

PATHOLOGY AND LABORATORY MEDICINE SERVICE

- 1. REASON FOR ISSUE.** This Veterans Health Administration (VHA) Directive establishes policy for all Department of Veterans Affairs (VA) laboratories performing testing that is used for the diagnosis and treatment of patients.
- 2. SUMMARY OF MAJOR CHANGES.** This VHA Directive requires that VA laboratories meet the requirements of Title 42 Code of Federal Regulations (CFR) Part 493 and that laboratory testing in VA will follow the 42 CFR Part 493 test categorization of “waived,” “moderately complex,” and “highly complex,” unless otherwise specified.
- 3. RELATED HANDBOOKS.** VHA Handbook 1106.1 and VHA Handbook 1106.2.
- 4. RESPONSIBLE OFFICE.** The National Director, Pathology and Laboratory Medicine Service (115A) is responsible for the contents of this Directive. Questions may be addressed to 202-273-8332.
- 5. RESCISSIONS.** VHA Directive 1106 dated August 22, 1997, is rescinded.
- 6. RECERTIFICATION.** The VHA Directive is scheduled for recertification on or before the last working day of October 2010.

Jonathan B. Perlin, MD, PhD, MSHA, FACP
Under Secretary for Health

DISTRIBUTION: CO: E-mailed 10/17/05
FLD: VISN, MA, DO, OC, OCRO, and 200 – E-mailed 10/17/05

PATHOLOGY AND LABORATORY MEDICINE SERVICE

1. PURPOSE: This Veterans Health Administration (VHA) Directive establishes policy for all Department of Veterans Affairs (VA) laboratories performing testing that is used for the diagnosis and treatment of patients.

2. BACKGROUND

a. In 1988, Congress passed the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88) as part of the Public Health Services Act (Title 42 United States Code (U.S.C.) 263a). These amendments codified into law requirements for the staffing, management, procedures, and oversight of United States laboratories that perform testing used in the diagnosis and treatment of patients. The Department of Health and Human Services (HHS) then published implementing regulations for CLIA-88, Title 42 Code of Federal Regulations (CFR) Part 493.

b. In 1992, Congress passed Public Law 102-139 Sec. 101(a), exempting VHA from CLIA-88 and stated that the Secretary of Veterans Affairs would, in consultation with the Secretary of HHS, publish regulations that would “establish standards equal to that applicable to other medical facility laboratories in accordance with the requirements of section 353(f) of the Public Health Services Act.” The intent was that VHA laboratories meet the requirements of CLIA-88, but left the enforcement and oversight of the regulations to VA.

c. Laboratory test systems, assays, and examinations are categorized as the same complexity as defined by the Food and Drug Administration in 42 CFR Part 493 except for those tests categorized as waived tests.

3. POLICY: It is VHA policy that all VA laboratories performing testing used for the diagnosis and treatment of patients meet the requirements of CLIA-88 while under VA regulations.

4. RESPONSIBILITIES

a. **National Director Pathology and Laboratory Service (P&LMS).** The National Director P&LMS, in concert with the P&LMS National Enforcement Officer and the Pathology Regional Commissioners, are responsible for providing oversight and enforcement of the policies defined in this Directive and its related Handbooks.

b. **Veterans Integrated Service Network (VISN) Director.** The VISN Director is responsible for ensuring that all laboratories or individuals performing testing used for the diagnosis and treatment of patients are in compliance with the policies in 42 CFR Part 493, this Directive, and the related Handbooks.

c. **Medical Center Director.** The medical center Director is responsible for ensuring that:

(1) The applicable requirements of 42 CFR Part 493 and appropriate accrediting agencies must be met when any laboratory patient care services are offered by VA laboratories, regardless

of the physical location of the laboratory, or the service or administrative structure assigned to direct the personnel or technical aspects of the test site.

(2) The clinical laboratory is directed by a licensed pathologist, board certified in pathology by an American Board of Pathology.

(3) When laboratory accrediting organizations require that certain tests be treated as if they are more complex than is listed in 42 CFR Part 493, the facility laboratory meets the needs of its accrediting organization(s).

(4) All testing sites that perform laboratory tests categorized as moderately or highly complex are inspected and accredited by a Center for Medicare and Medicaid Services (CMS)-approved accrediting organization.

(5) Sites performing only VA-recognized waived testing and provider-performed microscopy procedures are inspected and accredited as part of the main laboratory accreditation or in conjunction with the main facility accreditation process.

(6) All testing, regardless of complexity level or the physical location, is under the direct or indirect oversight of the Chief or Director, P&LMS.

(7) All Ancillary Testing Sites (ATS) are under the quality oversight or technical direction of the Chief or Director P&LMS. ATS are defined as laboratory testing or services performed within a VA Medical Center or its outreach functions (clinics, et al.), but outside the physical facilities of the main clinical laboratory.

(8) Individuals performing testing meet the personnel requirements defined in 42 CFR Part 493 for the identified testing complexity.

(9) P&LMS and all ATS successfully participate in a CMS-approved proficiency testing program. The laboratory proficiency testing program must meet the requirements of CLIA-88, the accrediting agency, and VA, for all analytes for which proficiency testing is available, including waived and unregulated analytes. For analytes where no proficiency testing is available, an alternate method must be in place. Laboratories must perform proficiency testing at all sites and on every instrument used for patient testing, including backup instruments.

(10) P&LMS providing anatomic pathology services participates in the Armed Forces Institute of Pathology (AFIP) Histopathology Quality Assessment Program, the AFIP Systematic External Review of Surgicals, the American Society of Clinical Pathologists CheckPath Program in cytopathology, the VA's National Cytopathology Proficiency Program, and any other such proficiency testing programs designated as mandatory by the National Director, P&LMS.

(11) The facility laboratory participates in the VHA and College of American Pathologists Customized Laboratory Management Index Program.

d. **Chief or Director, P&LMS.** Each Chief or Director, P&LMS:

- (1) Serves as an active member of the medical staff for those facilities served by directing and coordinating the patient care, administration, education, and research functions of P&LMS.
- (2) Assumes responsibility for implementation of the quality improvement plan.
- (3) Ensures that there are sufficient qualified personnel with adequately documented training and experience to meet the needs of the laboratory.
- (4) Performs planning for setting goals and the development and allocation of resources appropriate to the medical environment.
- (5) Provides effective and efficient administration of the pathology service to include budget planning and control.
- (6) Selects and monitors all reference laboratories and ATS for quality of service.
- (7) Acts as a consultant 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 CLIA-88 certified and that all test results are entered into Veterans Health Information System and Technology Architecture (VistA).
- (8) Establishes a laboratory management data collection system using VistA.

5. REFERENCES

- a. Public Law 102-139.
- b. Title 42 U.S.C. Part 263.
- c. Title 42 CFR Part 493.
- d. VHA Handbook 1106.1.
- e. VHA Handbook 1106.2.