RFP 36C24218R0169

D.20 ANCILLARY TESTING POLICY (CM 113-10, JANUARY 21, 2016)

VA WESTERN NEW YORK HEALTHCARE SYSTEM

January 21, 2016 CENTER MEMORANDUM **NO. 113-10**

ANCILLARY TESTING POLICY

1. **PURPOSE**: To establish policies, procedures and requirements for performing and maintaining the ancillary testing program in order to ensure high test quality, patient safety, and compliance with Joint Commission (TJC) standards, College of American Pathologists (CAP) standards, and Department of Veterans Affairs, Veterans Health Administration Handbook 1106.1, *Pathology and Laboratory Medicine Service Procedures*.

2. **DEFINITIONS**:

A. A laboratory test is a diagnostic or monitoring procedure on any specimen from a human source to determine specific information for patient care, the prevention of disease, and to detect the impairment of health status or assess the health of human beings.

B. Ancillary testing is laboratory testing or services within a VA Medical Center or its outreach functions that are performed outside the physical facilities of the main clinical laboratory. It is often referred to as point of care testing (POCT).

C. Waived testing is testing so simple and accurate as to render the likeliness of erroneous results negligible and pose no risk or harm to the patient if the test is performed inaccurately.

D. Non-waived testing is considered moderately or highly complex testing.

E. Provider performed microscopy/Testing (PPM/PPT) is limited to unstained microscopic bright field exams performed by a physician, mid-level practitioner or a dentist as part of the patients physical exam.

F. Ancillary Testing Coordinator is under the direction of the Director, Pathology and Laboratory Medicine Service, and is a fully qualified Medical Technologist with at least 4 years experience in appropriate areas of laboratory testing. The Ancillary Testing Coordinator performs the responsibilities indicated in section 4 C below.

G. Site Director is the Director of the Service performing ancillary testing or designee who has supervisory authority over the on-site supervisor.

H. On-site Supervisor has direct supervisory authority over the authorized testing personnel and performs the responsibilities indicated below.

I. Privileged providers are members of the VA Western New York Healthcare System (VAWNYHS) staff, licensed independent practitioners, nurse practitioners, and physician assistants' privileged through the medical staff credentialing process.

3. **POLICY**:

A. All ancillary testing sites that perform tests categorized as moderate complexity or higher must be accredited and inspected by the Laboratory Accreditation Program (LAP) of an accrediting agency with deemed status from the Center of Medicare and Medicaid Services (CMS). Reaccreditation inspections for these sites are required every 2 years. The inspection of these sites will be performed during the same inspection visit for the VA Medical Center's main clinical laboratory.

B. Sites that perform only tests categorized as waived or provider-performed microscopy (PPM) procedures may be inspected as part of the main laboratory LAP or may optionally be accredited and inspected as part of the main facility accrediting process.

C. Ancillary testing will be under the quality management oversight responsibility of the Medical Director, Pathology and Laboratory Medicine Service. Quality Management records for all ancillary test sites, except those with dedicated space, will be maintained in the main clinical laboratory.

4. **RESPONSIBILITIES**:

A. **Medical Director, Pathology and Laboratory Medicine**:

1. Decides in consultation with the medical and nursing staff, which tests may be performed outside the main clinical laboratory for patient care diagnostic or monitoring purposes, and the equipment needed.

2. Responsible for assuring that all ancillary testing performed within the facility or its outreach functions is of high quality, safe and in compliance with accreditation regulations.

B. **Ancillary Testing Task Group**:

1. An Ancillary Testing Task Group will be formed whenever the need arises to provide input on new test methodology, compliance with accreditation regulations, policies, procedures, medical appropriateness, or the need to perform ancillary testing.

2. The Task Group will consist of a representative from all areas that have a stake in the process.

C. **Ancillary Testing Coordinator**:

1. Acts as technical oversight supervisor for quality control, records control, proficiency testing and inspection and accreditation for all ancillary testing sites.

2. Participates in the selection of methodologies appropriate for the clinical use of the test, the validation of methods and test procedures performed and the establishment of the test performance characteristics, including precision and accuracy.

3. Provides and documents training, authorization and annual competency evaluation for all persons who perform ancillary testing. For privileged providers, this may be accomplished through the privileging process.

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

5. The Ancillary Testing Coordinator will report to the Medical Director, Pathology and Laboratory Medicine, Laboratory Manager and the On-site Supervisor any areas that are not in compliance.

D. **Ancillary Testing Site Director**:

The Site Director or designee is responsible for seeing that all requirements are carried out in accordance with applicable VA, regulatory and accreditation regulations.

E. **On-site Supervisor**:

1. Has supervisory authority over testing personnel and ensures that all requirements of CAP, Joint Commission, and the Department of Veterans Affairs, Veterans Health Administration Handbook 1006.1 are adhered to in the testing area.

2. Determines which ancillary testing site personnel should be authorized to perform testing and must inform the Ancillary Testing Coordinator of specific tests the individual is required to perform.

3. Works with the Ancillary Testing Coordinator to ensure training of site personnel on policy and procedure, proficiency and "competency" testing is completed, maintains inventory control, insures routine maintenance is being performed and that testing records are maintained.

4. Informs Ancillary Testing Coordinator of any changes in testing performed on the site.

F. **Authorized Personnel**:

Are individuals who have participated in the certification and training program. They are the only personnel allowed to perform ancillary testing as described in the contained policy and established procedures maintained in the WNY Resources Folder, Buffalo Reference Folder, Ancillary Testing Procedure Manual.

5. **PROCEDURES**:

A. Authorization of Testing Personnel:

1. Authorization to perform ancillary testing will be limited to those individuals who have satisfied the certification requirements established for each ancillary test.

2. The Ancillary Testing Coordinator or designee in collaboration with the On-Site Supervisor will oversee compliance with the requirements. A complete listing of all the mandatory requirements are contained in the chart listed as Attachment A.

3. Renewal of authorization will consist of demonstration of clinical competency through satisfactory completion of the competency assessment program established for each ancillary test procedure as listed in Attachment A.

4. Individuals not showing satisfactory QC and proficiency records or who are not following the stated policies and procedures will be counseled and retrained. Repeated non-compliance will lead to loss of privileges (for any point of care test), and additional disciplinary action by the on-site supervisor. Reinstatement will occur only with proof of documented corrective action and monitoring as determined by the Laboratory Director.

5. Documentation of staff training and competency will be maintained by Pathology and Laboratory Medicine Service and/or each test site as applicable.

B. Provider Performed Microscopy/Testing (PPM/PPT) and Waived Testing:

1. A provider must be trained to perform the specific PPM/PPT and competency assessed for the waived/nonwaived procedures that are appropriate and performed within the health care provider's specialty. Provider credentialing alone is not sufficient to be privileged to perform a blanket category or procedures such as "all waived tests".

2. Minimal testing standards must be met for all PPM/PPT, waived and nonwaived testing as follows:

a) Personnel performing these procedures must follow good laboratory practice in terms of QC, quality assurance, and proficiency testing whenever possible.

b) The procedure must be performed strictly in accordance with the manufacturer's instructions.

c) Written policies and procedures must be in place for performing the test.

d) Patient and quality control test results must be documented.

e) All such sites must enroll in a formal proficiency-testing program or have a system in place that verifies, at least twice a year, the accuracy of test results.

f) All testing must be carried out in accordance with applicable accreditation standards.

C. Contracted Community Based Outpatient Clinics:

The Medical Director or Pathology and Laboratory Medicine Service serves as a consultant for the medical center whenever a non-VA provider is contracted to perform laboratory testing for veterans at a satellite clinic. Documentation must be provided to ensure that the contracted laboratory is appropriately CLIA '88 certified.

D. Quality Control (QC):

1. All individuals who perform ancillary testing must participate in the QC program established for each ancillary test.

2. When applicable, QC must be run - per manufacturer's recommendations - to assure proper functioning of the test system. If a control value falls outside of the established acceptable range, corrective action must be taken and documented before any patient test results can be reported. The Inform II Glucometer will prevent you from using the meter when the QC has failed. The I-Stat 1 analyzer will also not report outpatient results when individual cartridge QC has failed.

3. The Ancillary Testing Coordinator (or designee) will review all QC results on weekly, bi-weekly or monthly basis, depending on the system involved. The On-site Supervisor will be notified if corrective measures are warranted.

E. Quality Management (QM):

1. All individuals who are authorized to perform ancillary testing must participate in the established QM Program.

2. Each instrument will have its own permanent log that will be kept for the life of the instrument. The log will be located in Pathology and Laboratory Medicine Service, in the RALS interface or at the test site, as applicable. This log will consist of the initial instrumentation/method verification and maintenance records. QC records will be retained in accordance with accreditation regulations.

3. The training and competency documentation along with a list of current authorized individuals will be maintained in Pathology and Laboratory Medicine Service.

4. If any ancillary test site shows a high degree of reporting unacceptable results on routine QC and/or proficiency testing, then the site in question will have the instrument/test system thoroughly checked and corrective action taken if needed. If reporting of unacceptable results continues, the ancillary test site may have the testing removed.

F. Proficiency Testing:

1. Periodically, a commercially prepared survey specimen will be received by the Pathology and Laboratory Medicine Service and distributed to all ancillary test sites for analysis. Testing will be rotated among staff members. These results are then evaluated by an external agency who determines the acceptability of the results. Corrective action will be taken for any unacceptable results.

2. If commercially prepared survey specimens are not available, an alternative test for accuracy will be performed. This could include blind specimens, split specimens, peer review of results obtained, review of Medical Training Solutions (MTS) quiz slides, or correlation to the clinical picture.

G. Reporting Results:

1. All test results must be carefully reviewed and verified before they are reported.

2. Test results cannot be released unless quality control material is within acceptable range or corrective action has been taken and documented.

3. All test results must be entered into the patient's permanent record. Whenever possible, test results must be entered into the VISTA system to facilitate integration of data and review by caregivers.

4. Patient test results should include: Patient identification (name and social security number), date and time of specimen collection, name of test performed, reference (normal) values with units of measure, test result, name of analyte, name of ordering provider, and location where testing was performed, as applicable.

5. Individuals performing ancillary testing are responsible for knowing the critical limits for each test performed. If a result falls outside the critical limits, the provider must be notified. A verification "read-back" is required by the person receiving the emergent test results (critical value) to confirm that the information was understood correctly.

6. Provider notification of critical results must be documented in the patient's electronic record as per established procedure (eg: via the Critical Fingerstick Glucose Template that includes the provider's name, date/time of notification, the critical result value, the documentation that read-back was performed, and any appropriate treatment action taken. For FSG, the Critical Fingerstick Glucose template should be used by all units, with the exception of the OR and outpatient lab).

7. 30 minutes is considered an acceptable length of time between the availability of the critical value and the receipt of results by the responsible provider in all settings except for the OR. In the OR, testing is an integral part of the procedure. The testing is performed in the surgical room and results are given directly to the provider or are performed by the provider. Any length of time over 30 minutes must be documented in the Critical Template

H. Maintenance/Troubleshooting:

1. Routine maintenance will be performed by the ancillary test site as specified in the manufacturer's guidelines. These procedures will be outlined in the method procedure and documented.

2. Pathology and Laboratory Medicine Service will assist in more complex maintenance, troubleshooting or repair.

3. If a major problem occurs on the off tours, most areas have more than one analyzer that can be utilized or can borrow one from another unit. If this does not resolve the issue, lab samples can be drawn and the testing can be performed in the main lab.

I. Infection Control:

1. All testing must adhere to all Infection Control procedures and policies, as found in the Infection Control Manual.

2. All glucometers must be disinfected with a 10% Clorox bleach wipe as per VHA Directive 2009-004.

J. Approved Ancillary Tests:

TEST NAME	CLASSIFICATION	EXTENT OF USE
Wet Prep/KOH Prep/Ectoparasites	Provider Performed Microscopy	Diagnostic
Fingerstick Glucose (Roche Inform II)	Waived Testing	Diagnostic
Fingerstick INR (Roche CoaguChek XS Plus)	Waived Testing	Diagnostic
ACT (i-STAT)	Moderately Complex	Diagnostic
O_2 Sat & THb (Avoximeter-1000E)	Moderately Complex	Diagnostic
Na+, K+, iCa++, Gluc., Hb, Hct (i-STAT)	Moderately Complex	Diagnostic
Blood Gas (i-STAT)	Moderately Complex	Diagnostic
Hgb A1C (DCA Vantage)	Waived Testing	Diagnostic
Buprenorphine	Waived Testing	Screening
Urine Pregnancy Test	Waived Testing	Diagnostic
Sonoclot	Moderately Complex	Diagnostic

6. **REFERENCES**:

   A. Department of Veterans Affairs, Veterans Health Administration, Washington, D.C., Veterans Health Administration Handbook 1106.01, 2008.

   B. College of American Pathologists, Ancillary Testing Inspection Checklist, 4/21/2014

   C. Current Joint Commission Manual

   D. VHA Directive 2009-004 "Use and Reprocessing of Reusable Medical Equipment (RME) in Veteran's Health Administration Facilities."

   E. CLIA'88.

7. **RESCISSION**: Center Memorandum No. 113-10, dated August 8, 2014

8. **FOLLOW UP RESPONSIBILITY**: Medical Director, Pathology & Laboratory Medicine

9. **AUTOMATIC REVIEW DATE**: January 1, 2019

//s//

BRIAN G. STILLER

Medical Center Director

DISTRIBUTION: 1 copy each (00, 00QM, 113)

VA WESTERN NEW YORK HEALTHCARE SYSTEM

January 21, 2016 CENTER MEMORANDUM **NO. 113-10**

ANCILLARY TESTING POLICY – ATTACHMENT A

VHAWNY HEALTHCARE SYSTEM

PATHOLOGY AND LABORATORY MEDICINE

ANCILLARY TESTING TRAINING GUIDE

The following training guide takes into account the regulations that govern Ancillary Testing including the College of American Pathologists, the Joint Commission and the VHA Handbook. Training includes attendance at the training class, running quality control (if necessary), performance of a test which includes performance of a fingerstick glucose, INR or HgbA1C on a class attendee, or running a previously tested sample (such as a blood gas), or running a previously tested CAP proficiency sample. Trainees will also complete a written quiz and fill out the training checklist (non-waived only). All staff will rotate participation in CAP proficiency testing challenges, MTS quizzes, direct observations or written tests as noted in the chart below for competency assessments.

REQUIREMENT	GLUCOMETER WAIVED TESTING	FINGERSTICK INR WAIVED TESTING	DCA VANTAGE WAIVED TESTING	BUPRENORPHINE URINE WAIVED TESTING	URINE PREGNANCY WAIVED TESTING	AVOXIMETER 1000 E	I-STAT 1	PHYSICIAN PERFORMED MICROSCOPY
INITIAL TRAINING					**Train the Trainer**			
TRAINING CLASS	X	X	X	X	X	X	X	X
TRAINING CHECKLIST	X	X	X	X	X	X	X	X
COMPETENCY ASSESSMENT FOLLOWING TRAINING								
Performing QC	X	X	X	X	X	X	X QC ON CARTRIDGE	X
DIRECT OBSERVATION of patient testing	X	X	X	X	X	X	X	X
WRITTEN QUIZ	X	X	X	X	X	X	X	X
ASSESSMENT OF TEST PERFORMANCE (Internal blind samples or external (PT) Proficiency Testing)						X	X	X
6 MONTH (1st year only) ASSESSMENT CHECK								
RUN QC (New staff)						X	X QC ON CARTRIDGE	X
PROBLEM SOLVING SKILLS WRITTEN QUIZ (New staff)						X	X	X

MTS QUIZ (All staff)								X
DIRECT OBSERVATION of Patient Testing						X	X	X
REVIEW OF MAINTENANCE LOGS/RALS						X	X	X
CAP PROFICIENCY TESTING SAMPLES Challenges per year rotate staff						X	X ACT X BLOOD GAS	X WWC X DERM
REQUIREMENT	GLUCOMETER WAIVED TESTING	FINGERSTICK INR WAIVED TESTING	DCA VANTAGE WAIVED TESTING	BUPRENORPHINE URINE WAIVED TESTING	URINE PREGNANCY WAIVED TESTING	AVOXIMETER 1000 E	I-STAT 1	PHYSICIAN PERFORMED MICROSCOPY
YEARLY ASSESSMENT								
*Critical elements								
DIRECT OBSERVATION OF INSTRUMENT FUNCTION CHECKS AND/OR PATIENT TESTING						X*	X*	X*
RUN QC (ALL STAFF)	X*	X*		X*		X*	X* QC ON CARTRIDGE	
PROBLEM SOLVING SKILLS (Written quiz to all staff)	X*	X*	X*	X*	X*	X*	X*	X*
QUIZ (MTS or written quiz)						X*	X*	X*
MONITORING RECORDING AND REPORTING RESULTS						X*	X*	X*
ASSESSMENT OF TEST PERFORMANCE (Internal blind samples or external (PT) Proficiency Testing)						X*	X*	X*
ADDITIONAL ASSESSMENT: DAILY, WEEKLY, MONTHLY, QUARTERLY								
REVIEW OF CRITICAL RESULTS	X	X					X	
REVIEW OF MAINTENANCE LOGS, QC LOGS, PROFICIENCY TESTING RESULTS, PATIENT RESULTS	X	X	X*	X	X *	X	X	X*