

ANCILLARY TESTING POLICY (70)

I. **PURPOSE:** To establish policy for performing and maintaining the Ancillary Testing Program in compliance with The Joint Commission, College of American Pathologists (CAP), and Department of Veteran Affairs (VA) standards. Ancillary testing is defined as laboratory testing performed within a VA facility including some Community Based Outpatient Clinics (CBOC) but outside the physical confines of the main clinical laboratory. Note: All testing is performed by non-laboratory personnel only.

II. **POLICY:**

A. All ancillary testing sites are required to be under the technical direction of the Laboratory Director, Pathology and Laboratory Medicine, and inspected and accredited during the same inspection visit for the facility's main clinical laboratory.

B. Quality management records for all ancillary testing sites will be maintained in the main clinical laboratory.

III. **RESPONSIBILITIES:**

A. The Laboratory Director, Pathology and Laboratory Medicine, decides which tests may be performed outside the main clinical laboratory for patient care diagnostic or monitoring.

B. The Ancillary Testing Coordinator (ATC) must be a fully qualified Medical Technologist with at least four years experience in laboratory testing. This individual:

1. Acts as the technical oversight supervisor for all testing sites;
2. Participates in the selection of methodologies appropriate for the clinical use of the test results;
3. Participates in the validation of methods and test procedures performed and the establishment of the test performance characteristics, including precision and accuracy;
4. Participates in the planning, design, implementation, and assessment for all elements of the Point of Care Testing (POCT) quality management program;
5. Documents training, authorization, and annual competence evaluation for all persons who perform ancillary testing; and
6. Ensures enrollment and participation in a proficiency program commensurate with the testing services offered, and oversees necessary remedial action when necessary.
7. Responsible for ensuring all CAP surveys for ancillary testing are completed and submitted in a timely manner for all sites.

C. The Laboratory Supervisor oversees and is responsible for supervisory aspects of ancillary testing and works with the ATC to assure that all ancillary functions are up to date and/or adequate. These functions include, but are not limited to training, evaluation of competency, maintenance, infection control, and supply checks. Site supervisors will provide the necessary documentation to the ATC. The ATC is responsible for this program.

1. CAP proficiency surveys for Prothrombin Time (PT) International Normalized Ratio (INR) & HgBA1C will be mailed to VA Butler Healthcare laboratory.

2. The VA Butler Healthcare laboratory will forward the CAP surveys to the designated CBOC.

3. The ATC will generate an e-mail to the lab supervisor and the nurse manager. The message will include the date of receipt, the required analysis and the time frame for completion.

4. The determined processing time allotted for PT (INR) is 72 hours and 48 hours for HgBA1C.

5. The nurse assigned to process the surveys will fax a copy of the completed results to VA Butler Healthcare laboratory after it has been determined that a copy has been faxed and received by the CBOC.

IV. PROCEDURES:

A. Ancillary Testing performed at this facility includes: Point of Care INR's, Point of Care A1C's, Point of Care capillary glucoses, and Point of Care urine HCG testing.

1. All routine maintenance and cleaning must be performed as specified by the manufacturer.

2. All sites are required to comply with current VA Directives and other applicable standards related to infection control.

3. The results of all ancillary testing must be entered in to the Veterans Health Information Systems Technology Architecture (VISTA).

B. Patient Self-Testing: Veterans enrolled in primary care and residents of the Community Living Center may not perform self testing. The only exception(s) is/are the domiciliary residents who may monitor capillary blood sugar (CBS) utilizing their own glucometers and supplies. Under no circumstances should any self-test values be entered in VISTA.

C. Critical Values: All critical values must be confirmed with repeat testing. All critical INR values must have a confirmation/follow-up PT sent to the main lab. All critical capillary blood sugars must be followed with serum glucose determination prior to treatment, at the discretion of the provider. All Nursing personnel should follow established nursing protocol for critical value notification.

D. All Veteran CBS values that are below or above the Analytical Measurement Range (AMR) of the analyzer must have a serum sample drawn before clinical intervention.

3.

Medical Center Memorandum MS-07

E. Any positive Urine Drug Screen will have confirmatory testing done.

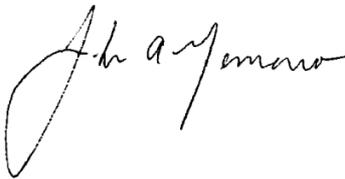
F. All PT (INR) values that display arrows, (eg. ↑ or ↓) for a patient test result, need to have a PT sample sent to the VA Butler Healthcare laboratory.

V. REFERENCES:

VHA Handbook 1106.1, Pathology and Laboratory Medicine Service Procedures, Department of Veteran Affairs, October 6, 2008.

CAP, Commission on Laboratory Standards, Inspection Checklist for Ancillary Testing, 2010.

VI. RESCISSION: Medical Center Memorandum MS-07 dated December 30, 2009.

A handwritten signature in black ink, appearing to read "John A. Gennaro". The signature is fluid and cursive, with a large initial "J" and "G".

JOHN A. GENNARO
Director

DISTRIBUTION: A

(Automatic Review Date: April 10, 2015)