DEPARTMENT OF VETERANS AFFAIRS HEALTHCARE SYSTEM Long Beach, California

HEALTHCARE SYSTEM POLICY No. 05-01

ISSUE DATE: June 9, 2015

ANCILLARY TESTING POLICY

1. **MAJOR POLICY CHANGES:** Addition of Definition: Critical Ill Patients.

2. **PURPOSE:** To aid in performing and maintaining the Ancillary Testing Program in compliance with Joint Commission (JC) standards, College of American Pathologists (CAP) standards, and Department of Veterans Affairs, Veterans Health Administration Handbook 1106.1 Chapter 8, "Ancillary Testing."

3. **POLICY:**

   a. Only approved ancillary tests are to be performed. All ancillary tests must be validated by a laboratory method, approved by the Ancillary Testing Board and testing monitored for compliance by the Ancillary Testing Coordinator (ATC).

   b. Ancillary testing will be under the quality management oversight responsibility of the Chief, Pathology and Laboratory Medicine Service, as mandated by the Department of Veterans Affairs, JC and CAP. This Healthcare System discourages the development of special function laboratories ("splinter" laboratories), which are not under the technical direction of the Pathology and Laboratory Medicine Service.

   c. The Ancillary Testing Board Chairperson, Ancillary Testing Coordinator, and Quality Improvement Coordinator will monitor the test procedures, Quality Control (QC), Quality Improvement (QI) proficiency testing, records control, documentation of training, authorization, and review of competency evaluation programs for all areas performing ancillary testing.

4. **DEFINITIONS:**

   a. **Ancillary testing:** Diagnostic laboratory testing performed outside the physical facilities of the clinical laboratory by non-laboratory personnel.

   b. **Critically ill patient:** In response to the FDA limitation on glucometer use in the critically ill the following definition will be applied as follows:

      **(1)** A patient on mechanical ventilation with a mean arterial pressure less than 60 mmHg despite the use of vasopressors.

      **(2)** Any patient with decreased peripheral blood flow; examples might be an individual with severe dehydration, hypotension (mean arterial pressure less than 60 mmHg), shock, decompensated heart failure, or peripheral arterial occlusive disease.

      If this applies then the patient will be tested using a venous or arterial specimen tested on a traditional laboratory methodology that is approved for use on critically ill patients.

5. **PROCEDURE:**

   a. **Authorization for the following will be provided by either the Ancillary Testing Board through the ATC or the Ancillary Testing Site Lead.**

(1) Authorization to perform ancillary testing in this institution by non-clinician providers and for all who perform tests of waived, moderate or high complexity will be limited to those individuals who have satisfied the authorization requirements. These requirements include participation in an approved training program and demonstration of clinical competency. A written test may be included, dependent on the complexity of the method involved.

(2) Continued authorization of non-clinician providers and all who perform tests of waived, moderate or high complexity will be dependent upon a satisfactory QC record and satisfactory performance on proficiency challenges along with adherence to procedures.

(3) Authorization will be renewed annually unless otherwise indicated by performance on routine QC, performance on proficiency challenges or lack of procedure compliance.

(4) Individuals not complying with the stated policy or incorrectly performing tests will be removed from the list of authorized personnel.

(5) Reinstatement will occur only after participation in additional training and after clinical competency is demonstrated.

(6) The current locations of ancillary testing sites are listed in Appendix A, "Location of Ancillary Testing Sites."

**b. <u>Physician-Performed Testing (PPT)</u>**

(1) Authorization of Clinicians to provide physician-performed testing (PPT) for select tests will be through credentialing and privileging for specific tests.

(2) PPT will be confined to the tests as defined by CAP which includes the following.

(a) Amniotic fluid pH
(b) Vaginal pool fluid smears for ferning
(c) Fecal leukocytes
(d) Gastric biopsy urease
(e) Nasal smears for eosinophils
(f) Occult blood, fecal and gastric*
(g) Pinworm examination
(h) Post-coital mucus examination
(i) Potassium hydroxide (KOH) preparations*
(j) Semen analysis, qualitative
(k) Urine dipstick
(l) Urine sediment microscopy
(m) Vaginal wet mount microscopy*

(3) Presently, only tests marked by an asterisk (*) (f, i and m) are performed by physicians at the VA Long Beach Healthcare System (VALBHS). Fecal occult blood (f) is performed by Emergency Department (E.D.) physicians. Potassium hydroxide (KOH) preparations (i) are performed by Dermatology and Women's Health physicians. Vaginal wet mount microscopy (m) is performed by Women's Health physicians. Those physicians in the E.D. who have not been tested for color blindness are required to be tested by Occupational Health.

(4) Physicians who wish to continue performing these or additional tests listed will have their names and the test requested submitted by their Health Care Group Chief / Service Chief to the Medical Staff Credentialing Committee. Such physicians, now under CAP regulations, may be privileged for those specific waived tests appropriate to their scope of practice.

(5) No further skills or documentation of competency are required if the Healthcare System Director decides physicians wishing to perform these tests are credentialed for "core activities" in each specialty.

(6) At the discretion of the Chief, Pathology and Laboratory Medicine Service (who is designated on the CLIA certificate or by organization policy) more stringent competency may be implemented. No additional competency is required if an instrument is not involved in the test. (Currently, physicians who perform these tests are periodically given proficiency samples to assess competency.)

**c. Verification of New Methods and/or Instrumentation (if applicable)**

(1) Initial verification: Performance criteria for the selected method and/or instruments, including precision, accuracy, linearity within assay range, and sensitivity, specified by the manufacturer or supplier must be verified by the HCG/Service performing the ancillary testing, according to Clinical and Laboratory Standards Institute (CLSI) guidelines. Documentation of this procedure will be retained for two years beyond the life of the instrument or two years longer than the method is in use.

(2) Verification of additional instruments: When the initial verification has been completed, subsequent instruments of the same type may be evaluated with an abbreviated procedure; e.g., comparison to initial instrument with a limited number of controls or patient specimens.

**d. Quality Control**

(1) All individuals who are authorized to perform ancillary tests must participate in the QC program.

(2) Different levels of commercial control material will be used if available. Each level will have an assigned acceptable range provided by the manufacturer. The manufacturer's range will be used until enough data is accumulated to determine a facility mean and standard deviation. Then the acceptable range will be adjusted. On a monthly basis, all results will be reviewed by the Ancillary Testing Coordinator for actual mean, standard deviation (SD) and coefficient of variation (CV). Minimum standards for each parameter will be set to evaluate the performance of instrument and operator.

(3) If the results are not within the expected range, corrective action must be taken. All corrective action must be documented. Information about appropriate documentation of corrective action will be available in the standard operating procedure (SOP) for each test.

**e. Proficiency Testing**

(1) Each site performing ancillary testing must participate in proficiency testing if available or split sampling with the Main Laboratory if proficiency testing is unavailable.

(2) Authorized individuals must participate in an in-house proficiency study on a regular basis. Performance on these surveys will determine the individual's ability to continue ancillary testing.

(3) If available, a commercially prepared survey specimen will be received by the laboratory and distributed to all sites for analysis at least two times per year. These results are then evaluated by an external agency that determines the acceptability of results based on results received by other users of the same method.

(4) For those ancillary tests that are also performed by the main laboratory, the Ancillary Testing Coordinator will complete a comparison and prepare a correlation evaluation between the

ancillary test and the main laboratory test. This comparison evaluation will be performed every six months.

**f.** Maintenance: Maintenance of instruments will be performed as specified by the manufacturer's guidelines. These procedures will be outlined in the test procedures, and written according to CLSI guidelines. All maintenance and repair work will be documented.

**g.** Infection Control: Infection Control will be included in the approved training program. Authorized individuals must be familiar with Universal blood/body fluid precautions. Refer to the Infection Control Guideline (ICG), "Exposure Control Plan for Bloodborne Pathogens." Hospital safety policies are to be observed.

**h.** Results: All results of ancillary tests or PPT must be entered into VistA or CPRS.

## 6. RESPONSIBILITIES:

### a. Administration

(1) Ancillary Testing Board Chairperson: The Ancillary Testing Board will be chaired by the Chief, Pathology and Laboratory Medicine Service (or Designee) and is responsible for the overall management of ancillary testing.

(2) Ancillary Testing Coordinator (ATC): The ATC must be a fully qualified laboratory technologist with at least four years experience in appropriate areas of laboratory testing. The ATC will act as a technical oversight supervisor for all ancillary testing sites. The coordinator will be responsible for the routine monitoring of the QC, QA, maintenance review and training of authorized individuals. The coordinator will report any areas that are not in compliance to the Ancillary Testing Site Lead and to the Ancillary Testing Committee. A copy of all procedures, QC, QA, maintenance, and relevant information related to the authorization of individuals performing ancillary tests will be kept in Pathology and Laboratory Medicine Service. Relevant information related to the authorization of individuals performing ancillary tests will at a minimum include the names of those individuals authorized to perform ancillary tests other than physician performed microscopy and fecal occult blood testing, and the training records of those individuals trained by the ATC.

(3) Ancillary Testing Board: The Ancillary Testing Board will be responsible for the overall policy, standards development and operational quality management of ancillary testing. The Board will decide which tests may be performed outside the main laboratory and in which areas of the Medical Center and its satellite clinics. The Board will advise and have input on the evaluation of instruments, develop procedures for testing, quality control and action to be taken when problems arise. The Board will have the authority to withdraw tests from areas not in compliance with regulatory agencies and withdraw tests that are no longer considered appropriate. The Board will be made up of the Ancillary Testing Chairperson, the Ancillary Testing Coordinator, selected members of all HCG's that perform or are involved with ancillary testing, and the Quality Improvement Coordinator. This Board will work with the Ancillary Testing Board Chairperson and the Ancillary Test Coordinator in instituting and maintaining compliance with the Ancillary Testing Policy.

(4) Ancillary Testing Site Lead: Ancillary Testing Site Leads will be appointed by the Chief or designee from each HCG/Service that provides ancillary testing. Each Ancillary Testing Site Lead is responsible for training, authorization, evaluation and documentation of clinical competency for individuals who will be performing the test. Each Ancillary Testing Site Lead will ensure the performance of calibration, quality control, routine maintenance of instrument, infection control and supply checks, and maintaining documentation of such.

**b. Authorized Individuals**

(1) Those individuals who have successfully participated in the authorization program will be responsible for the performance of ancillary tests as described in the contained policy and procedures.

**7. REFERENCES:**

**a.** CAP, Commission on Laboratory Accreditation, Laboratory Accreditation Program, Point-of-Care Testing Checklist Current Edition.

**b.** Clinical and Laboratory Standards Institute, CLSI Document GP2-A3, 3rd Edition, Clinical Laboratory Technical Procedure Manuals, Approved Guideline, Current Edition.

**c.** Clinical and Laboratory Standards Institute, CLSI Document AST2-P, Volume 15 Number 2, Point-of-Care in vitro Diagnostic (IVD) Testing; Proposed Guideline, Current Edition.

**d.** Department of Veterans Affairs, Veterans Health Administration Handbook, 1106.1, Pathology and Laboratory Medicine Service Procedures, Chapter 8, "Ancillary Testing."

**8. RESCISSIONS:** HSP 05-01, Ancillary Testing Policy, dated March 6, 2012.

**9. REVIEW AND FOLLOW-UP RESPONSIBILITY:** This policy will be reviewed annually by the Policy Coordinator and the Medical Executive Council (MEC). It will be reissued on or before June 9, 2020.

**10. POLICY COORDINATOR:** The Ancillary Testing Coordinator, Pathology and Laboratory Medicine Service is responsible for the contents of this policy.

Michael W. Fisher
Healthcare System Director

# LOCATIONS OF ANCILLARY TESTING SITES (Appendix A, HSP 5-01)

| Location | | | Tests | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Whole Blood Glucose (Glucometer) | Urine Pregnancy | Vaginitis Testing | Occult Blood | Blood Gases (Rapid Point) | I-Stats | | | | | |
| | | | | | | | | Arterial Blood Gases | Troponin | Hb/Hct | ACT | Chemis-tries |
| VA Long Beach Medical Center | 1 | Emergency Department | X | X | | X | | X | X | X | | X |
| | 2 | Medical ICU | X | | | | | | | | | |
| | 3 | Pulmonary (Resp. Ther.) | | | | | X | X | | | | |
| | 4 | Women's Clinic | X | X | X | | | | | | | |
| | 5 | Cardiac Cath Lab | | | | | | | | | X | |
| | 6 | Hemodialysis | X | | | | | | | | X | |
| | 7 | Home Oxygen | | | | | | X | | | | |
| | 8 | OR | X | | | | | X | | | | |
| | 9 | PACU | X | | | | | | | | X | |
| | 10 | Employee Health | X | | | | | | | | | |
| | 11 | EYE Clinic | X | | | | | | | | | |
| | 12 | Mental Health Clinic | X | | | | | | | | | |
| | 13 | G.I. Lab | X | | | | | | | | | |
| | 14 | L1 | X | | | | | | | | | |
| | 15 | M1 | X | | | | | | | | | |
| | 16 | Minor Procedures | X | | | | | | | | | |
| | 17 | N4 | X | | | | | | | | | |
| | 18 | OP-132 | X | | | | | | | | | |
| | 19 | Alpha/Bravo | X | | | | | | | | | |
| | 20 | Charlie/Delta | X | | | | | | | | | |

# LOCATIONS OF ANCILLARY TESTING SITES (Appendix A, HSP 5-01)(cont.)

| Location | | | Tests | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Whole Blood Glucose (Glucometer) | Urine Pregnancy | Vaginitis Testing | Occult Blood | Blood Gases (Rapid Point) | I-Stats | | | | | |
| | | | | | | | | Arterial Blood Gases | Troponin | Hb/Hct | ACT | Chemis-tries |
| VA Long Beach Medical Center (cont.) | 21 | Eagle/Foxtrot | X | | | | | | | | | |
| | 22 | S10 | X | | | | | | | | | |
| | 23 | S8 | X | | | | | | | | | |
| | 24 | SCI-OP | X | | | | | | | | | |
| | 25 | Same Day Surg | X | | | | | | | | | |
| | 26 | DOU | X | | | | | | | | | |
| | 27 | T2 | X | | | | | | | | | |
| | 28 | V1 | X | | | | | | | | | |
| | 29 | V2 | X | | | | | | | | | |
| | 30 | X- Pod | X | | | | | | | | | |
| | 31 | Z-Pod | X | | | | | | | | | |
| Community Clinics | | Anaheim | X | X | | | | | | | | |
| | | Cabrillo | X | X | | | | | | | | |
| | | Laguna | X | X | | | | | | | | |
| | | Santa Ana | X | X | | | | | | | | |
| | | Whittier | X | X | | | | | | | | |