider performing the test;

4. Results of test ordered;

5. Normal range of test ordered;

6. Name of laboratory performing test;

7. Date test was ordered; and

8. Date and time test was performed.

F. Local Operating Procedure(s) (LOP) or Manuals will be written and available for reference in the laboratory to include the following:

1. Specimen collection;

2. Specimen processing;

3. Rejection criteria for specimen;

4. Panic values;

5. Cookbook directions for each test available in-house. Manufacturer's package inserts may be used; and

6. Procedure manual must be reviewed annually by laboratory director and laboratory supervisor.

G. Laboratories operating under a Certificate for Provider Performed Microscopy will follow guidelines listed under Certificate of Waiver. In addition, the following test(s)/procedures can be performed by the physician, dentist, nurse practitioner, or physician assistant:

1. Urinalysis microscopic for urine sediment examinations;
2. All potassium hydroxide (KOH) preparations;
3. Wet mounts, including preparations of vaginal, cervical, or skin specimens;
4. Pin worm examinations;
5. Fern test;
6. Post-coital direct qualitative examinations of vaginal or cervical mucous;
7. Fecal leukocyte examination;
8. Nasal smear for granulocytes; and
9. Qualitative semen analysis (limited to presence or absence of sperm and detection of motility).

H. Laboratories will have available at a minimum:

1. Dipstick urinalysis;
2. Finger-stick materials;
3. Blood glucose test; and
4. Stool blood-testing material.

I. Facilities housing female offenders/probationers will have on-site, KOH preps.

V. Attachments: None.

VI. <u>Record Retention of Forms Relevant to this Policy</u>: None.