

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. **AUTHORITY:** Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988, and title 42 Code of Federal Regulations Part 493.
- 2. SUMMARY OF MAJOR CHANGES.** This revision of VHA Directive 1106 contains no major changes other than updating titles and routing symbols.
- 3. RELATED ISSUES.** VHA Handbook 1106.01.
- 4. RESPONSIBLE OFFICE.** The Office of the National Director, Pathology and Laboratory Service (10P4D) is responsible for the contents of this Directive. Questions may be addressed at 202-632-8421.
- 5. RESCISSION.** VHA Directive 1106, Pathology and Laboratory Medicine Service, dated October 13, 2005, is rescinded.
- 6. RECERTIFICATION.** This VHA Directive is scheduled for recertification on or before the last working day of April 2018.

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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, Public Law 100-578, the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), was enacted. This law amended section 353 of the Public Health Services Act (Title 42 United States Code (U.S.C.) 263a) to codify in law certain 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) promulgated regulations for CLIA-88, which are codified at Title 42 Code of Federal Regulations (CFR) Part 493.

b. In 1991, Public Law 102-139, Sec. 101(a) was enacted, exempting VHA from CLIA-88 and requiring instead that the Secretary of Veterans Affairs, 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 Service Act.” The intent was that VHA laboratories would meet the requirements of CLIA-88 and that VA was in charge of enforcement and oversight of its own regulations. The Secretary of Veterans Affairs delegated authority to the Under Secretary for Health to issue regulations implementing requirements and standards for VHA laboratories, in accordance with 38 U.S.C. §§ 501, 512, and 7301(b) and 38 CFR 2.6(a)(1). It is noted that VA participates on HHS’ partnership panel for Pathology and Laboratory Medicine with bi-directional communication regarding their respective programs.

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.

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

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, is responsible for providing oversight and enforcement of the policies defined in this Directive and its related Handbooks.

b. **Veterans Integrated Service Network (VISN) Director.** Each VISN Director is responsible for ensuring that all laboratories or individuals, within the VISN, 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 Facility Director.** The medical facility 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 facility 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 The 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 the accrediting organizations.

(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 VHA-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 facility Chief or Director, P&LMS.

(7) All Ancillary Testing Sites (ATS) are under the quality oversight or technical direction of the facility Chief or Director P&LMS. ***NOTE: ATS are defined as laboratory testing or services performed within a VA medical facility 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.

(a) 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.

(b) For analytes where no proficiency testing is available, an alternate method must be in place.

(c) 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, Histopathology, and/or Cytopathology Services must participate in an approved proficiency testing program.

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

d. **Facility Chief or Director, P&LMS.** Each facility Chief or Director, P&LMS is responsible for:

(1) Serving 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) Assuming responsibility for implementation of the quality improvement plan.

(3) Ensuring that there are sufficient qualified personnel with adequately documented training and experience to meet the needs of the laboratory.

(4) Planning and setting goals for the development and allocation of resources appropriate to the medical environment.

(5) Providing effective and efficient administration of the pathology service to include budget planning and control.

(6) Selecting and monitoring all reference laboratories and ATS for quality of service.

(7) Acting as a consultant whenever a non-VA provider is contracted to perform laboratory testing for Veterans at a satellite clinic; this includes providing documentation to ensure the contracted laboratory is CLIA-88 certified and that all test results are entered into Veterans Health Information System and Technology Architecture (VistA).

(8) Establishing a laboratory management data collection system using VistA.

5. REFERENCES

a. Public Laws 100-578 and 102-139.

b. The Public Health Service Act Section 353 (codified at 42 U.S.C. 263a).

c. Title 42 CFR Part 493.

d. Title 38 U.S.C. §§501, 521, 7301(b).

e. Title 38 CFR § 2.6(a)(1).

f. VHA Handbook 1106.01.

6. DEFINITIONS

a. **Ancillary Testing.** Ancillary Testing is laboratory testing performed within and under the administration of the VA medical center, health care system, or its outreach functions (clinics, etc.), but outside the physical facilities of the main clinical laboratory. This includes all laboratory testing sites, such as point of care testing, satellite or specialty laboratories, CBOC testing sites, and Home-Based Health Care (HBHC) when such testing is performed by an VA employee in a patient's home. Ancillary testing includes all laboratory testing sites that fall under the auspices of the main parent facility even when they may be under a separate laboratory director, CLIA registration number, or separate accreditation.

b. **Laboratory Test.** A laboratory test is an examination, diagnostic, or monitoring procedure on a human specimen removed from the body to determine specific information for diagnosis, treatment, or prevention of disease, and to detect the impairment of health status, or to assess the health of human beings.

c. **High Complexity.** High complexity refers to the most complicated laboratory tests, requiring the most rigid testing requirements outlined in the CLIA regulations. Test complexity is determined by the Food and Drug Administration (FDA) according to the criteria outlined in the 42 CFR 493.17. Testing sites performing highly-complex testing must obtain a highly complex CLIA certificate.

d. **Moderate Complexity Testing.** Moderate Complexity Testing is the rating given by the FDA to commercially marketed *in vitro* diagnostic tests based on their risks to public health level. The complexity is determined based on the scoring criteria outlined in 42 CFR 493.17. Testing sites performing moderate complexity testing must obtain a moderately-complex CLIA certificate.

e. **Proficiency Testing.** Proficiency Testing is a program in which samples are periodically sent to a laboratory for analysis in which each laboratory's results are compared with peer laboratories and reported to the participating laboratory and the VA CLIA program.

f. **Specialty Laboratory.** A Specialty Laboratory is a laboratory dedicated to a single specialty of testing or esoteric testing.

g. **Testing Site.** A Testing Site is any location that performs laboratory testing (waived or non-waived) used in the diagnosis, treatment or assessment of patients within the VA healthcare organization and outreach functions. This includes any testing that may occur outside the physical facilities of the main laboratory.

h. **Waived Testing.** Waived Testing is a category of tests defined as simple laboratory examinations. Testing sites performing waived tests must obtain a VA CLIA certificate for minimal complexity.