FIU Herbert Wertheim College of Medicine
FLORIDA INTERNATIONAL UNIVERSITY

Departmental Policy
POLICY NO.: 200.02.105P

POLICY TITLE: Laboratory Point of Care Testing (POCT)

Submitted by: Sergio Gonzalez- Arias, MD, PhD, FAANS, FACS
Title: Executive Associate Dean, Office of Clinical Affairs

Approved by: Quality Improvement Patient Safety Committee (QIPSC)

Committee Chair: Sergio Gonzalez- Arias, MD, PhD, FAANS, and FACS
Title: Executive Associate Dean, Office of Clinical Affairs

Creation Date: 01/02/2019
Effective Date: 02/2019
Review date:
Revision Date: 02/20**22**

SUMMARY & PURPOSE: Herbert Wertheim College of Medicine (HWCOM) establishes this policy to ensure that Point of Care Testing (POCT) specimens are completed accurately and that quality control testing is completed as recommended by the manufacturer on all point of care tests that are performed. Point of Care tests are relatively simple laboratory tests that can be performed in any of our clinical settings and that render results immediately without having to send the patient to a contracted laboratory. The Point of care Testing performed at HWCOM are the following: Hemoglobin A1C, urine Human Chorionic Gonadotropin (HCG- pregnancy test), nasal rapid influenza swab, throat rapid strep Test (tests Group A Streptococcus), fingerstick blood glucose levels, and Urine dipstick reagents.

SCOPE/APPLICABILITY: This policy applies to the HWCOM Clinical Locations where faculty, students and /or staff perform POCT testing. POCT is performed at the following HWCOM locations: FIU Health Modesto Maidique, ("MMC"), FIU Health Broward, Green Family Foundation NeighborhoodHELP Mobile Health Centers, and household visits, Linda Fenner 3 D Mobile Mammography Center and Community Health Fairs. The types of Point of Care testing done may differ at each of HWCOM Clinical locations. Please refer to your specific location to verify tests performed at your clinical location.
This policy *excludes*: Green Family Foundation NeighborhoodHELP Mobile Dental Van because POCT is not performed at this location.
For faculty, students and staff that are obtaining specimens in an *affiliated* hospital, outpatient, and diagnostic center, the policies and procedures of those institutions will govern their responsibilities for POCT.

POLICY: To safely and accurately obtain Point of Care testing at our HWCOM clinical locations without having to send patients to an outside laboratory (Quest, LabCorp)**.** These tests are permitted to be performed at HWCOM under the Clinical Laboratory Improvement Amendments (CLIA) waived testing certification.
This HWCOM Laboratory policy correlates with Departmental Policy: *Laboratory Policy: Specimen Collection, Labeling and Handling* Policy No.: **200.02.100P**

DEFINITIONS:

Point-of-Care Testing (POCT): Defined as a laboratory test that is completed at or near the point of care that is, at the time and place of patient care instead of the test being performed at a contracted laboratory for processing. These tests are relatively simple to perform and yield results quickly. POCT brings the test results immediately to the patient and the provider. POCT does not require a dedicated laboratory space, but instead includes kits or instruments, which are either hand carried or transported to the patient care area for immediate testing and results.

Quality Control (QC): Control solutions of known values are often times used for checking the quality of the kit or POCT being done. The QC check is done when the kits are first opened. The purpose of the QC is to ensure that the kit is functional, and yields results within the standard of care for that particular POCT. The QC minimizes false positive and false negative results. Once QC check is completed the date and initials are placed on the box and on the QC log (samples attached)
QC is performed on the following POCT tests:

- Urine Human Chorionic Gonadotropin (HCG- pregnancy test)
- Nasal Rapid Influenza swab
- Throat rapid strep test (Tests Group A Streptococcus)
- Fingerstick Blood glucose

Exception: QC is not performed on urine dipstick

Quality Control Log (QC log): The QC log is completed when a POCT kit is opened.

Test kit: Each POCT has its own test kit. The kits contain the test and the reagents needed to perform the QC test.

Patient Identifiers: For the purposes of this policy the *Patient Identifiers* for HWCOM are: (Full name and date of birth) (Month–Day-Year). Medical record identification number can be utilized as a third patient Identifier if necessary. See HWCOM Administrative Policy: *Patient Identifiers* Policy No.: **200.02102A**

Active Communication of asking *Patient Identifiers*
Asking the patient to tell the healthcare worker their name and date of birth. (Month–Day-Year).

Passive Communication of asking *Patient Identifiers*
The healthcare worker *telling* the patient their name and date of birth.

CLIA Certification: Clinical Laboratory Improvement Amendments (CLIA). HWCOM Clinical facilities POCT laboratory testing are regulated under CLIA licensing and regulations.

PROCEDURE:

1. Current CLIA certification will be posted in the following locations for FIU Health MMC, FIU Health Broward and NeighborhoodHELP Mobile Centers. For NeighborhoodHELP Household and Community events, the current CLIA is current and available upon request.
2. Provider will enter the order in Centricity for the specific POCT test, excludes Community Health Fairs.
3. Preventative maintenance is performed and documented in accordance with manufacturer's

instructions and regulatory standards on all equipment utilized for POCT on the box and QC log.

4. Specimens, POC supplies, and reagents are stored according to the manufacturer recommendations, handled using Universal Standard Precautions, and are disposed of in the appropriate biohazard or sharps container.
5. Always identify yourself to the patient and what tests you will be performing
6. **Wash your hands between patients** for at least 20 seconds with soap and water or utilize hand sanitizer. Apply Gloves.
7. Ask the patient the two Patient Identifiers: **Patient Name and Date of Birth (Month, Day, Year).**
8. When asking patients their Patient Identifiers use active communication versus passive communication. Ask the patient to state his or her full name and date of birth and wait until the patient actively tells you his full name and date of birth. Active patient involvement is best practice.

   Example: Active Communication: "Can you tell me your name and date of birth?"

   Example: Passive Communication: "Mr. Smith your date of birth is September 13, 1960."
9. A third Patient Identifier can be utilized if there are two patients with the same name. In this case, the patient's Medical Record Identification number can be used. In the Centricity EMR, the Patient ID # serves this purpose. The third identifier is necessary in instances of a patient name alert because two (or more patients) have the same name, names close to being spelled the same and /or pronounced the same. This third identifier also serves to clarify when patient specimens are obtained so that the specimen is properly designated to the right patient.
10. Draw and obtain specimen.
11. If POC testing is not possible for any reason, the patient specimen should be sent to the contracted laboratory for testing.
12. Tests and procedures should only be performed by staff who have been trained and designated as certified users.
13. All QC results must be recorded on the box and the QC log.
14. The results of the POCT should be communicated back to the ordering provider and documented accordingly in the electronic medical record.

SUPPORTING/REFERENCE DOCUMENTATION:

- https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/wfact.pdf

RELATED POLICIES, PROCEDURES, AND ASSOCIATED FORMS

- HWCOM Administrative Policy: *Incident Reporting No.:* **200.03.100A**
- HWCOM Departmental Policy: *Laboratory Specimen Collection, Labeling and Handling* Policy No.: ***200.02.100P***
- HWCOM Administrative Policy: *Patient Identifiers No.:* **200.02102A**