

D.14 ANCILLARY TESTING POLICY

- I. **PURPOSE:** To establish policies, procedures and requirements for performing and maintaining the ancillary testing program in compliance with all regulations and standards, including the College of American Pathologists (CAP), the Joint Commission (TJC), and the Department of Veterans Affairs.

Definitions:

- A. **Laboratory Test:** A diagnostic or monitoring procedure performed on a specimen from a human source, used to determine specific information for patient care, including the prevention of disease, detection of impairment of health status, and assessment of health.
- B. **Ancillary Testing:** Laboratory testing within a VA Medical Center (VAMC) or its outreach areas performed outside the physical facilities of the main clinical laboratory.
- C. **Program Director:** The lead pathologist, Pathology & Laboratory Medicine Service (PLMS) or his/her designee.
- D. **Ancillary Testing Coordinator:** Provides technical oversight and operates under the direction of the program director. At minimum, the ancillary testing coordinator is a medical technologist with at least 4 years of experience in appropriate areas of laboratory testing. Responsibilities are delineated in section 4.0.
- E. **On-Site Supervisor:** Holds direct supervisory authority over the authorized testing personnel. Responsibilities are delineated in section 4.0.
- F. **Authorized Testing Personnel:** Individuals who directly perform ancillary testing.

II. **POLICY:**

- A. All ancillary test sites are required to be inspected and fully accredited by the CAP and the Joint Commission, regardless of the scope of testing activity. Inspection of these sites is performed at the time of inspection of the VAMC main clinical laboratory.
- B. The program director holds responsibility for oversight of quality management. Quality management records for all ancillary testing sites, except those with dedicated space, are maintained in the main clinical laboratory.
- C. In consultation with the program director, the chief of staff specifies the type and location of ancillary test sites, and their designated supervisors.

III. **SCOPE:** Ancillary test sites are limited to those areas approved by the program director. Approved ancillary tests and test sites consist of:

- A. **Blood glucose testing:** Wards, clinics, community based outpatient clinics (CBOCs) and emergency room
- B. **Urine dipstick:** Urology clinic
- C. **Activated Clotting Time (ACT):** Cardiac Catheterization Laboratory
- D. **Practitioner Performed Microscopic Procedures (PPMP):**
 - 1. **Potassium (KOH) preparations:** Dermatology clinic
 - 2. **Urine microscopy:** Urology & dialysis clinics

E. Urine Point of Care Pregnancy (bHCG): CBOC staff models

IV. RESPONSIBILITIES:

A. Program Director:

1. Responsible for the overall quality management of the ancillary testing program.

B. Ancillary Testing Coordinator:

1. Provides technical oversight for quality control, records, controls, proficiency testing, inspections, and accreditation for all ancillary test sites.
2. Advises and assists on-site supervisors and authorized testing personnel with selection of methodologies, verification of methods, procedures, analytic performance, proficiency testing, competency assessment, assessment of test performance, and resolution of technical problems.
3. Establishes and monitors the quality control program, quality management program, and record keeping.
4. Reports any areas that are not in compliance to the program director and the on-site supervisor

C. On-Site Supervisor:

1. Maintains direct supervisory authority over testing personnel and ensures that all regulatory requirements are met.
2. Works with the ancillary testing coordinator to ensure training/competency testing of authorized testing personnel on policies and procedures. Maintains inventory control. Ensures routine maintenance is performed and that testing records are maintained.
3. Informs ancillary testing coordinator of any changes in performed testing.

D. Authorized Testing Personnel:

1. After appropriate training and authorization, directly perform ancillary testing while adhering to all policies and procedures.

V. PROCEDURES:

A. Authorization of Testing Personnel:

1. The on-site supervisor or designee designates individuals that are authorized to perform ancillary testing. Authorization is limited to individuals who satisfy the certification requirements established for each ancillary test.
2. In collaboration with the on-site supervisor, the ancillary testing coordinator oversees compliance with requirements. This includes participation in a training program with demonstration of clinical competency. Measurement of clinical competency is dependent upon the test procedure, and may include the successful recovery of a control material, correct documentation and interpretation of data, a written exam, direct observation, testing of proficiency samples or split samples, or comparison of test results to a laboratory method.

3. Authorization is renewed annually unless otherwise indicated by performance or compliance. Renewal requires demonstration of clinical competency through satisfactory completion of the competency assessment program established for each ancillary testing procedure.
4. Documentation of staff training and competency is maintained by the ancillary testing coordinator and/or each test site, as applicable. PPMP can only be performed by a privileged physician, physician's assistant or nurse practitioner. Privileging of physicians performing PPMP is accomplished through the annual VAMC credentialing and privileging process.

B. Test Performance:

1. Patient preparation, identification, and testing are performed in strict accordance with test protocols.
2. Test results are acceptable only if all quality control criteria are met.

C. Quality Control (QC) and Quality Management (QM):

1. Individuals authorized to perform testing must participate in the QC program.
2. Control material is run each shift that a test is performed. If a control value falls outside of the established acceptable range, corrective action must be taken and documented before any patient test results are reported.
3. If testing is performed at different sites using different methodologies or instruments, correlation studies are performed at least twice a year to ensure there is consistency in reporting normal values, ranges of variation and other patient-related information.
4. QC results are reviewed by the ancillary testing coordinator or designee on a monthly basis. The on-site supervisor is notified if corrective measures are needed.
5. A permanent log of each instrument is kept in the clinical laboratory. Logs are kept for the life of the instrument. They consist of the initial instrumentation/method verification and completed QC records.
6. Documentation of training and competency, along with a list of current authorized testing personnel, is maintained in the main clinical laboratory.
7. QC and proficiency test results are monitored. Instrument/test systems are thoroughly checked based upon performance, with corrective actions taken as needed.

D. Proficiency Testing:

- a. Each test site participates in proficiency testing (PT).
- b. The laboratory participates in third party PT programs such as the CAP. Survey specimens are periodically distributed to all ancillary test sites for analysis. Results are evaluated for acceptability.

E. Maintenance:

- a. Routine maintenance is performed by ancillary test sites as specified by manufacturer's guidelines. Requirements are outlined in the appropriate procedures.
- b. The main clinical laboratory assists in any in-depth maintenance, troubleshooting or repair.

F. Reporting Results:

- a. All test results are reviewed and verified before they are reported.
- b. Test results are released only when QC results are within acceptable ranges, or corrective action has been taken and documented.
- c. Test results are entered into the patient's medical record. Whenever possible, test results are entered into VISTA to facilitate integration of data and review by caregivers.
- d. Results should include the following: patient identification, date and time of specimen collection, test performed, reference values, test results, name of analyte, ordering practitioner, and testing site
- e. Critical values are reported in compliance with the Stratton VAMC Pathology & Laboratory Medicine Service Critical Results policy.

G. Infection Control:

All testing adheres to infection control procedures and policies, as specified in the infection control manual.

H. Ancillary testing programs at the Stratton VAMC are outlined in [Attachment A](#).

VI. REFERENCES:

- Department of Veterans Affairs, Veterans Health Administration, Washington, DC, Veterans Health Administration Handbook 11006.1.
- College of American Pathologists, Ancillary Testing Inspection Checklist, 2008.
- The Joint Commission Accreditation Manual, 2008.
- CLIA 1988.

VII. FOLLOW-UP RESPONSIBILITY:

- Lead Pathologist, Pathology & Laboratory Medicine (518) 626-5708

Attachment A

Ancillary Testing performed at the Albany VA Medical Center

Test	Bedside Glucose Test [AccuChek Advantage]
Sites	Wards, CBOCs, clinics, & ER
Usage	Patient management
Authorization	RNs, LPNs, and Nurse Assistants who participate in training and demonstrate competency
QC Requirements	2-level controls daily when patient testing is performed. Also for new vials of test strips, battery changes, and after major maintenance
Maintain Competency	Acceptable results in running at least 2 levels of control per year; annual review and competency testing.
Proficiency Testing	Unknown samples from CAP three times/year
Results Reporting	Documented in VISTA and CPRS

Test	Urine Dipstick
Site	Urology clinic
Usage	Screening; patient management
Authorization	RNs and LPNs by training and credentials
QC Requirements	Run 2-level controls each day of clinic
Maintain Competency	2 successful controls per quarter; successful proficiency test results
Proficiency Testing	Unknowns from CAP two times/year
Results Reporting	Documented in patient's progress notes in CPRS

Test	Urine Microscopy
Site	Urology and dialysis clinics
Usage	Screening; patient management
Authorization	Urologists and nephrologists (by credentials)
QC Requirements	Maintenance of microscope and centrifuge
Maintain Competency	Physician participation in proficiency testing
Proficiency Testing	Unknown clinical microscopy colored photographs from CAP 2x/year
Results Reporting	Documented in patient's progress notes in CPRS

Test	KOH Preparation
Site	Dermatology clinic
Usage	Evaluation and patient management
Authorization	Dermatologists (by clinical credential privileges)
QC Requirements	Maintenance of microscope, check reagent for outdates
Maintain Competency	Annual credentialing process and competency assessment from CAP
Results Reporting	Documented in patient's progress notes in CPRS

Test	Urine Pregnancy, Sure-Vue bHCG
Site	CBOC (staff models)
Usage	Screening; patient management
Authorization	RNs & LPNs trained and demonstrating competency annually.
QC Requirements	Demonstration of positive control
Maintain Competency	Participation in CAP proficiency testing
Results Reporting	Documentation in VISTA lab package and CPRS

Test	Activated Clotting Time (ACT)
Site	Cardiac Catheterization Laboratory
Usage	Evaluation and patient management
Authorization	RNs by training and competency
QC Requirements	Run 2 levels control before patient testing is performed
Maintain Competency	Annual review and competency assessment from CAP
Results Reporting	Documented in Vista lab package and CPRS