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| Manual Title | Nursing Policy & Procedure |
| Policy Title | Waived Testing Clinical Laboratory Improvement Amendments (CLIA)  |
| Approval  |  |
| Effective Date |  |
| Revision Date |  |

**Policy:**

The Center /Community will maintain a CLIA Waiver in order to perform specific testing within the facility.

CLIA Waive Testing:

Health care providers use test results to diagnose disease, determine prognosis, and monitor a patient’s treatment or health status. Current practice shows an increased trend for medical decisions based on simple tests performed at the point of care. Many of these tests are called waived tests and can be performed without routine regulatory oversight under a Certificate of Waiver from the Centers for Medicare & Medicaid Services (CMS).

Waived tests include test systems cleared by the Food and Drug Administration (FDA) for home use and those tests approved for waiver under the Clinical Laboratory Improvement Amendments of 1988 (CLIA)

 *Office of Surveillance, Epidemiology, and Laboratory Services Laboratory Science, Policy, and Practice Program*

Waived tests may only be performed using unprocessed samples.

Examples of unprocessed samples include:

* Whole blood (fingerstick),
* Urine,
* Throat swab, nasopharyngeal swab, nasal wash, (includes COVID-19 swabs,)
* Stool,
* Saliva, oral fluid
* Point Of Care (POC) Antigen testing

Collection Devices are an important part of sample collection and must be used properly to obtain good results.

Finger stick collection devices are for one-time use only.

Collection devices ensure the delivery of the correct sample volume and some contain additives that are needed for the test to work correctly.

Therefore, it is important to follow the manufacturer’s instructions when using sample collection devices.

**Purpose:**

To enable Licensed Professional/ Certified Medication Tech (CMA) staff immediate access to testing equipment/devices for the purpose of evaluating a Resident routinely or when there is a change of condition.

**Procedure:**

**Section I**

1. Facility/Community will apply bi-yearly for CLIA Waiver and display the CLIA Waiver in a visible area.
2. Licensed Professional Staff/ CMA will be oriented to procedures under the waiver test with a return demonstration as part of an initial competency and annually thereafter.
	1. Glucometer Testing
	2. Occult Blood Testing
	3. PT/INR testing
	4. If permitted and available Antigen Testing
3. Appropriate documentation will be maintained in the employee’s personal file regarding competency performance

**The following are areas of competency performance for a CLIA Waived test**

**Section II**

1. The Licensed Nurse/Certified Medication Tech (CMA) practice standard precautions when handling all blood and body fluids.
2. The Licensed Nurse/CMA will follow Transmission-Based precautions testing individuals who may potentially be infected (i.e., COVID-19). See bullet #4.
3. The use of disposable gloves does not eliminate the need for cleaning hands. Handwashing does not eliminate the need for gloves.
	1. To ensure proper hand hygiene when performing testing, handwashing or alcohol-based gels should be used before and after each resident \*Reference the Hand Washing Policy
4. Licensed Nurse will don appropriate personal protective equipment (PPE) such as gloves and when necessary facemask, face shield, gown.
5. The Licensed Nurse/ CMA will be cautious of exposure to mucous membranes such as eyes, nostrils, and mouth,
	1. Wear goggles or face shields,
6. The Center /Community will supply the Licensed Nurse/ CMA with safety lancets.
7. All safety lancets are single-use devices.
8. The Licensed Nurse/ CMA will safely dispose of used sharps properly in puncture-proof sharps containers.
9. The Licensed Nurse/ CMA will report all occupational exposures promptly to ensure there is appropriate follow-up care.
10. The Licensed Nurse/ CMA will participate in education training related to infection prevention, on orientation, annually, and as scheduled by the Infection Preventionist.
11. The Licensed Nurse will perform tests based on physician’s orders and recorded in the resident/patient’s medical record.
12. Before collecting a sample,

The Licensed Nurse/CMA will confirm:

* 1. The test orders,
	2. If there is a question whether the order is correct, check with the Physician who requested the test.
	3. Resident identification will be confirmed names can be similar and lead to confusion, use birth dates, middle initials, Picture ID, medical record numbers

 13) Consult with the resident regarding:

Pretest instructions —

1. Some tests require preparation by the patient such as fasting for a glucose test.
2. The License Nurse will document instructions were followed before collecting the sample in the resident/patient’s medical record
3. The Licensed Nurse will discuss with the resident whenever possible, factors such as medical indications, medications, or other interfering substances that can affect test results.
4. The Licensed Nurse/ CMA will disinfect surfaces before performing any test procedure, whenever contamination is visible, and before leaving the testing area.
5. The Licensed Nurse/ CMA will use the facility/community recommended disinfectant for decontaminating the work area, EPA “N” list approved disinfectants.
6. During the testing process, the Licensed Nurse/ CMA will have a disposal bag for used alcohol pads and all other non-sharp supplies,
7. The sharps container used for disposal of contaminated materials will be as close as possible to the immediate testing area.

**Performing the test:**

1. The Licensed Nurse/ CMA when performing a test:
2. Will follow the required testing steps in the exact order as they are written in the manufacturer’s instructions of the individual test/device.

**Test Quality Control**

**Section III**

1. Following the manufacturer’s instructions, site specific procedure, or a quick reference guide at the testing area.
2. Use timers if necessary and follow the required timing intervals before reading test results.
3. Quality control checks and documentation.
	1. Glucometer (monthly record will be kept in the Nursing office)
	2. POC will follow manufactures instructions for quality control.
4. The 12-8 shift Licensed Nurse assigned to facility will be responsible for monitoring controls nightly.
5. Occult Blood Positive/Negative monitoring will be completed at the time of the resident’s testing is completed.
6. Documented on the Resident’s TAR below the recorded results/initials

**Resources:**

CLIA waiver:

* LabExcellence@cms.hhs.gov.
* CLIA Law & Regulations
* CDC CLIA website
* FDA CLIA web