Pathology & Laboratory Medicine Service
Jack C. Montgomery VAMC
& all associated CBOC's

ANCILLARY TESTING PROGRAM
SOP 113-1
(July 15, 2013)

I. PURPOSE: To establish the policies, procedures and requirements for Ancillary Testing within the Medical Center, outpatient clinics (CBOC) and Home Based Primary Care (HBPC) areas. To provide guidance for the scope of testing, training and supervision, quality management and reliability of testing performed outside the controlled main laboratory environment.

II. POLICY: The Pathology & Laboratory Medicine Service (P&LMS) will be responsible for overall policy, standards development and operational quality management of ancillary testing sites. The Ancillary Testing Coordinator(s) will be responsible for overseeing and monitoring day-to-day operations.

III. RESPONSIBILITIES:

a. Chief P&LMS – The Chief P&LMS will provide guidance and technical/quality control support for all hospital and outreach testing functions that are assigned to the Medical Center. The Chief P&LMS decides in consultation with the medical and nursing staff, which tests may be performed outside the main clinical laboratory for diagnostic patient care or monitoring purposes and the equipment needed.

b. Ancillary Testing Coordinator – The Ancillary Testing Coordinator acts as a technical oversight supervisor for all ancillary testing sites and:

(1) Participates in the selection of methodologies appropriate for the clinical use of the test results.

(2) Participates in the verification of methods and test procedures performed and the establishment of the test performances characteristics, including precision and accuracy.

(3) Participates in the planning, design, implementation, and assessment for all elements of the point of care testing quality management program.

(4) Documents training, authorization, and annual competency evaluation for all persons in the medical center who perform ancillary testing.

(5) Ensures enrollment and participation in a proficiency program commensurate with the testing services offered, and oversees necessary remedial action when necessary.

c. Employees - All personnel involved in ancillary testing will be trained and competent to perform ancillary testing. All ancillary testing personnel will be monitored by quality control results and proficiency testing as appropriate for the level of specific testing.

IV. PROCEDURE: The Ancillary Testing Program includes testing performed within the VA Medical Center and outside the physical facility of the main clinical laboratory. This includes its outpatient clinics (Ernest Childers OPC, Vinita OPC and Hartshorne OPC and Home Based Primary Care areas. The Ancillary Testing program includes: capillary blood glucose, fecal occult blood, fingerstick PT/INR testing, influenza A & B testing, urine hCG testing and Rapid HIV-1/2 testing. All ancillary testing sites are inspected and fully accredited by an appropriate, nationally recognized CMS (Centers for Medicare & Medicaid Services) "deemed" accrediting body.

V. DEFINITIONS: Tests for certificate of waiver (Waived Tests) must meet the descriptive criteria as specified: Tests that meet the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) requirements for waived tests:

a. Are cleared by FDA for home use;
b. Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or
c. Pose no reasonable risk of harm to the patient if the test is performed incorrectly.
(Title 42 CFR Part 493.15 "Laboratories performing waived tests", 10-1-95)

VII. RECISSIONS:

P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing Program, same subject, dated April 30, 2001.
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing Program, same subject, dated July l1, 2005.
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing program, same subject, dated April 6, 2007.
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing program, same subject, dated July 2, 2008
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing program, same subject, dated March 10, 2010
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing program, same subject, dated August 29, 2012
P&LMS SOP 113-1, Ancillary Diagnostic Laboratory Testing program, same subject, dated July 15, 2013

Attachments: Appendices A – F

DAVID W. POTTS, M.D. Chief, P&LMS	BONNIE PIERCE Chief Patient Care Services	THOMAS SCHNEIDER, D.O. Chief of Staff
David Potts, M.D. /s/	Bonnie Pierce, RN /s/	Thomas Schneider, D.O. /s/
Date: 7/30/2013	Date: 7/30/2013	Date: 7/30/2013

Pete Amann, Ancillary Testing Coordinator 7/29/2014
/s/

Pete Amann, Ancillary Testing Coordinator 7/25/2015
/s/

Pete Amann, Ancillary Testing Coordinator 6/13/2016
/s/

APPENDIX A

August 28, 2012

BLOOD GLUCOSE MONITORING (BGM)

1. BGM will be performed as a definitive test for purposes of point-of-care glucose monitoring. Personnel allowed to perform BGM include nursing staff (RNs, LPNs, and Nursing Assistants/Health Techs), providers, optometry technicians and the Ancillary Testing Coordinator (ATC) if appropriate training has been completed.

2. Personnel Training:

A. Mandatory training and competency assessment will be performed on a scheduled basis. See the procedure for training and competency assessment tools being used. Upon successful completion, personnel will be certified. Records documenting staff competency will be kept by the Nursing Educational Coordinator and/or the Ancillary Testing Coordinator office.

3. A method validation will be performed before clinical use of instruments. This validation includes linearity studies, precision studies and a method comparison of patient results to the main chemistry analyzer in the lab. These studies are reviewed and if they fall within the manufacturers specifications, the meter will be available for patient testing.

4. Proficiency testing will be performed three times yearly. Survey samples will be processed in a similar manner as patient specimens and are analyzed by personnel who routinely test patient samples. Replicate analysis of survey samples is acceptable only if patient specimens are routinely analyzed in the same manner. Samples will be tested on all analyzers and among all personnel who routinely test patient specimens. Results will be recorded and sent for comparative analysis. Results will be reviewed by the ATC, Chief of P&LMS, and Laboratory Manager.

5. Two levels of control material will be tested on each meter in use on a scheduled basis.

6. Blood glucose test strips and control material must be stored and used according to the manufacturer's recommendations.

7. The Ancillary Testing Coordinator will act as a technical oversight supervisor for all ancillary testing sites for:
   a. Quality control
   b. Records control
   c. Proficiency testing
   d. Inspection and accreditation for ancillary testing on a hospital-wide basis.
   e. Correcting problems with the instruments detected by quality control, linearity, calibration verification or maintenance checks.

8. Only one brand of blood glucose testing meter and test strips will be used for in-house ancillary testing. When possible, sufficient quantities of blood glucose testing strips and control solutions with the same lot number must be purchased to allow consistency in testing, the strips must be compatible with the one brand of glucose meter to be used.

9. Supplies for inpatient testing for BGM are provided by SPD and Pharmacy. SPD provides lancets. Pharmacy provides reagent strips and high-low control solutions.

.

APPENDIX B
August 28,2012

FECAL OCCULT BLOOD TESTING

1. Occult blood testing on fecal specimens will be performed by providers and mid-level practitioners (Physician Assistants and Nurse Practitioners) upon completion of training and competency testing. They will be required to undergo initial training and competency assessment for this procedure. Mid-level practitioners will undergo competency testing initially, six months, twelve months and annually thereafter. The Ancillary Testing Coordinator will be responsible for providing this training and the storage of these records.

2. Occult blood tests are visually read and require color differentiation. Therefore, neither test should be interpreted by the visually impaired.

3. Personnel performing the test must ensure the occult blood card and the developer have not outdated. If outdated, the test should not be run and all expired occult blood cards and/or developer must be discarded.

4. Personnel performing the test must ensure the positive and negative control is acceptable in order for the test to be valid. If the controls are unacceptable, do not report results and contact the Ancillary Testing Coordinator or Microbiology Supervisor.

5. Validation of quality control for each lot of Instaccult cards is performed and documented by the Ancillary Testing Coordinator or the microbiology department upon arrival in SPD.

6. Providers and mid-level practitioners will record the occult blood test results that they obtain in a progress note using the Occult Blood template in CPRS. All test results performed by the Laboratory Service will be entered electronically in the laboratory results menu.

APPENDIX C
August 28,2012

PT/INR (I-STAT) TESTING IN THE COAGULATION CLINICS & HOME BASED PRIMARY CARE

The i-STAT PT/INR test is a whole blood determination of the prothombin time used for monitoring oral anticoagulant (warfarin) therapy. The test determines the time required for complete activation of the extrinsic pathway of the coagulation cascade when initiated (activated) with thromboplastin.

1. PT/INR testing on whole blood specimens will be performed by upon completion of training and competency testing. Mandatory training will be performed initially. Competency will be assessed initially, six months, twelve months and annually thereafter. See the procedure for training and competency assessment tools being used. Upon successful completion, personnel will be certified. Records documenting staff competency will be stored in the Ancillary Testing Coordinators office.

2. Personnel performing the test must ensure the cartridges are not outdated. If outdated, the test should not
be run and all expired cartridges must be discarded.

3. Validation of the analytical measurement range (AMR) and a method comparison will be performed before clinical use of instruments. Linearity is not required for the Abbott i-STAT per manufacturer.

4. Each analyzer automatically does an internal simulator check daily. This assures us that the meter is operating correctly. Two levels of control material will be tested on each meter each month and at change of reagent lots. An external electronic simulator check will also be tested monthly.

5. Proficiency testing will be performed three times yearly. Survey samples will be processed in a similar manner as patient specimens and are analyzed by personnel who routinely test patient samples. Replicate analysis of survey samples is acceptable only if patient specimens are routinely analyzed in the same manner. Samples will be tested on all analyzers and among all personnel who routinely test patient specimens. Results will be recorded and sent for comparative analysis. Results will be reviewed by the ATC, Chief of P&LMS, and Laboratory Manager.

6. The Ancillary Testing Coordinator will act as a technical oversight supervisor for all ancillary testing sites for:

c. Quality control
d. Records control
c. Proficiency testing
d. Inspection and accreditation for ancillary testing on a hospital-wide basis.
e. Correcting problems with the instruments detected by quality control or maintenance checks.

7. Supplies will be kept in the Pharmacy.

APPENDIX D
August 28,2012

BINAXNOW INFLUENZA A&B TESTING

The BinaxNow Influenza A&B test is an in vitro immunochromatic assay for the qualitative detection of Influenza A&B nucleoprotein antigens in nasopharyngeal (NP) swabs and nasal wash/aspirate specimens. It is intended to aid in the differential diagnosis og Influenza A&B viral infections.

1. Mandatory training and competency assessment will be performed initially. Competency will be assessed initially, six months, twelve months and annually thereafter. See the procedure for training and competency assessment tools being used. Upon successful completion, personnel will be certified. Records documenting staff competency will be kept by the Nursing Educational Coordinator and/or the Ancillary Testing Coordinator office.

2. Personnel performing this testing must ensure the positive and negative control is acceptable before reporting patient results. If controls are not acceptable, do not report patient results and contact the Microbiology Supervisor or the Ancillary Testing Coordinator.

3. Personnel performing testing must ensure that the testing kit is not expired. If the kit is expired, the test should not be run and all expired kits should be discarded.

4. Proficiency testing will be performed 3 times each year. Survey samples will be processed in a similiar manner as patient specimens and are analyzed by personnel who routinely test patient samples. Surveys will be rotated among those who perform this testing.

5. The Ancillary Testing Coordinator will act as technical oversight supervisor for all ancillary testing sites. This includes quality control review, records control, proficiency testing, inspection preparation.

APPENDIX E
August 28,2012

QUALITATIVE URINE HCG TESTING

The QuickVue One-Step hCG Combo test is a sensitive immunoassay for the qualitative detection of human Chorionic Gonadotropin (hCG) in urine for the early detection of pregnancy. Human Chorionic Gonadotropin is a hormone produced by the placenta shortly after implantation. Since hCG is present in urine of pregnant women, it is an excellent marker for confirming pregnancy.

1. Mandatory training and competency assessment will be performed initially. Competency will be assessed initially, six months, twelve months and annually thereafter. See the procedure for training and competency assessment tools being used. Upon successful completion, personnel will be certified. Records documenting staff competency will be kept by the Nursing Educational Coordinator and/or the Ancillary Testing Coordinator office.

2. Personnel performing this testing must ensure the positive and negative control is acceptable before reporting patient results. If controls are not acceptable, do not report patient results and contact the Microbiology Supervisor or the Ancillary Testing Coordinator.

3. Personnel performing testing must ensure that the testing kit is not expired. If the kit is expired, the test should not be run and all expired kits should be discarded.

4. Proficiency testing will be performed two times each year. Survey samples will be processed in a similiar manner as patient specimens and are analyzed by personnel who routinely test patient samples. Surveys will be rotated among those who perform this testing.

5. The Ancillary Testing Coordinator will act as technical oversight supervisor for all ancillary testing sites. This includes quality control review, records control, proficiency testing, inspection preparation.

APPENDIX F
July 15,2013

Rapid HIV-1/2 Antibody Test - Oraquick

OraQuick Advance Rapid HIV-1/2 test is a manually performed visually read 20 minute immunoassay for the qualitative detection of antibodies to HIV-1 and HIV-2 in whole blood or plasma. The OraQuick Advance rapid test utilizes a proprietary lateral flow immunoassay procedure. The test cartridge holds an assay test strip comprised of special materials that provide the matrix for the immunochromatography of the specimen and the platform for the indication of the test results. The assay test strip, which can be viewed through the test device result window, contains synthetic peptides representing the HIV envelope region and a goat anti-human IgG procedural control immobilized onto a nitrocellulose membrane in the Test zone and Control zone respectively.

1. Mandatory training and competency assessment will be performed initially. Competency will be assessed initially, six months, twelve months and annually thereafter. See the procedure for training and competency assessment tools being used. Upon successful completion, personnel will be certified. Records documenting staff competency will be kept by the Nursing Educational Coordinator and/or the Ancillary Testing Coordinator office.

2. Personnel performing this testing must ensure the positive and negative control is acceptable before reporting patient results. If controls are not acceptable, do not report patient results and contact the Microbiology Supervisor or the Ancillary Testing Coordinator.

3. Personnel performing testing must ensure that the testing kit is not expired. If the kit is expired, the test should not be run and all expired kits should be discarded.

4. Proficiency testing will be performed two times each year. Survey samples will be processed in a similiar manner as patient specimens and are analyzed by personnel who routinely test patient samples. Surveys will be rotated among those who perform this testing.

5. The Ancillary Testing Coordinator will act as technical oversight supervisor for all ancillary testing sites. This includes quality control review, records control, proficiency testing, inspection preparation.