ANCILLARY/ POINT OF CARE TESTING

MCP 113-03

VA North Texas Health Care System
Dallas, TX 75216

Rescinded Document:
see paragraph 7.

Signatory Authority:
Stephen R. Holt, MD, MPH, MSNRS
Director

Effective Date:
April 19, 2021

Recertification Date:
April 30, 2026

Responsible Owner:
Chief, Pathology and Laboratory
Medicine Service

1. POLICY

This medical center policy (MCP) establishes policy to ensure that only fully qualified and trained individuals with documented competencies perform ancillary testing. This policy establishes compliance with Veterans Health Administration Laboratory Testing (VHA Handbook 1106.01), The Joint Commission Provider Performed Microscopy (PPM), College of American Pathologists (CAP) Provider Performed Testing (PPT), and the CLIA of 1988 PPM standards regarding ancillary/point of care testing (waived, non-waived, and PPT testing).

2. JUSTIFICATION

This MCP exists to define the policy on all ancillary/point of care testing; to include waived, non-waived, emergency use authorization (EUA), PPT and PPM performed within VA North Texas Health Care System (VANTHCS), specifically for VA-owned and/or managed (leased) facilities (not applicable to contracted, non-VA sites). It also defines the responsibilities of individuals who perform, document, or oversee such testing.

3. RESPONSIBILITIES

a. **VA Medical Facility Director.** The VA Medical Facility Director is responsible for ensuring overall VA medical facility compliance with this policy and appropriate corrective action is taken if non-compliance is identified.

b. **Chief, Pathology and Laboratory Medicine Service.** The Chief Clinical, Pathology and Laboratory Medicine Service is responsible for establishing policy and procedures for all laboratory testing.

c. **Ancillary Testing Coordinator/Pathology and Laboratory Medicine Service.** The Ancillary Testing Coordinator/Pathology and Laboratory Medicine Service (ATC/P&LMS) is responsible for:

(1) Administering and documenting specific training to qualified staff identified as responsible for performing ancillary testing.

(2) Ensuring current competency of all staff performing ancillary testing.

(3) Ensuring a current written procedure for each ancillary/point of care test is readily available. The procedure elements will include appropriate specimen collection and preservation guidelines, instrument calibration, quality control and remedial actions, equipment performance evaluation, reporting of results, and performance of the test.

(4) Performing and documenting periodic review for compliance with written procedures.

(5) Periodically surveying all VANTHCS services to identify all ancillary testing that is performed, by whom, and for what purpose(s).

d. **Service Chief or Designee of the Service Performing Ancillary Testing.** The Service Chief or designee of the service performing ancillary testing is responsible for:

(1) Notifying the Ancillary Testing Coordinator/Pathology and Laboratory Medicine Service (ATC/P&LMS) of its intentions to perform testing, so that the proposed test can be brought before the P&LMS Ancillary Testing and Laboratory Utilization Review (ATLUR) workgroup for review and approval.

(2) Reporting to P&LMS the specific locations performing waived, non-waived testing, and/or PPT within the service.

(3) Assessing the use of each test performed and define the extent to which it will be used for diagnosis, treatment, or screening, with or without follow-up using confirmatory testing.

(4) Identifying the staff responsible for the testing activity. Staff must meet CLIA ‘88 qualification standards. The identified staff must have received training specific to the testing activity, received orientation specific to the needs of the service, and have been documented to be competent to perform the test.

(5) Notifying ATC/P&LMS of the addition of any new staff who will require initial training.

(8) Addressing non-compliance issues and carrying out corrective actions.

e. **Staff of Services Performing Ancillary Testing.** The staff of services performing ancillary testing are responsible for:

(1) Explicitly following the procedure manual and the manufacturer’s guidelines.

(2) Performing and documenting quality control checks as defined in the test procedure.

(3) Documenting patient test results in the patient's medical record utilizing Electronic Health Records (EHR) templates, when available.

(4) Maintaining quality control records, equipment maintenance records, and any other documentation related to testing according to applicable accrediting agencies and VA guidelines.

(5) Maintaining failover binders of current test procedures.

(6) Participating in all mandatory competency assessment exercises.

(7) Performing CAP proficiency testing.

4. OTHER PARAGRAPHS

a. **Competency**. Documentation of assessed competency is required prior to performing testing, six months and one year after performing duties, and annually thereafter. Six-month competency is not required for waived testing. Annual competency must be directed and documented by the immediate supervisor or designee (nurse educator, ATC/P&LMS) for everyone performing testing. Physicians performing Fecal Occult Blood tests (FOBT) are excluded from annual competency testing on that procedure. Elements of competency assessment include but are not limited to:

(1) Direct observation of patient test performance, including patient identification and preparation where applicable, sample handling, processing, and testing.

(2) Monitoring the recording and reporting of test results, including use of EHR templates and, as applicable, reporting critical results

(3) Review of immediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

(4) Direct observation of performance of instrument maintenance and function checks, as applicable.

(5) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples, or external proficiency testing samples.

(6) Evaluation of problem-solving skills.

Other elements of competency may be assessed, as applicable. For non-waived tests, all six elements (above) must be assessed annually. For waived tests, it is not necessary to assess all elements at each assessment event. The ATC/P&LMS may select which elements to assess for waived tests.

Ongoing review is an acceptable method of assessing competency for certain elements (for example, direct observation of test performance, instrument maintenance, problem solving skills, etc.).

The ATC/P&LMS or testing service designee will document the competency assessment. Competency assessment records will be retained by the ATC/P&LMS and/or testing service. Documentation of annual competency must be readily available. Retraining must occur when problems are identified with employee performance.

b. **Diagnostic vs. Screening**. Diagnostic vs. screening will be defined to what extent (diagnostic vs. screening) the testing is utilized, and the purpose of the tests performed by each service providing waived testing.

c. **Orientation and Training**. The ATC/P&LMS or designee will conduct a thorough orientation and training for all new testing personnel before performing ancillary testing. Orientation and training for residents may be performed by the attending provider. Training applicable to the type and complexity of testing performed is documented. This training should be such that the person can demonstrate that he/she has the skills required for proper performance of pre-analytic, analytic, and post-analytic phases of testing.

d. **Policies and Procedures**. P&LMS will periodically survey all services to identify and monitor any ancillary testing that is being performed. Testing will be reviewed by the Ancillary Testing Coordinators/Pathology & Laboratory Medicine Service (ATC/P&LMS) for compliance with the following: appropriate policy and procedures, qualified and trained staff, documentation of test data and quality control, equipment maintenance forms, participation in CAP proficiency testing, and ongoing competency assessments for designated staff. The Ancillary/Point of Care Testing Policy and standard operating procedures are in Proquis, the P&LMS document control program. Proquis is accessed through the facility intranet P&LMS sharepoint. Failover binders containing hard copies of procedures are maintained at each testing location for use during computer downtime only. The ATC/P&LMS will assist in preparation of documents, as needed. The testing service will review the test procedures at least annually.

e. **Proficiency Testing**.

(1) The ATC/P&LMS will determine CAP proficiency testing needs as required by accrediting agencies. The ATC/P&LMS will distribute proficiency testing surveys in a timely manner to the test sites upon receipt in P&LMS. The ATC/P&LMS will review proficiency testing results as they are received, communicate the results to the testing sites, and ensure that appropriate corrective actions are initiated and documented for all instances of unacceptable performance.

(2) Successful performance on proficiency testing is required to perform ancillary testing.

f. **Result Reporting.** Results will be reported as per each individual test standard operating procedure.

5. DEFINITIONS

a. **Ancillary/Point of Care Testing.** Ancillary/point of care testing is testing performed outside the clinical laboratory; to include waived, non-waived, and PPT.

b. **Approved Staff**. Approved staff are testing personnel who have been oriented and trained for specific lab procedures performed outside the clinical laboratory. They have been approved by the Chief P&LMS through the Ancillary Testing and Lab Utilization Review (ATLUR) workgroup.

c. **Non-waived Tests**. Non-waived tests are CLIA moderate complexity level tests that may be performed outside or in the laboratory and meet the requirements of 42 C.F.R. § 493. See Appendix A for non-waived tests performed at VANTHCS.

d. **Privileged Providers**. Privileged providers are members of the medical staff, licensed independent practitioners, nurse practitioners, and physician assistants privileged through the medical staff credentialing process.

e. **Provider Performed Test**. Provider performed test, performed at VANTHCS (except Fecal Occult Blood), is moderate complexity level testing performed outside the laboratory by privileged providers at the time of the patient's physical exam. See Appendix A for PPT performed at VANTHCS.

f. **Waived Testing.** Waived testing refers to a category of tests defined as simple laboratory examinations usually performed at the bedside of the patient, in the clinic, or other sites remote from the laboratory by approved staff and/or privileged providers. See Appendix A for waived tests performed at VANTHCS.

6. REFERENCES

a. Pursuant to 42 C.F.R. § 493.https://www.ecfr.gov/cgi-bin/text-idx?node=pt42.5.493&rgn=div5

b. VHA Handbook 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, http://vaww.va.gov/vhapublications/ViewPublication.asp?pub_ID=3169

c. The Joint Commission E-dition, TJC Laboratory Requirements, January 1, 2020. https://e-dition.jcrinc.com/MainContent.aspx

7. RESCISSION

113-03, Ancillary/Point of Care Testing, dated May 5, 2016, is rescinded.

8. REVIEW

This MCP must be reviewed at minimum at recertification and including when there are changes to the VHA Handbook 1106.01, and TJC Laboratory Requirements.

RECERTIFICATION

This MCP is scheduled for recertification on or before the last working day of April 2026. This MCP will continue to serve as local policy until it is recertified or rescinded. In the event of contradiction with national policy, the national policy supersedes and controls.

9. SIGNATORY AUTHORITY

Stephen R Holt, MD, MPH, MSNRS
VA North Texas Health Care System
Director
Date Approved: April 19, 2021

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: MCPs are available at:
https://dvagov.sharepoint.com/sites/ntx/Programs-Groups/memo/default.aspx

ANCILLARY/POINT OF CARE TESTS

1. **Waived Tests**

a. Creatinine

b. Glucose Finger Stick

c. Qualitative Urine HCG

d. Urine Dipstick

2. **Non-Waived Tests**

a. ABG PANEL-POC (pH, tHb, pCO2, pO2, sO2, O2hb, COHb, MetHb, HCO3, ABE, Cl-, K+, Na+, Glucose, Lactate, Ionized Calcium)

b. Activated Clotting Time (ACT)

c. Cardiac Troponin I

d. Glomerular Filtration Rate

e. Oximetry (O2Hb, tHb)

3. **Provider Performed Testing (PPT)** includes certain waived tests under CLIA as well as Provider Performed Microscopy (PPM).

a. Fecal Occult Blood (waived)

b. KOH

c. KOH Vaginal Wet Prep

d. Urine Sediment Microscopy (PPM)

4. **Emergency Use Authorization (EUA)**

a. COVID-19 Antigen