REFERENCES:

Clinical Laboratory Improvement Amendments of 1988 (CLIA)
Title 42 CFR (Code of Federal Regulations), Subpart M

DEFINITIONS:

**Laboratory**: a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. These examinations also include procedures to determine, measure, or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

**Doctor**: Individual employed by the Boards of Health possessing either a Medical Doctor (MD) or Doctor of Osteopathy (DO) with a valid license to practice medicine in the State of Georgia.

**Laboratory Technologist**: Individual employed by the Boards of Health with a Medical Technology (MT) Degree or a combination of formal training and work experience, American Society for Clinical Pathology (ASCP), Clinical Laboratory Technologist (CLT), or other laboratory technologist credentials from a nationally recognized credentialing body for laboratory technologist such as the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS).

**Nurse Practitioner**: Individual employed by the Boards of Health who is a registered nurse and meets the educational, practice and national certification requirements specified by the Georgia Board of Nursing and has a valid license to practice by the Georgia Board of Nursing.

**Expanded Role Nurse**: Individual employed by the Boards of Health who is a registered nurse, and meets the preparation and performance requirements specific to each protocol mutually agreed upon and signed by the nurse and delegating physician as required by the Department of Public Health.

**Registered Nurse**: Individual employed by the Boards of Health with a degree in nursing and a valid license as a registered nurse in the State of Georgia.

**Licensed Practical Nurse**: Individual employed by the Boards of Health who meets the education requirements specified by the Georgia Board of Examiners of Licensed Practical Nurses, and is authorized to practice by the Georgia Board of Examiners of Licensed
Practical Nurses. Licensed Practical Nurses provide care under the supervision of a physician, dentist, or registered nurse.

**Phlebotomist**: Individual employed by the Boards of Health with phlebotomy certification from an accredited agency which satisfies the Boards of Health and Department of Public Health requirements.

**Medical Assistant/CNA**: Individual employed by the Boards of Health who meets Board of Health requirements to provide administrative, clerical, and technical support to a health care provider and who encompasses knowledge of standard laboratory principles, techniques, terminology, equipment and materials.

**NOTE**: The duties and responsibilities of each employee involved in laboratory testing will be specified in writing by scientific and technical knowledge and/or training and experience.

**PROCEDURE**:

A. The following are laboratory tests currently performed within the Boards of Health clinical laboratory services:

1. Waived Tests, as designated by the Clinical Laboratories Improvement Amendments:
   a. Whole Blood Glucose
   b. Whole Blood Hemoglobin
   c. Urinalysis
      i. Short Dip
      ii. Full Urinalysis
   d. Urine Pregnancy Test – Qualitative
   e. Rapid Strep Testing
   f. Fecal Occult Blood
   g. Rapid INSTI
   h. Rapid Determined
      i. Rapid Hep C
   j. Rapid Lead
Laboratory Testing Duties and Procedure/Clinical Services Responsibilities for Staff

Effective: Date
Revised: Date

Page 3 of 4

A. Name of Agency

B. Laboratory Duties and Responsibilities:

1. **Doctor:** A doctor is allowed to perform waived and moderate complexity testing within the laboratory system of the Boards of Health after meeting one of the following requirements:
   
   a. Certification of proficiency in laboratory testing by a Board of Health lab technologist after demonstrating expertise in performance of all lab tests he/she will routinely perform as part of his/her clinical practice.
   
   b. Review of professional credentials by Board of Health laboratory director.
   
   c. Doctors are required to complete annual laboratory testing competency training and participate in regularly scheduled proficiency testing for individuals engaged in moderate complexity testing. Lab results from doctor testing will not require review prior to reporting.

2. **Laboratory Technologist:** is allowed to perform all waived and moderate complexity testing within the Boards of Health laboratory system. A laboratory technologist must be tested and his/her proficiency in laboratory testing must be verified by a peer Board of Health lab technologist, before commencing his/her lab responsibilities. Lab technologists will participate in regularly scheduled proficiency testing. Results obtained from lab technologist testing will not require review prior to reporting.

3. **Nurse Practitioners and Expanded Role Nurses:** are allowed to perform waived and moderate complexity testing required for their particular clinical practice within the Name of Agency. Nurse practitioners and expanded role nurses are required to participate in regularly scheduled proficiency testing, involving all moderate complexity testing they perform in their clinical practice. They must also undergo annual competency testing by Boards of Health lab technologists and any internal peer review procedures for laboratory testing that are required by the nursing protocols that guide their clinical position. Results obtained from nurse practitioner and expanded role nurse testing will not require review prior to reporting.

4. **Registered Nurses (RN) and Licensed Practical Nurses (LPN):** are allowed to perform waived testing within the Boards of Health laboratory system. RNs and

k. Rapid Syphilis

2. Moderate Complexity Tests, as designated by the Clinical Laboratories Improvement Amendments:
   
   a. Gram Stain – Urethral Smear
   
   b. KOH/Wet Mount
LPNs may commence testing after undergoing lab training and demonstrating proficiency in performing the lab tests they will routinely perform in their clinical position. Training and certification will be conducted by a Boards of Health laboratory technologist. RNs and LPNs will engage in annual lab training, conducted by the Boards of Health. Lab results reported by RNs and LPNs will not require review prior to reporting.

5. **Phlebotomist:** is allowed to engage in all waived testing procedures after completion of lab competency training, testing and certification by a Board of Health laboratory technologist. Phlebotomists are required to undergo annual Board of Health lab competency testing. Results performed by phlebotomists will not require review prior to reporting.

6. **Medical Assistants/CNAs:** is allowed to engage in the following waived testing: Urinalysis dipstick, Rapid Strep, Hemocue hemoglobin testing and pregnancy testing only after completion of lab competency training, testing and certification by a Boards of Health lab technologist. Medical Assistants/CNAs will be required to undergo annual Board of Health lab competency training. The results obtained from the aforementioned lab testing performed by Medical Assistants/CNAs will not require review prior to reporting, with the exception of Rapid Strep testing results, which will require MD review.