



# LINCOLN COMMUNITY HEALTH CENTER, INC.

1301 Fayetteville Street • P.O. Box 52119  
Durham, North Carolina 27717 -2119

**SUBJECT:** Waived Testing

**EFFECTIVE DATE:** 11/2002

**REVISION DATE (S):** 01/2009, 11/2012, 2/2014, 5/2017, 12/2018

**REVIEWED DATE:** 4/2014

## DEFINITIONS:

POC- Point-of-Care

CLIA- Clinical Laboratory Improvement Act

- Lincoln Community Health Center uses Waived Testing also known as point-of-care testing for diagnosis and screening. If any waived test is abnormal, the provider may order a more definitive test to be done by the laboratory.
- Competency training is done, where indicated, as part of orientation for new employees.
- Competency testing is done annually for all staff responsible for Waived Testing.
- Part of the orientation to new testing is a presentation by the company representative for all designated staff.
- Recommended quality controls and test records are maintained.

**See Attached: WAIVED TESTING PROTOCOL**

**PREPARED BY:** \_\_\_\_\_ **DATE:** \_\_\_\_\_  
Edwina D. Gabriel, RN, BSN, Med, Director of Nursing

**APPROVED BY:** Howard Eisenson MD. **DATE:** 1/29/2019  
Howard Eisenson, MD, Chief Medical Officer

**APPROVED BY:** Linda Small RN **DATE:** 1/29/2019  
Linda Small, MBA, RN, NE-BC, Patient Safety and Clinical Quality Committee Chair



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## WAIVED TESTING PROTOCOL

**Goal:** Waived tests are performed to assist the provider in determining diagnosis, in screening for disease, and following prescribed therapy to determine effectiveness. Waived tests are performed according to established standards (FDA and CMS) for instrument and non-instrument based waived tests. Therefore, all staff performing waived tests must be trained and deemed competent to perform the testing.

### **Responsibility:**

CLIA Director: Designated medical provider

Clinical Nurse Managers

LCHC and Off-Site Liaison: Employee Health/Infection Control Manager (EH/ICM)

### **Scope:**

This protocol applies to LCHC Clinics and Satellite Clinics

### **Protocol for Patient Testing:**

1. Only staff with demonstrated competency will perform waived tests.
2. Staff will:
  - a. Perform each test by following the manufacturers' instructions.
  - b. Follow standard precautions at all times.
  - c. Document waived test results in the patient's electronic medical record.
3. A provider will assess each waived test result.
4. Each waived test has its own documented procedure in the CLIA manual located in each clinic.
5. CLIA Certifications are maintained and posted at each site.

### **Quality Controls:**

Staff will:

1. Test waived testing instruments per quality control guidelines and according to the preventive maintenance schedule in the manufacturer's guidelines.
2. Log (document) quality control checks.



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3. If control results are out of range or displays an error warning, the test will be repeated.
  - a. If the control results are still out of range, report findings to the supervisor.
  - b. Do not use the machine until the problem is corrected.
  - c. If the control results are within range after repeating, the machine may be used and testing can be done.
  
4. Maintain quality control logs for a minimum of two years.

### **Expiration Date of Controls:**

Staff will:

1. Follow the manufacturer's guidelines for the expiration date of each waived test control. There will be an unopened expiration date and another expiration date once the product is opened.
  
2. Document the expiration date on the bottle.

### **Training:**

1. A Certified Medical Technologist defines competency, based on established standards (FDA and CMS) for instrument and non-instrument based waived tests and on the Manufacturers' instructions.
  
2. A Certified Medical Technologist recertifies the Clinical Nurse Managers annually.
  
3. Clinical Nurse Managers orient and train new hires.
  
4. All performers of waived tests are required to attend annual training, conducted by the Clinical Nurse Managers.
  
5. A Clinical Nurse Manager documents training and signs off on the competency of each employee and sends the document to Human Resources.