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DEPARTMENT OF VETERANS AFFAIRS
MEDICAL CENTER
WEST PALM BEACH, FLORIDA

MEDICAL CENTER MEMORANDUM
NUMBER: 548-113-074
March 9, 2016

POINT OF CARE / ANCILLARY TESTING POLICY

1. PURPOSE: To establish policy and procedure for laboratory testing performed by staff outside the physical facilities of the main clinical laboratory, including testing performed by contracted staff at the Community Based Outpatient Clinics (CBOCs) or by a VA employee in a patient's home under the HBPC Program. All such testing is performed in accordance with Veterans Health Administration (VHA) Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures.

2. **POLICY:**

A. The Point of Care Testing (POCT) / Ancillary Testing procedures must comply with the CLIA '88, College of American Pathologists (CAP), Joint Commission (JC), Clinical and Laboratory Standards Institute (CLSI) and all other applicable regulatory agencies.

B. The Ancillary Tests will be performed in order to provide rapid results of certain laboratory tests to aid clinicians in diagnosis and treatment; to monitor therapy or the progression of disease and will be under the jurisdiction of the Chief, Pathology and Laboratory Medicine Service as mandated by the Department of Veterans Affairs.

C. Tests to be performed at the point of care must be approved by an Ancillary Testing Committee, composed the Chief of Pathology & Laboratory Medicine Service, Ancillary Testing Coordinator, and representatives from the Services where POCT will be performed. All new POCT methodologies must also pass through a validation protocol or performance verification to include Precision, Accuracy or Correlation and Linearity or Calibration Verification before methodology is used for patient testing. Manufacturer's guidelines will be followed.

D. The Ancillary Testing Coordinator (ATC) will maintain a current list of approved ancillary tests, where the tests are performed, and whether the test is considered a screening or definitive test (see Attachment A). A list of POCT personnel delineating specific tests each individual is authorized to perform is maintained in the POCT office.

The Point of Care tests currently approved at West Palm Beach VA Medical Center are:

(1) Waived tests:

a. Capillary glucose; a definitive test to be used for glucose monitoring, but not to be used to establish an initial diagnosis or to test "critically ill" patients as defined by the West Palm Beach VA Medical Center.

b. i-STAT Creatinine Test: a definitive test for a quantitative determination of creatinine in whole blood used to determine kidney function prior to procedures.

c. Urine Pregnancy Test; a definitive test for qualitative determination of human chorionic gonadotrophin (hCG) in urine. Follow up confirmation testing, if considered appropriate by the provider, is performed in the main clinical laboratory.

(2) Moderate Complexity Laboratory Tests performed as part of the Ancillary Testing Program are:

a. i-STAT ABG (Arterial Blood Gas) Profile
b. i-STAT ACT (Activated Clotting Time) Test
c. i-STAT Troponin Test
d. i-STAT INR Test

E. Adherence to the standards of good laboratory practices; including quality control, quality assurance, and the documenting of results in the patient's electronic medical record are required as part of each test procedure.

3. PROCESS:

A. POCT will be performed only by those individuals who have satisfied all authorization requirements. The requirements include an initial training either at New Employee Orientation or scheduled by the unit manager. The following will be covered: specimen collection techniques, quality control testing, test procedures, reporting and documenting.) Competency assessment shall be updated annually or as often as necessary to meet accreditation standards.

B. Procedures for POC testing, obtaining reagents and quality control materials, troubleshooting protocols, documenting of control and patient results, and expected clinical limits and critical values will be found in the Point of Care Testing procedure manual located at each unit where testing is performed.

C. Control results are evaluated by testing operators and must be within the acceptable range prior to patient testing. Instruments will automatically lock out, preventing patient test performance if Quality Control is not performed or unacceptable. Corrective Action and Quality control results will be directly entered into computer-based programs or on log sheets. The ATC will review quality control results.

D. All POCT results must be entered into the LIS or transferred immediately to the data management system through the network down loaders located at each site performing testing. Results will transfer into the electronic medical record in real time after downloading of data is performed.

E. Proficiency testing materials will be periodically distributed to the ancillary sites by the Ancillary Testing Coordinator or sent directly to the CBOCs from the PT provider. These proficiency-testing materials will include, but not necessarily be limited to, those supplied by the College of American Pathologists (CAP) two or three times per year.

F. Instruments that do not perform to acceptable standards will be removed from ancillary testing sites and not used for patient testing. The instruments will be repaired or replaced by the manufacturer as coordinated through the Ancillary Testing Coordinator. All maintenance records will be filed at the POCT office for the instrument life.

4. RESPONSIBILITY:

A. The Chief, Pathology & Laboratory Medicine is responsible for overall operation of the Point of Care/ Ancillary Testing Program.

B. The Ancillary Testing Committee will advise and have input on the evaluation of methodology and instrumentation, development of testing procedures and evaluations of actions to be taken when problems arise. The Ancillary Testing Committee will review all implementation validation protocols before test methods or instruments are placed in service and will be responsible for review and approval of the overall policy, standards development and operation of Quality Management of all POC Testing.

C. The Ancillary Testing Coordinator (ATC), Laboratory Designee, will:

1. Act as technical consultant and coordinator for the Quality Management of all ancillary testing sites.

2. Develop and monitor testing procedures, including but not limited to: Initial validation Protocols, Quality Control (QC), Quality Assurance (QA), Proficiency Testing (PT), Continuous Quality Improvement Program (CQI) and documentation of initial training and competency assessment at required intervals for staff.

3. Monitor and report all areas that are not in compliance with all regulations and will implement corrective actions to bring all POCT areas to compliance with regulations.

4. Be responsible for the Document Control of pertinent procedures, maintenance and information related to the authorization of individuals performing Ancillary Testing.

5. Serve as the liaison in coordination of patient care testing within the main facility and outreach sites, with emphasis on performance improvement.

D. Site Coordinators/Unit managers: The Site Coordinator is the working manager responsible for assuring that all procedures described in the POCT Procedure Manual are followed. The Site Coordinator is responsible for assuring that all staff performing POCT in their area of responsibility complete initial training and required competency assessments, and are compliant with infection control protocols, instrument maintenance, supply inventory, and handling of critical results with follow-up actions as required.

E. Testing Personnel: Testing personnel are responsible for completing training, maintaining competency and adhering to POCT policies and procedures.

F. All laboratory tests performed on patients at POCT sites must be performed by personnel who are qualified to perform testing according to the level of complexity as defined by the qualification for personnel performing testing as define in 42 Combine Federal Register (CFR), Part 493. The operators will be responsible to follow methodology procedures as described in the POCT Procedure Manual and manufacturer's instructions.

G. Logistics Service will be responsible for the glucose reagent strips and control solutions inventory. The service will also supply the services/units/clinics with the testing strips and control solutions. All new test strips and Quality Control lots must be first submitted to the ATC for verification prior patient testing. The ATC maintains all other POCT supply inventory.

5. REPORTING STRUCTURE: Ancillary Testing Committee

6. REFERENCES:

- Department of Veterans Affairs, VHA Handbook 1106.01, Pathology and Laboratory Medicine Service Procedures, "Ancillary Testing" 2016.
- Comprehensive Accreditation Manual for Laboratory and Point of Care Testing. JC Current Edition.
- College of American Pathologists, Commission on Laboratory Accreditation, Laboratory Accreditation Program, Inspection Checklist for Point-of-Care Testing, current edition.
- The Clinical Laboratory Improvement Amendments of 1988 Federal Register, Vol. 57, NO 40 and 42CFR 493.15 (b) and 493.15 (c) February 28, 1992.

6. FOLLOW-UP RESPONSIBILITY: Chief, Pathology & Laboratory Medicine Service (113).

7. RESCISSION: MCM 548-074, Alternate Site Testing dated June 25, 2016.

8. RECERTIFICATION DATE: March 9, 2019

Charleen Szabo, FACHE
Medical Center Director

Attachments: A (Scope of waived & moderate complexity ancillary testing)

Distribution:

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ATTACHMENT A

SCOPE OF WAIVED AND MODERATE COMPLEXITY ANCILLARY TESTING

WAIVED TESTS

Test Name	Definitive	Screening Tool	Staff approved to perform	Quality Control Performed/Frequency	Location of Results in Medical Record.
Glucose	√		Trained staff – list maintained by ATC.	Two quantitative levels/run each day of testing	VistA and CPRS
Creatinine test(i-Stat)	√		Trained Imaging staff -list maintained by ATC	i-STAT internal electronic simulation / every 8 hours Liquid controls monthly	VistA and CPRS
Urine Pregnancy test	√		Trained staff -list maintained by ATC	Built in procedural control with each test. Pos and Neg controls performed at designated intervals-see procedure.	VistA and CPRS

MODERATE COMPLEXITY TESTS

Test Name	Staff approved to perform	Quality Control Performed/ Frequency	Location of Results in Medical Record.
ABG-Blood Gases (i-STAT)	Trained staff in Respiratory Therapy, Cardiac Cath Lab,and OR. List maintained by ATC	i-STAT internal electronic simulation / every 8 hours 2 levels of Liquid controls monthly	VistA and CPRS
ACT test (i-STAT)	Trained staff – list maintained by ATC	i-STAT internal electronic simulation / every 8 hours 2 levels of Liquid controls monthly	VistA and CPRS
Troponin test (i-Stat)	Trained Nurses in ER - list maintained by ATC	i-STAT internal electronic simulation / every 8 hours 2 levels of Liquid controls monthly	VistA and CPRS
INR test (i-Stat)	Trained Nurses in Anti-Coagulation -list maintained by ATC	i-STAT internal electronic simulation / every 8 hours 2 levels of Liquid controls monthly	VistA and CPRS