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 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/INR, urine Human Chorionic Gonadotropin (HCG-pregnancy test), nasal rapid influenza swab, throat rapid strep Test (tests Group A Streptococcus), fingerstick blood glucose levels, covid testing, Urine dipstick reagents, urine toxicology.

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”), Green Family Foundation NeighborhoodHELP Mobile Health Centers, and household visits, Linda Fenner 3D 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. 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 obtain Point of Care testing safely and accurately 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 simple to perform and yield results quickly. POCT brings the test results immediately, within minutes to the patient and the provider. POCT does not require a dedicated laboratory space, but instead includes kits, instruments, and reagents 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 used for checking the quality of the kit or POCT being done. The quality control known as 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 POCT. The QC minimizes false positive and false negative results. Once the 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
- Urine Toxicology screening
- Covid testing
Exception: QC is not performed on urine dipstick

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

Test kit: Each POCT has its own test kit. The kits contain the test and the reagents needed to perform the QC test for each test. The reagents cannot be inter-changed. You must utilize the reagents contained within each specific POCT kit.

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 for same name that look alike or sound alike or with same date of birth. Please refer to 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 who perform POCT laboratory testing are regulated under CLIA licensing and regulations.
**Universal Standard Precautions:** Standard precautions are a set of infection control practices used to prevent transmission of diseases that can be acquired by contact with blood, body fluids, non-intact skin (including rashes), and mucous membranes. This is accomplished by using disposable gloves and other protective barriers as needed while performing POCT and while handling needles, body fluids. Performing hand hygiene and cleaning surfaces that may be contaminated with blood or body fluids post results of POCT testing.

**PROCEDURE:**
1. All HWCOM clinical locations that perform POCT will display and post the current CLIA certification: These include the following locations: FIU Health MMC, and NeighborhoodHELP Mobile Centers. For NeighborhoodHELP Household and Community events, the current CLIA certificate must be in active status, unexpired and be available upon request. **If your CLIA certificate is expired, you are no longer allowed to test or get reimbursed for testing.** The CLIA certificate must be maintained in current active and unexpired status.
2. Provider will enter the order in electronic medical record (EMR) for the specific POCT test, this step is excluded in 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, POCT supplies, and reagents are stored according to the manufacturer recommendations, and are 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. **Perform Hand hygiene. Wash your hands between patients and after glove removal** for a minimum of 20 seconds with soap and water or utilize hand sanitizer. Apply Gloves. Please refer to: HWCOM Administrative Policy: **Hand Hygiene No.: 200.02.103P**
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. 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 or same date of birth. This third identifier also serves to clarify when patient specimens are obtained so that the specimen is properly designated to the right patient. Please refer to: HWCOM Administrative Policy: **Patient Identifiers No.: 200.02102A**
10. Draw and obtain the specimen.
11. If the POCT cannot be performed on the patient, the patient specimen should be sent to the contracted laboratory for testing and processing.
12. Tests and procedures should only be performed by staff who have been trained and deemed competent by designated certified users to perform POCT.
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 EMR.
15. Any laboratory incidents are reported through the clarity system located through the desk icon Clarity. Please refer to HWCOM Administrative Policy: Incident Reporting No.: 200.03.100A

Clarity Icon

SUPPORTING/REFERENCE DOCUMENTATION:

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
• HWCOM Administrative Policy: Hand Hygiene No.: 200.02.103P