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1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Programs," Part VI, "Pathology and Laboratory Medicine Service," Chapter 4, "Laboratory Medicine," formerly entitled "VA Special Reference Laboratory for Pathology at the Armed Forces Institute of Pathology, Washington, DC."

2. Principal changes are:

a. Paragraph 4.02: Establishes policy for providing laboratory medicine services in VA medical centers and their outreach functions.

b. Paragraphs 4.03 through 4.11: Establish policy for testing standards for each category of laboratory medicine and ancillary testing sites that perform laboratory medicine tests for patient care.

3. Filing Instructions

Remove pages	Insert pages
15 through 18a	4-i through 4-ii 4-1 through 4-61

4. RESCISSIONS: M-2, Part VI, Chapter 4, Change 68, dated November 1, 1985; and VHA Circulars: 10-64-143, 10-65-159, 10-78-230, 10-79-146, 10-81-100, 10-81-146, 10-84-019, 10-84-114, 10-84-194, 10-85-169, 10-86-121, 10-88-109, 10-89-097, and 10-90-118.

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RESCISSIONS

The following material is rescinded:

1. Manuals

M-2, Part VI, Chapter 4, change 68, dated November 1, 1985.

2. Circulars

10-64-143
10-65-159
10-78-230
10-79-146
10-81-100
10-81-146
10-84-019
10-84-114
10-84-194
10-85-169
10-86-121
10-88-109
10-89-097
10-90-118

CHAPTER 4. LABORATORY MEDICINE

4.01 PURPOSE

The purpose of this chapter is to define the requirements for providing laboratory medicine services for patient care in Department of Veteran Affairs (VA) medical centers and its outreach functions.

4.02 POLICY

a. All VA medical center main clinical laboratories, laboratories in outpatient clinics and VA outreach functions that perform laboratory tests for patient care purposes will provide an adequate number of laboratory medicine sections according to the policies and standards defined in this chapter.

b. The type and number of laboratory sections required in the VA medical center's main clinical laboratory will be determined by the mission of the VA medical center, and special program needs within the VA medical center.

c. This policy establishes standards for VA testing sites, for patient test management, preanalytical testing components (such as standards for positive patient identification, specimen collection and handling, and inventory, and storage of supplies), analytical testing components (such as specifications and standards for method and instrument selection, validation of manufacturers' claims, calibration, preventive maintenance, internal and external quality control, and standardization), and postanalytical testing components (such as verification of test results and electronic data transmission, documentation, utilization review and quality assurance) for Clinical Chemistry, Endocrine Chemistry, Microbiology, Hematology, Coagulation and Special Coagulation, Diagnostic Immunology, Flow Cytometry, Clinical Cytogenetic Services, and Urinalysis.

4.03 CLINICAL CHEMISTRY

a. Clinical Chemistry includes the subspecialties of automated chemistry, special chemistry (including blood gases, and some immunological and routine chemistries), therapeutic drug monitoring, and endocrinology (which includes all radioimmunoassay procedures, if they are performed in the Clinical Chemistry Laboratory). NOTE: Due to its complex and unique requirements, toxicology is defined in a separate chapter (see Ch. 8.).

b. Each VA medical center will have a Clinical Chemistry Laboratory that provides accurate testing and reporting of results.

(1) The guaranteed reliability of laboratory test measurements includes:

(a) Ensuring precision and accuracy of testing,

- (b) Accuracy of reporting,

- (c) Appropriate utilization of Clinical Chemistry information for patient care.

- (d) Obtaining the highest practical degree of uniformity and reliability of chemistry values.

(2) The Department of Veterans Affairs National Center for Laboratory Accuracy and Standardization (VANCLAS), standardization materials will be utilized as they become available for selected analytes. Each testing site that performs clinical chemistry tests for patient care in VA medical centers will utilize manufacturers standards and calibrators in addition to VANCLAS standards. An integral part of VA's Quality Improvement (QI) Program, VANCLAS is a VA clinical resource center that:

a. Facilitates standardization of testing methods in VA. This includes providing timely surveys to assess, monitor, and assist in accuracy of testing, precision and linearity of analytical systems.

b. Provides consultative services for troubleshooting problems associated with the College of American Pathologists (CAP) proficiency testing (PT) surveys and the VANCLAS Standardization Program.

c. Provides education to ensure standardized, accurate and precise chemistry results on measurements of patient specimens in all VA medical center chemistry laboratories.

NOTE: Other QI components include inspection, accreditation, quality control, PT and Total Quality Improvement (TQI) Programs.

(3) All testing sites that provide clinical chemistry services will utilize TQI standards, as outlined in Chapter 2.

(4) The CAP Commission on Inspection and Accreditation will be the primary inspection and accreditation agency for all VA Clinical Chemistry Services.

(5) The most recent and highest level of applicable National Committee for Clinical Laboratory Standards (NCCLS) consensus standards and guidelines for good laboratory practice will be used for technical guidance. NOTE: Supervisory personnel must weigh the cost of following these guidelines against the benefit they offer to improving the quality of test result.

(6) The standards for Clinical Chemistry in VA medical center Pathology and Laboratory Medicine Services will be in accordance with those published in the current edition of Accreditation Manual for Hospitals by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and the CAP Laboratory Accreditation Program Manual.

c. Chemistry Personnel

(1) The Chief, Pathology and Laboratory Medicine Service, is responsible for:

(a) Having a written organizational plan for the Clinical Chemistry Section; and

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(b) Providing for adequate number of qualified personnel, and may, if appropriate, delegate a qualified Chief for the Clinical Chemistry Section.

(c) Providing a written personnel policy.

(d) Following MP-5, Chapter 430, "Performance Management System," to provide performance standards for each employee. NOTE: Each laboratory section supervisor will specify the tests that personnel are qualified to perform.

(e) Providing a functional in-service continuing education program to ensure the educational development of the laboratory's personnel.

(2) The Chief, Clinical Chemistry Laboratory will be a qualified clinical laboratory scientist, or clinical pathologist, who has earned a doctoral degree and has had relevant experience and qualifications in clinical chemistry. NOTE: In a non-affiliated VA medical center, this position may be difficult to fill; The Chief, Pathology and Laboratory Medicine, will provide consultants when necessary to ensure appropriate clinical chemistry operations.

(3) The clinical chemistry supervisor must have work experience, education, and training of a professional quality and scope to perform functions at the grade level for which being considered, and meet the supervisory credentials required by CAP (see Ch. 12).

(4) Medical technologists must have the appropriate educational background to meet the VA personnel qualification standards (see Ch. 12).

(5) Technicians must have the appropriate educational background to meet VA personnel qualification standards, and to perform laboratory tests or procedures according to established and approved protocols. NOTE: These tests are performed directly under the supervision of a qualified technologist, supervisor, Chief, Pathology and Laboratory Medicine Service, or designee (see Ch. 12).

d. Chemistry Facilities. The medical center Director, Chief of Staff, and Chief, Pathology and Laboratory Medicine Service, will ensure that the appropriate space, facilities, and environmental conditions are provided to produce a quality test product in the Clinical Chemistry Laboratory.

(1) The Clinical Chemistry Laboratory shall be constructed, arranged, and maintained to ensure the appropriate space, ventilation, workbench areas, hoods, computers, and other utilities and facilities, to conduct laboratory testing and reporting.

(2) Instruments which are micro-processor driven and are sensitive to electrical current instabilities must be protected from electrical fluctuations and interruptions.

(3) Proper laboratory room temperature (25 degrees \pm 3 degrees Centigrade) and relative humidity (50 percent \pm 15 percent) shall be maintained. NOTE: Some instruments allow \pm 5 degrees variation at room temperatures, and in some States such as, NV, 50 percent humidity \pm 15 percent is virtually impossible.

(4) The Clinical Chemistry Laboratory will conform to all the appropriate health and safety regulations as required by JCAHO, Occupational Safety and Health Administration (OSHA), and other State and local agencies, as appropriate.

e. Chemistry Test Requests

(1) The Chief of Staff shall be responsible for defining the providers who may request laboratory tests. This may include physicians, physician assistants, nurse practitioners, dentists, optometrists, podiatrists and others in the VA medical center who are certified to order tests as noted in the minutes of the VA medical center's Clinical Executive Board (CEB) and the Medical Staff Bylaws.

(2) All testing will only be done at the written request and/or computerized order entry of an authorized provider. Oral requests for laboratory tests will not be honored. NOTE: This will be enforced by the Chief, Pathology and Laboratory medicine Service. At a minimum, the request must include:

(a) The patient's name, Social Security Number (SSN), and the name of the requesting provider;

(b) Location of the patient;

(c) Time and date of specimen collection;

(d) Test(s) to be performed; and

(e) Any additional information that is relevant and necessary to ensure accurate and timely testing, and reporting of results. NOTE: This additional information shall be determined by each VA medical center's CEB, as recorded in the minutes of the CEB and the Medical Staff Bylaws.

(3) Ward clerks and other trained health care personnel may enter test requests for Clinical Chemistry tests through the order entry menu of Decentralized Hospital Computer Program (DHCP) in the VA medical center.

(4) Test requisition forms must be kept for 2 years (see Ch. 2, App. 2C) and the daily collection list will be retained for at least 1 month in the DHCP system. NOTE: Records are to be disposed of in accordance with the Veterans Health Administration (VHA)'s Records Control Schedule (RCS) 10-1.

f. Preanalytical Phase TQI. The Chief, Pathology and Laboratory Medicine Service, shall be responsible for all professional and technical aspects of the Clinical Chemistry Laboratory. This includes policies on preanalytical, analytical, and postanalytical phases of testing. For example, for the preanalytical phase, written standards must be established for:

(1) Patient preparation.

(2) Specimen collection and handling.

(3) Proper maintenance and identification of numbers throughout the entire testing process.

(4) Specimen storage integrity and storage conditions.

(5) Inventory control of supplies.

(6) Other components which will affect the accuracy and reliability of testing of patient specimens in the laboratory.

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(1) Positive Patient Identification. The Chief, Pathology and Laboratory Medicine Service, shall be responsible for establishing policies and procedures to ensure the positive identification of the correct specimen of each patient for Clinical Chemistry testing. As an example, inpatients can be properly identified with a legible hospital identification (I.D.) bracelet (where applicable) containing the patient's name and Social Security Number.

(2) Specimen Collection and Handling

(a) The Chief, Pathology and Laboratory Medicine Service, shall establish a written policy for a specimen collection and handling manual in Clinical Chemistry. This policy shall contain:

1. Clearly written standards of the nature and amounts of specimen to be collected.

2. Any special requirements for timing of collections.

3. Types and amounts of preservatives or anticoagulants.

4. Appropriate containers.

5. Any unique requirements for handling between the time of collection and the time received by the laboratory.

6. Any special patients' preparation procedures.

7. Instructions for proper labeling of containers.

8. Any special need for appropriate clinical data that is to accompany the specimen.

9. Mechanisms for accurate documentation of specimen arrival, the date and time of arrival into the laboratory, and assurance the identity is maintained throughout processing and storage.

10. Clearly written criteria for appropriate specimen integrity, which includes policies on rejection of unacceptable specimens, and, where applicable, interfering substances that cause analytical biases (e.g., medications, anticoagulants, preservatives).

11. Clearly written instructions regarding the handling of sub-optimal specimens and for cancellation of tests, or requests for additional specimens.

12. Defined time limits will be established for each VA medical center for all specimens analyzed so as to provide clinically useful laboratory data for the user and not compromise the integrity of the specimen being measured.

a. A written standard must be established in which all testing will be done in a timely manner, in accordance with clinically useful criteria, by each medical center to ensure quality patient care.

b. A monitoring system to evaluate the adequacy of the turn-around time of the test results must be implemented, evaluated, and documented on a regular basis.

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13. Clearly written instructions for appropriate storage conditions, which will not compromise the integrity of the specimen being analyzed, must be available. NOTE: Tests not done on a routine basis must be properly stored in a refrigerator (at 2 degrees to 6 degrees Centigrade) or non-defrosting freezer (at -20 degrees to -70 degrees Centigrade).

14. Instructions and methods for specimen collection and processing in the main clinical laboratory, nursing stations, operating rooms, emergency areas, outpatient areas, and all phlebotomy stations. These instructions and methods must be prepared using the following NCCLS guidelines:

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a. HI-A3, "Evacuated Tubes for Blood Specimen Collection" (see subpar. 4.12a);

b. H3-A3, "Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture" (see subpar. 4.12b);

c. H18-A, "Procedures for Handling and Processing of Blood Specimens" (see subpar. 4.12c).

d. GP8-P, "Collection and Transportation of Single-Collection Urine Specimens" (see subpar. 4.12d).

e. GP-13-P, "Collection and Preservation of Timed Urine Specimens" (see subpar. 4.12e);

f. T/DM6-P, "Blood Alcohol Testing in the Clinical Laboratory" (see subpar. 4.12f);

g. C27-T, "Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls" (see subpar. 4.12g).

NOTE: Instructions and methods for specimen collection and processing will be available in the main clinical laboratory, at all nursing stations, the operating rooms, outpatient areas, emergency areas, and all VA medical center phlebotomy stations.

(b) The Chief, Pathology and Laboratory Medicine Service, must develop a written specimen collection and identification policy for drugs of abuse testing for patients, which will include:

1. Standards on specimen requirements.
2. Validity of specimen and person.
3. Chain of custody.
4. Security of specimen.
5. Preservation of the confidentiality of the results and the identity of the individual (see Ch. 8.)

(3) Equipment, Reagents and Supplies. The Clinical Chemistry Laboratory must utilize test procedures, instruments, reagents, calibrators, quality control materials and other supplies that provide accurate and reliable test results and test reports. Each item supplied shall be of sufficient quantity and quality to ensure accurate and/or precise laboratory results that are reported in a timely manner.

(a) The Chief, Pathology and Laboratory Medicine Service, shall:

1. Ensure the acquisition, in sufficient supply so as to not compromise the quality of laboratory testing or patient care, of instruments, reagents, calibrators, quality control materials and other required supplies and consumables.

2. Be responsible for defining criteria for acceptable storage conditions for reagents, standards, calibrators, and quality control materials:

- a. The storage conditions must be monitored on a regular basis.
- b. Remedial actions taken to correct conditions that fail to meet the specified standards must be documented, and those records must be kept; records are to be disposed of in accordance with VHA's RCS 10-1.
3. Ensure that reagents, calibrators, and quality control materials shall be of the highest quality, stable with long shelf life, and must provide accurate patient test results that are traceable, whenever possible, to a definitive, reference, consensus or comparative method. NOTE: At a minimum, all materials must be dated upon receipt, when opened or used, and when reagents were prepared, In addition, a label must include the contents of the prepared reagents and an expiration date.
4. Ensure that a written policy on the appropriate labeling of reagents, chemicals, calibrator and quality control materials that meet CAP Laboratory Accreditation Standards. Guidelines for immunochemistry shall include such items as:
 - a. Identity;
 - b. Titer strength, or concentration of, the antibodies, when significant;
 - c. Recommended storage requirements for the antigen;
 - d. Antibodies;
 - e. Calibrators;
 - f. Quality control materials and reagents; and
 - g. Other pertinent information required for proper use.
5. Establish tolerance limits for:
 - a. Water purity,
 - b. Refrigeration,
 - c. Freezer, and
 - d. Room temperature.
6. Ensure that all toxic and biohazardous chemicals and radioactive materials are labeled and stored according to the safety policies and procedures established in the medical center, as well as those in the Pathology and Laboratory Medicine Service Safety Manual.

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a. The Pathology and Laboratory Medicine Service Safety Manual should include policies on hazardous waste disposal, safe work practices, and internal and external disaster preparedness.

b. Guidelines which must be followed include NCCLS:

(1) GP5-T, "Clinical Laboratory Waste Management" (see subpar. 4.12h);

(2) M29-T2, "Protection of Laboratory Workers from Infectious Diseases Transmitted by Blood, Body Fluids and Tissue" (see subpar. 4.12i);

(3) I17-P, "Protection of Laboratory Workers from Instrumentation Biohazards" (see subpar. 4.12j); and

(4) H5-A2, "Procedures for the Handling and Transport of Domestic Diagnostic Specimens and Etiologic Agents" (See subpar. 4.12k).

7. Have written policy and procedures for inventory control. NOTE: The NCCLS GP6-P, "Inventory Control Systems for Laboratory Supplies," guidelines must be adhered to when developing the written policies (see subpar. 4.12l).

(b) Every effort must be made to practice cost-containment without sacrifice of quality of in Pathology and Laboratory Medicine Service. Whenever possible, consideration should be given to regional group purchasing and/or other recommendations of the VA National Center for Cost Containment. NOTE: The guidelines on NCCLS GP11-P, "Cost Accounting in the Clinical Laboratory," must be implemented (see subpar. 4.12m).

(c) The requesting of equipment, materials and other consumables must be accomplished according to the procedures and guidelines of the Integrated Funds Distribution, Control Point Activity (IFCAP), Accounting and Procurement, a function of the VA medical center's Office of Acquisition and Materiel Management.

g. Analytical Phase

(1) Method Selection and Procedure Manuals. The Chief, Pathology and Laboratory Medicine Service, shall have the responsibility of establishing standards and policies for the selection of instruments, test procedures, preventive maintenance schedules and quality control methods that represent the best available technology to ensure accurate and reliable laboratory testing. Each analytical component must be of high quality and cost-effective. This includes appropriate selection of instruments, reagents, procedures, calibrator materials, calibration methods, quality control protocols, and preventive maintenance schedules.

(a) The selected test method must represent currently utilized chemistry procedures, which will ensure reproducible and accurate test results.

(b) The Chief, Pathology and Laboratory Medicine Service, or qualified designee, shall be responsible for:

1. A written procedure for all test methods, using the NCCLS, GP2-A-2, "Clinical Laboratory Procedure Manuals," guidelines. (See subpar. 4.12n.)
NOTE: These guidelines must be present in the testing area(s).

a. As a minimum the written test procedures should contain:

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- (1) The principle of the test,
- (2) Specimen requirements,

- (3) Reagents,
- (4) Calibration frequency and procedure,
- (5) Quality control,
- (6) Test procedure,
- (7) Calculation section,
- (8) Reference range or test results,
- (9) References, and

(10) Any pertinent information such as interferences (endogenous and exogenous) known about the test method. NOTE: The NCCLS C28-P guidelines on "How to Define, Determine, and Utilize Reference Intervals in the Clinical Laboratory," (see subpar. 4.12o.) and NCCLS EP7-P guidelines on "Interference Testing in Clinical Chemistry," (see subpar. 4.12p.) must be utilized.

b. If the appropriate package insert information is not provided by the manufacturer, the laboratory must provide the information. The manufacturer's package inserts cannot be used as the only written procedure, unless they follow the NCCLS GP2-A-2 guidelines (see subpar. 4.12n).

2. Ensuring that each procedure manual is reviewed, approved, signed and dated on an annual basis by qualified supervisory personnel.

3. All technical and procedure manual reviews.

4. Approving, signing and dating each change in a procedure. NOTE: The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance. NOTE: Records are to be disposed of in accordance with VHA's RCS 10-1.

5. Establishing a written protocol for any in-house developed methods, or modified analytical systems, to evaluate the adequacy of the precision, linearity, lower limits of detection, reference, range, and accuracy (whenever possible, with the use of definitive, reference, or comparative method comparison).

a. Criteria for reagent stability, calibration frequency, and appropriate quality control materials must be established.

b. The following references must be used to document acceptability of Clinical Chemistry test methods:

(1) For clinical chemistry methods, the NCCLS EP10-T, "Preliminary Evaluation of Clinical Chemistry Methods," (see subpar. 4.12q).

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(2) For immunochemistry methods, NCCLS:

(a) D12-A, "Immunoprecipitin Assays: Procedures for Evaluating the Performance of Materials," (see subpar. 4.12r).

(b) D13-T, "Agglutination Analyses: Characteristics of Antibody, Methodology, Limitations, and Clinical validation," (see subpar. 4.12s).

(c) D14-T, "Enzyme and Fluorescence Immunoassays," (see subpar. 4.12t).

(d) Analytes measured from analytical test-kit procedures must be FDA (Food and Drug Administration (FDA)-approved and meet the same general guidelines and standards of the analytical system section. Because many kit methods may be manual tests, the precision requirements may exceed a monthly Coefficient of Variation (C.V.) of 5 percent but should not exceed, as a maximum, 20 percent.

(e) The same standards and guidelines for the performance of routine and special Clinical Chemistry tests in each VA medical center apply for all VA Reference Laboratory Services, which includes the Special Clinical Resource Centers (see Ch. 11).

1. The NCCLS H5-A2, "Procedures for the Handling and Transportation of Domestic Diagnostic Specimens and Etiologic Agents," guidelines must be followed for establishing standards and policies (see subpar. 4.12k).

2. All analytic testing referral work must be provided by laboratories, which are licensed by Department of Health and Human Services (HHS), or another accrediting body acceptable to HHS, under the regulations of the Clinical Laboratory Improvement Act of 1988, (see Ch. 11).

6. Reviewing, re-approving, signing and dating all laboratory service policies. NOTE: The Acting Chief, Pathology and Laboratory Medicine Service, shall be responsible in the event the Chief, Pathology and Laboratory Service changes.

(2) Instrument Selection. The Chief, Pathology and Laboratory Medicine Service, shall follow analytical guidelines for selection of analytical instrument systems commensurate with the guidelines of the Director, Pathology and Laboratory Medicine Service has established for VA medical centers of varying size and patient-mix complexity.

(a) For automated routine analytical instruments (including desk-top or alternate-site analyzers), VA medical centers will select only FDA-approved analytical systems.

(b) Selection must be based on documented evidence that the instrument:

1. Has good analytical precision (i.e., a long-term or between-run precision of automated analytical chemistry systems should generally have 5 percent C.V. or less, immunochemical systems 6 to 10 percent, and RIA (Radioimmunoassay (RIA) systems 11 to 15 percent).

2. Is microprocessor controlled to minimize sample manipulation.

3. Does not require frequent calibration and preventive maintenance.

4. Is dependable based on experience of other VA medical centers and private sector laboratories.

(c) Whenever possible, the VA medical center's major, routine automated analytical chemistry systems must be interfaceable to the VA medical centers
DHCP computer

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system. NOTE: The Director, Pathology and Laboratory Medicine Service, must be consulted if there are any doubts about the purchase or lease of an analytical system, especially if it is a new model or from a new vendor that has never been clinically evaluated.

(3) Validation of Test Performance Characteristics. The Chief, Pathology and Laboratory Medicine Service, shall, whenever necessary, be responsible for establishing a policy for validation of test performance characteristics of an analytical system.

(a) All newly purchased analytical systems (including test kits and in-house developed systems) should follow the NCCLS EP 10-T, "Primary Evaluation of Clinical Chemistry Methods," (see subpar. 4.12q.), to validate the performance characteristics on precision, linearity, accuracy or comparability of results, and reference ranges. Potential carry-over, drift, outliers and bias, reagent stability, DHCP computer interfacing, and other functions must be part of the evaluation process using fresh patient specimens as specified in the NCCLS EP 10-T protocol.

(b) For more extensive precision, linearity and accuracy documentation the NCCLS EP5-T, "User Evaluation of Precision Performance of Clinical Chemistry Devices," (see subpar. 4.12u.) and NCCLS EP-9-P, "User Comparison of Quantitative Clinical Laboratory Methods Using Patient Samples," (see subpar. 4.12v.) are the protocols of choice for verification of the method's analytical performance characteristics, and must be followed.

(c) If the analytical system is replacing an existing system, parallel testing must be done to ensure that the same reference ranges can be used. Parallel testing must be used when the lot numbers of reagents, calibrators, or quality control materials are changed.

1. There must be a written protocol which includes the scope and design of the parallel testing and statistical model used to ensure that the accuracy of testing of the patient specimens is not compromised.

2. Records are to be disposed of in accordance with VHA's RCS 10-1,.

(d) The verification of all test methods must include:

1. Precision,

2. Accuracy and linear range,

3. Sensitivity (lower limits of reliable detection in which two analytical points or values are distinguishable), and

4. Whenever possible, analytical specificity, which includes a list of interfering substances.

(e) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications. NOTE: Records are to be disposed of in accordance with VHA's RCS 10-1.

(4) Calibration

(a) To ensure accuracy of testing, a written protocol is necessary, which shall include:

1. Type and number of calibrators to be used;
2. Specifications of the accuracy of the assignment values (target values) of the calibrating materials;
3. Frequency of calibration;
4. Stability of the calibration materials;
5. Appropriate storage conditions; and
6. A protocol and documentation that the patient's specimens are being analyzed accurately and/or precisely.

(b) Stable calibration materials and standards (primary and secondary) with accurate assignment of values must be used.

(c) The laboratory must, as a minimum, follow the schedule recommended by the manufacturer for FDA-approved systems. More frequent calibration may be necessary with some analytes such as blood gases, especially with non-automated instruments and when there are frequent changes in lots of reagents, calibrating and quality control materials.

(d) For in-house developed methods, or systems, the frequency of calibration will depend on scientific data to ensure reliable testing provided by the laboratory.

(e) The Chief, Pathology and Laboratory Medicine Service, shall establish a policy for calibration procedures and methods, which requires each Clinical Chemistry Laboratory to participate and follow VANCLAS guidelines for standardization.

1. The laboratory shall calibrate to the designated definitive, reference, or consensus methods and, if available, reference materials (i.e., from National Institute of Standards and Technology and VANCLAS) to maintain certification in the VANCLAS Program.

2. Verification of accuracy of testing of patient specimens shall be evaluated on fresh, unfrozen materials with assignment values that are traceable to a definitive, reference, or consensus method.

3. For example, VANCLAS has materials available for cholesterol, sodium, potassium, and chloride testing. Laboratories must use this resource to validate their calibration procedure for cholesterol, sodium, potassium and chloride.

4. Whenever inappropriate or inaccurate calibration procedures lead to inaccurate laboratory results, immediate sanctions such as suspension of patient testing will be imposed on the 10 critical analyte(s) (i.e., analytes

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whose inaccurate results endanger the patient's life), which exceed Action Limits as defined in subpar. 4.03 g. (7)(c)8.).

a. There will be no patient care testing of the critical analyte in question until the problem has been identified, corrected, and has met the VANCLAS requirements for satisfactory performance.

b. All other regulated analytes that are not on the critical testing list will result in remedial and educational activities, but no discontinuance of patient testing.

(5) Preventive Maintenance

(a) The Chief, Pathology and Laboratory Medicine Service, shall be responsible for establishing standards and policies for preventive maintenance, and equipment function checks.

1. As a minimum, to ensure optimal function of instruments, the manufacturer's preventive maintenance schedule and function verification checks will be adhered to, documented, and reviewed by a supervisory personnel or designee on a regular interval.

2. All equipment in the Clinical Chemistry Laboratory will have:

a. A schedule and description for instrument and equipment function checks; and

b. A detailed protocol for comprehensive preventive maintenance which will include:

(1) Whom to notify when there is a malfunction,

(2) Completion of down-time report, and

(3) A log book documenting the corrective action taken.

NOTE: The supervisory staff must immediately review daily quality control data to ensure that the instrument and/or equipment is performing to the manufacturer's specifications and is reporting accurate and reliable test results.

(b) The Chief, Pathology and Laboratory Medicine Service, shall be responsible for establishing written standards and policies for preventive maintenance and function checks for thermometers, timers, centrifuge speed, heating blocks, spectrophotometers, photometers, radioactive counters, automated pipettes, glassware cleanliness, water, electrical outlets, and other associated equipment used in the chemistry laboratory. NOTE: It is required that, as a minimum, the standards be set according to the CAP, JCAHO and OSHA guidelines, and the documents be kept; records are to be disposed of in accordance with VHA's RCS 10-1.

1. Log books must be established to ensure equipment and test system overall performance necessary for accurate and reliable test results and reporting for:

a. In-house developed methods, or associated equipment, used for FDA-approved test kits;

b. Standards and policies for preventive maintenance;

c. Frequency schedule; and

d. Equipment function checks. NOTE: All log book data must be kept; records are to be disposed of in accordance with VHA's RCS 10-1.

2. Policies must be written with clearly defined instrument preventive maintenance and function check procedures. The extent and frequency of maintenance and function checks must be clearly defined, meeting the established specifications and

recommendations to ensure accurate and reliable testing. NOTE: All maintenance and function checks performed must be documented and the records must be kept; records are to be disposed of in accordance with VHA's RCS 10-1.

(6) Internal Quality Control

(a) The Chief, Pathology and Laboratory Medicine Service, shall be responsible for:

1. A written policy for quality control for each test method, which should include clearly defined policies, procedures, tolerance limits, corrective action and related information.

2. Establishing standards and policies concerning the quality control program that is practical and effective in preserving quality testing in the Clinical Chemistry Laboratory. The NCCLS protocol C24-A, "Internal Quality Control Testing: Principles and Definitions," must be followed (see subpar. 4.12w).

(b) All internal quality control programs must have a written document for the design and evaluation of the program, and a written protocol in operation to routinely detect significant analytical errors due to instrument malfunction, deteriorated or unsuitable reagents, and/or quality control materials.

1. As a minimum, a two-level quality control material must be used each day for each 8 hours of testing.

2. The quality control materials must be used in the same manner as the patient specimens, and immediate action must be taken along with proper documentation whenever the VA-modified Shewhart-Westgard quality control rules are violated.

3. The quality control results (i.e., DHCP Levy-Jennings chart and Monthly Summary Report) must be actively reviewed (daily, weekly, monthly), initialed and dated by the supervisory personnel each day the test is employed.

4. A monthly summary of the chemistry laboratory's problems (if any) shall be forwarded to the Pathology and Laboratory Medicine Service Quality Assurance Committee for review.

5. All changes in quality control values during the analytical phase must be entered into the control database by laboratory personnel; a summary of the changes must be documented and submitted to the Chief, Pathology and Laboratory Medicine Service, or qualified designee, for review. All quality control records shall be kept; records are to be disposed of in accordance with VHA's RCS 10-1.

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6. There must be complete and detailed documentation of corrective action taken when the control values exceed defined tolerance limits and violate the quality control action rules. A corrective action report must be written for any unacceptable quality control result and be submitted to the Chief, Pathology and Laboratory Medicine Service, or designee, prior to the service's monthly Quality Assurance Committee meeting.

NOTE: If the quality control problem becomes frequent, an in-service continuing education must be provided.

(c) For qualitative tests, quality control will include a positive as well as negative quality control specimens with each batch of analyses.

1. For electrophoresis, at least one control sample containing fractions representative of those routinely evaluated in patient specimens, must be used in each electrophoretic plate.

2. For blood gases (pO₂, pCO₂, HCO₃, pH) measurements, two-level quality control specimens (high and low), as a minimum, must be run every 8 hours. The NCCLS C27-T, "Blood Gas Preanalytical Considerations: Specimen Collection, Calibration and Controls," guideline must be used as the quality control protocol (see subpar. 4.12g).

3. For quantitative radial immunodiffusion and Enzyme-Linked Immunoabsorbant Serum Assay (ELISA) methods, at least two quality control samples must be run with each plate. If immunochemistries, including radioimmunoassays, are employed in the Clinical Chemistry Laboratory, the laboratory must employ a Quality Control Program, which will evaluate all phases of the test system (antigens, antibodies, complement, etc.) to ensure reactivity and uniform dosages when positive and negative controls alone are not sufficient. NOTE: For immunochemistry tests, particular attention should be given to the potency of antibodies when exceeding the expiration date.

(d) Whenever possible, another type of internal quality control should be effected in the form of periodic blind retesting of patient specimens. Depending on the critical nature of the tests, specimens from the previous day's run should be resubmitted for re-analysis to ensure accuracy, repeatability and reliability of the analytical testing process. There must be defined acceptable limits, which must be reviewed and documented, in a timely manner, by the Chief, Pathology and Laboratory Medicine Service, or qualified designee.

(e) The Chief, Pathology and Laboratory Medicine Service, must have a written policy for extending the expiration date of reagents, calibrators, quality materials, and other consumable materials without compromising patient care.

1. Particular attention should be given to any abrupt changes in quality control results should they occur when the reagent(s), calibrator(s), or quality control material(s), exceed the expiration date.

2. In general, all out-dated materials (which includes reagents, calibrators, standards, quality control materials and other consumables) must not be used for patient testing unless authorized by the Chief, Pathology and Laboratory Medicine Service, or designee.

3. If the materials are kept beyond the expiration date, it is recommended that the laboratory has a testing method defined to determine the

acceptability of the materials without sacrificing the clinical usefulness of the test. The following NCCLS guidelines must be followed:

a. D12-A, "Immunoprecipitin Assays: Procedures for Evaluating the Performance of Materials," (be used to evaluate performance of materials used in immunoprecipitin analyses) (see subpar. 4.12r);

b. D13-T, "Agglutination Analyses: Characteristics of Antibody, Methodology, Limitations, and Clinical Validation" (see subpar. 4.12s);

- c. D14-T, "Enzyme and Fluorescence Immunoassays;" (see subpar. 4.12t); and
- d. LA1-A, "Assessing the Quality of Radioimmunoassay Systems" (see subpar. 4.12y).

4. Whenever possible, another type of internal quality control should be instituted in the form of periodic blind retesting of patient specimens. Depending on the critical nature of the tests, specimens from the previous day's run should be resubmitted for reanalysis to ensure accuracy, repeatability, and reliability of the analytical testing process. There must be defined acceptable limits reviewed and documented, in a timely manner, by the Chief, Pathology and Laboratory Medicine Service, or qualified designee.

(7) External Quality Control. Each VA medical center Clinical Chemistry Laboratory must have an established external Quality Control Program to ensure reliability of patient testing in the laboratory, and to maintain accreditation requirements.

(a) All VA medical center Pathology and Laboratory Medicine Services will jointly participate in both the VANCLAS PT Standardization and Certification Program and the CAP PT Program.

(b) All laboratories will participate in the CAP's PT Program to meet the following goals:

1. Assessment of Clinical Chemistry Laboratory testing performance for those analytes for which no VANCLAS Program exists (i.e., serum enzymes).

2. Documentation for the CAP and JCAHO for accreditation purposes.

(c) For those regulated analytes evaluated by the CAP PT Surveys Program, for Clinical Chemistry, the following grading criteria will be followed:

1. The testing site must attain at least 80 percent of acceptable responses (four out of five specimens in each survey) for each graded analyte in each CAP survey challenge to be considered satisfactory performance (see Analyte Testing Event score in subpar. 4.03 g.(7)(d)).

2. Also, 80 percent of the graded analytes in each survey challenge (overall Testing Event Score, see subpar. 4.03 g.(7)(e)) must have a satisfactory score.

3. Failure to achieve either 80 percent score or failure to achieve satisfactory performance for the same graded analyte in two consecutive testing events or two out of three consecutive testing events is considered unsuccessful performance.

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4. Failure to achieve an overall testing event score of 80 percent or better for two consecutive survey challenges, or two out of three consecutive survey challenges, is also considered unsuccessful performance.

5. Failure to participate in any particular survey challenge or failure to submit results on any particular graded analyte, will result in a zero score for the testing event and particular analyte being graded.

NOTE: Consideration will be given to the laboratory testing site if it has participated in the previous two PT survey challenges and has documentation that the issue(s), or

problem(s), have been subsequently resolved; and has documentation that the assay method is generating accurate patient results.

6. If the CAP PT challenges are not acceptable for any laboratory analyte performance or testing event (for reasons other than a failure to participate), VANCLAS will be notified of the unacceptable performance. Immediate interaction between VANCLAS and the laboratory will take place to identify and correct the problem concerning the analyte in question. The laboratory testing site will be challenged with five pools of reference material specimens within 5 working days to verify that the problem has been corrected. NOTE: The VANCLAS staff will provide appropriate training to ensure that satisfactory performance can be demonstrated.

7. The criterion for acceptable performance for qualitative routine Clinical Chemistry tests is positive or negative.

8. The criteria for acceptable performance (percentage from definitive or reference value) for the graded analytes in routine Clinical Chemistry shall be the following:

YEAR 3	TEST	YEAR 1	YEAR 2
1.	Albumin*	± 10 percent	± 5 percent
2.	Alk Phos	± 30 percent	± 30 percent
3.	ALT	± 20 percent	± 20 percent
4.	Amylase	± 30 percent	± 30 percent
5.	AST	± 20 percent	± 20 percent
6.	Bili, Total*	± 25 percent	± 10 percent
7.	pO2*'	± 6 mm Hg	± 6 mm Hg
8.	pCO2*'	± 5 mm Hg	± 5 mm Hg
9.	pH*'	± 0.04	± 0.04
10.	Calcium*'	± 10 percent	± 10 percent
11.	Chloride*	± 5 percent	± 5 percent
12.	Cholesterol*	± 3 percent	± 3 percent
13.	CK, Total	± 30 percent	± 30 percent

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14. CK, MB iso-
enzyme*'

MB elevated
or

MB elevated
or
 $\pm 3SD\pm$

MB elevated
or
3SD

$\pm 3SD$

*VANCLAS Standardization Program

Criteria (Continued)

YEAR 3	TEST	YEAR 1	YEAR 2
15. Creatinine*'	± 10 percent	± 10 percent	± 7 percent
16. Glucose*'	± 10 percent	± 10 percent	± 7 percent
17. Glycated Hb*'	± 15 percent	± 15 percent	± 10 percent
18. HDL-Chol*	± 15 percent	± 15 percent	± 10 percent
19. Iron, Total	± 20 percent	± 20 percent	± 10 percent
20. LDH, Total	± 20 percent	± 20 percent	± 20 percent
21. LDH, Iso-enzyme	LDH 1/2 or ± 20 percent	LDH 1/2 or ± 20 percent	LDH 1/2 or ± 20 percent
22. Magnesium*'	± 20 percent	± 20 percent	± 10 percent
23. Potassium*'	± 10 percent	± 10 percent	± 5 percent
24. Protein, Total*	± 10 percent	± 10 percent	± 5 percent
25. Sodium*	± 3 percent	± 3 percent	± 2 percent
26. Triglycerides*	± 20 percent	± 20 percent	± 10 percent
27. Urea nitrogen	± 8 percent	± 8 percent	± 5 percent
28. Uric Acid*	± 15 percent	± 15 percent	± 10 percent

*VANCLAS Standardization Program

'Critical tests (± 3SD of a laboratory's customary performance for action limits).

(d) To determine the ATE (Analyte Testing Event) score, the following formula will be used:

$$X \quad 100 \quad \text{ATE} = \frac{\text{Number of Acceptable Responses or the Analyte}}{\text{Total Number Analyte Challenges}}$$

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(e) To determine the OTE (Overall Testing Event) score, the following formula will be used:

$$X \quad 100 \quad \text{OTE} = \frac{\text{Number of Acceptable Responses for all Challenges}}{\text{Total Number of ALL Challenges}}$$

NOTE: Whenever possible VANCLAS will use fresh, unfrozen human specimens to eliminate any matrix effects of processed materials so as not to compromise the accuracy of testing during the standardization process.

(8) Standardization and Certification. The VANCLAS and CAP Programs are independent; however, both ensure accuracy of testing of patient specimens.

(a) The goals of the VANCLAS Program are to:

1. Provide PT Programs and materials to standardize clinical chemistry test methods to ensure accuracy of patient testing.

2. Provide technical assistance for unacceptable performance in the VANCLAS Standardization and Certification Program,

3. Develop remedial and educational programs for laboratory staff and personnel,

4. Provide assessment and technical expertise for CAP Survey Exception Reports.

(b) In the VANCLAS Standardization and Certification Program, each laboratory shall participate, as a minimum, in the two challenges (six fresh, unfrozen specimens) per year, which will serve as a means of assessing precision, linearity, and accuracy for those analytes with scientifically accepted definitive, reference, comparative or consensus methods.

(c) The "fixed limit" acceptance criteria will be used. VANCLAS standards must used as a working model for other analytes undergoing standardization. For example:

1. For the total cholesterol, the reference method values, assigned by the Centers for Prevention and Disease Control (CDC) Lipid Standardization Section serves as the target values for the specimens used in the VANCLAS Cholesterol Standardization and Certification Program.

2. The acceptable limits of performance is ± 3 percent or less from target value (the average overall bias), which will be used to evaluate the VA medical center laboratories.

3. If the overall bias exceeds 3 percent on two consecutive challenges (minimum of every 6 months), the laboratory will be asked to identify the problem and the VANCLAS will provide the technical support and interact with the local laboratory to identify and correct the problem.

4. For the standardization of the other analytes (presently with the exception of enzymes) target values will be determined with accepted definitive or reference methods. All other methods will use comparative, or consensus method values, to standardize all VA laboratories to achieve uniformity of reporting and achieve interlaboratory comparison, regardless of peer group.

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5. Each VA medical center's successful participation in the VANCLAS Program will serve as the bases for accuracy of testing of patient materials. In the event that unacceptable results are found with the CAP PT Survey Exception Reports with laboratories in good standing in the VANCLAS Standardization and Certification Program, the VANCLAS Program will supersede until sufficient data can be provided to indicate that no matrix effects are observable with CAP PT materials, and the accuracy base can be transferred to CAP PT Survey materials.

6. Those VA laboratories who fail the VANCLAS program on the critical tests presently listed in subparagraph 4.03g.(7)(c)8., shall suspend testing for the analyte in question until the problem is resolved, and the laboratory has demonstrated to VANCLAS that accuracy of testing is not compromised.

a. Failure of the laboratory to meet acceptable performance for those analytes in which the outcome of inaccurate testing (present tolerance limits = Target Values \pm 3 SD for that particular laboratory's customary performance) is detrimental, and critical, to patient care will lead to:

(1) Remedial action by the Director, Pathology and Laboratory Medicine Service.

(2) Immediate interaction between VANCLAS and the laboratory to isolate and correct the problems(s). Within 5 working days, the laboratory will be challenged with six pools of fresh human specimens to verify that accuracy of testing is ensured.

(d) The successful implementation of standardization of cholesterol sodium, potassium and chloride measurements within VHA (Veterans Health Administration) medical centers, will be extended to other regulated analytes in the future as more definitive/reference methods are developed.

h. Postanalytical Phase TQI

(1) Verification of Test Results. The Chief, Pathology and Laboratory Medicine Service, must establish written standards and policies for verification of reported test results that are timely accurate, reliable, clear and are retained on the patient's chart, or other acceptable locations, that allow clinical staff easy access to test results.

(a) The standards shall include a review policy to detect;

1. Clerical errors,

2. Methods of documentation and tracking of errors,

3. Follow-up procedures for correction of errors, and

4. Remedial measures, such as in-service continuing education.

(b) The Chief, Pathology and Laboratory Medicine Service, must:

1. Establish a written policy on the mechanism of manual data review procedures.

2. Ensure that all laboratory data are verified before they are available to physicians or clinical providers.

3. Ensure that the laboratory test results that are acceptable for release are verified by qualified laboratory personnel.

4. Effect a policy to indicate the initials, or signature, of the person(s) performing each test.

5. Have a written protocol for all internal quality control programs in operation to routinely detect:

a. Clerical errors, and

b. Unusual laboratory results, which include critical values.

6. Have a mechanism in effect to provide for timely correction of errors.

7. Review the data to verify the accuracy of the manual data input and automated data transfer.

a. If an error is found on a released patient result, the appropriate designee will communicate immediately with the physician, or other authorized person, in charge of the patient. The Chief, Pathology and Laboratory Medicine Service, or designee, will correct the report in the computer system, which will prompt a corrected report. Both corrected and incorrect results will automatically become part of the patient's permanent record.

b. This review process must be documented in the laboratory's TQI program, and a summary must be included as part of the Clinical Chemistry Unit's Quality Improvement Report.

8. There shall be a written policy and standards for the laboratory personnel to respond to "panic values" or test values which may be life-threatening to the patient even if the original request for the test was not ordered "STAT". For example, the Chief, Pathology and Laboratory Medicine Service, may have a policy to repeat the test, then notify the physician or authorized personnel of the panic value by telephone.

a. The person performing the test(s) is required to:

(1) Recheck the results and immediately call the patient's physician, nurse, or ward personnel, for all panic values; and

(2) Indicate in the computer in the "comment" section the person they communicated the information to, the analyte in question, the time, and any other pertinent information for documentation.

b. There shall be documentation as to:

(1) Identification of the laboratory personnel calling the appropriate provider, nurse or authorized person;

(2) Person receiving the call;

(3) Contents of the transaction of the call; and

(4) Date and time.

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c. The Chief, Pathology and Laboratory Medicine Service, or qualified designee, shall be responsible for a regular review of this process to ensure that the policies and standards are being implemented on all critical values.

(2) Review of Electronic Data Transmission

(a) The Chief, Pathology and Laboratory Medicine Service, shall establish written policies and develop programs so that the DHCP computer system will check the entered data against predefined limits for some tests, such as when high, low and critical values are identified. Entries outside of the specified ranges will not be accepted.

(b) Previous patient test results should be displayed and a delta check performed. All significant changes must be identified by an audible "beep" and a visual "flag" observed next to the test values.

(c) Any unlikely test values, regardless of the quality control results, must be verified by other existing methods and the Chief, Pathology and Laboratory Medicine Service, must be notified.

(d) All errors must be documented.

(e) Any software changes from the manufacturer for test procedures must be documented and kept; records are to be disposed of in accordance with VHA's RCS 10-1.

(3) Quality Assurance and Utilization Management. All laboratory test results must be carefully reviewed for accuracy of reporting by qualified laboratory personnel before verification. After verification, the data are released to the physicians and wards. Records will be retained and will be able to be promptly retrieved for use by clinical and laboratory staff; records are to be disposed of in accordance with VHA's RCS 10-1.

(a) Responsibilities of the Chief, Pathology and Laboratory Medicine Service. The Chief, Pathology and Laboratory Medicine Service, must:

1. Develop a written policy, for all problems identified in the production of test results that could cause injury to patients, that establishes standards, a plan of action, and dissemination of these to the clinical staff.

a. The written document must specifically contain standards, procedures, and policies for effective detection of potential errors before the verification of laboratory results.

b. The instructions should be especially clear for:

(1) Specific problems, such as detection of clerical errors in general;

(2) Who is authorized to enter corrected results;

(3) Methods of documentation and tracking;

(4) Follow-up procedures for correction of errors;

(5) Remedial measures such as in-service continuing education; and

(6) Who should be notified of errors in the event that it affects or alters the outcome of the diagnosis, treatment, or any other medical decision, regarding the care of the patient.

c. The policy must contain plans for continuing improvements in the quality of laboratory testing and patient care.

d. A plan for evaluation of test ordering and utilization must be established.

NOTE: Cost effective approaches to laboratory testing must be part of this program.

2. Develop programs to monitor and evaluate utilization of physiologically abnormal test results by clinical providers for patient care activities within each medical center.

3. Be responsible for adhering to the standards on Quality Management provided in chapter 2.

4. Establish a quarterly utilization review program for appropriate laboratory test and resource utilization.

(b) Regular Review

1. A planned meeting on a regular basis must be developed to review:

a. All complaints from the providers and users of laboratory test results;

b. Laboratory errors; and

c. All documented remedial actions taken.

2. As part of this monitoring process, test turn-around time, laboratory safety issues, appropriate test utilization, accuracy and reliability of the reporting system should also be included.

(c) Monthly Review. Whenever laboratory quality control rules are violated, when laboratory errors are consistently committed, or when the laboratory fails to pass the acceptable tolerance limits for the VANCLAS or CAP PT Programs, this shall result in remedial measures, documentation and a written report to the Pathology and Laboratory Service Quality Improvement Committee for review on a monthly basis.

(d) In-service Education. The Chief, Pathology and Laboratory Medicine Service, is responsible for developing provisions for in-service education for laboratory personnel designed to:

1. Update and enhance the technical skills of the technicians and technologists;

2. Aid in troubleshooting abilities; and

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3. Strengthen deficiency areas in general laboratory and VANCLAS and CAP PT Programs.

NOTE: Participation in formalized educational programs such as CAP Q-Probes and American Society for Clinical Pathologists (ASCP) Check Sample are recommended.

4.04 ENDOCRINE CHEMISTRY

a. Access to Diagnosis and Monitoring. Each VA medical center's Pathology and Laboratory Medicine Service must provide service, or access, to the diagnosis and monitoring of endocrine disorders to serve the needs of the VA medical center's patient case type and mix. Tests must be of a quantitative analytical nature performed by radiometric or nonradiometric technique; quality control parameters will be appropriately applied.

b. Accessioning and Examination of Specimens. Specimens will be accessioned and examined for conformance to specimen requirements. Specimen rejection is to be documented and the report of rejection, with reason, included in the DHCP.

c. Reports and Retention of Specimens

(1) Reports will be retained in the DHCP.

(2) Specimens are saved in a fashion that best facilitates the needs of the laboratory, for example, refrigeration of all excess blood until completion of the analysis, and for at least 1 week after verification of results.

d. Use of Specimens for Scientific/Research Purposes. Specimens that are submitted for analytical testing shall not be used for research purposes unless the research protocol has been subjected to the scrutiny of, and approval of, the medical center's Human Research Review Board.

e. TQI

(1) An overall program in quality improvement will be established in each VA medical center laboratory with a PT Program, and quality control as described in Chapter 2.

(a) The endocrine laboratory must engage in formal quality improvement studies to include:

1. Investigation and interventions that seek to identify problems in test utilization.

2. Specimens and their transport.

3. Analytical testing.

4. The distribution, or effective utilization, of test results.

(b) These studies are documented and reported, for review and approval, to the TQI committee of the laboratory and the TQI committee of the VA medical center.

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(2) Different laboratories are subject to different sets of problems; therefore, these elements of quality assurance shall be individualized to the needs of the VA medical center.

(3) VA consultants named by the Director, Pathology and Laboratory Medicine Service, VA Central Office, will share with other VA laboratories their TQI Programs as examples that may be useful for incorporation in other laboratory settings.

(4) Successful quality assurance is a program that fully meets the requirements of the JCAHO, CAP and VANCLAS.

f. PT in Endocrinology. The PT Program employed by the endocrine laboratory must provide challenges for assays which the laboratory currently performs.

(1) There will be at least three testing events at approximate equal intervals per year. There will be at least five samples per event.

(2) Approved PT Programs include those that are offered by national accreditation bodies. Unapproved programs will not be accepted for utilization by VA laboratories. The Director, Pathology and Laboratory Medicine Service, in conjunction with expert VA chemists, will determine which programs meet the VA's needs (see subpar. f(6)).

(3) In order to pass a PT the laboratory testing site must determine the correct response for each analyte by the distance of the response from the target value. This must be determined by using either fixed criteria based on the percentage difference from the target value or the number of standard deviations (SD) the response differs from the target value.

(4) The criteria for acceptable performance are:

Analyte or Test Performance	Criteria for Acceptable
(a) Cortisol	Peer group mean +/- 25 percent
(b) Free Thyroxine	Peer group mean +/- 3SD
(c) T3 Uptake	Peer group mean +/- 3SD
(d) Triiodothyronine	Peer group mean +/- 3SD
(e) TSH	Peer group mean +/- 3SD
(f) Thyroxine	Peer group mean +/- 3SD
(g) HCG	Peer group mean +/- 3SD Positive or Negative

NOTE: Peer group mean and Target Value may be synonymous terms.

(5) When a laboratory testing site fails to achieve the 80 percent pass rate, it may elect to consult with the VA expert consultant on those items in which it has failed. Such a consult will provide outside perspective, training, suggestions, and/or procedural changes that will allow the laboratory to improve its performance.

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(6) When a laboratory testing site has failed twice in a row, such a consult is mandatory. The consultant will introduce changes that will assist the laboratory in improving its performance. The consulting VA expert advises the Director, Pathology and Laboratory Medicine Service, VA Central Office, regarding the continuance of testing by the involved laboratory.

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g. Quality Control in Endocrinology. The design of each VA medical center's quality control program depends upon the laboratory's complexity level, mode of operation and unique needs:

(1) Written procedures must specify the appropriate quality control steps for reagents and devices.

(2) Quality control limits must be established and clearly recorded. When quality control measurement parameters fall outside these limits, there must be specific instructions about the restrictions on test results reporting, notification of supervisor, or other appropriate responses.

(3) All quality control activities must be documented. There must be evidence of a monthly (at a minimum) review of this documentation with details on intervention activities, both short and long-term, relevant to the problems encountered.

(4) Quality control records shall be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

(5) Preventive maintenance records shall be maintained beyond the life of the applicable instrument; records are to be disposed of in accordance with VHA's RCS 10-1.

4.05 MICROBIOLOGY

a. General Policy for All Microbiology Sections. Each VHA medical center's Pathology and Laboratory Medicine Service will provide laboratory services for the diagnosis and monitoring of infections to meet the needs of the center's patient case type and mix.

(1) The Microbiology Laboratory shall comprise one, or more, of the subspecialties of bacteriology, mycobacteriology, mycology, parasitology and virology, depending on VA medical center case mix and type, and the medical center's complexity level.

(a) Where tests of a quantitative analytical nature, resembling chemical analysis, are done in this section, e.g., antibiotic levels with quantitative analytical methods, the TQI parameters of Chemistry will be appropriately applied (see subpars. 4.03 f,g, and h).

(b) Where microbiologic tests are performed in other sections or services, the TQI parameters described in subparagraph 4.05a.(4), are applicable. NOTE: Since other government agencies have removed the aerobic actinomycetes from the Mycology category and placed them in Bacteriology, VA medical center laboratories will comply with this change.

(c) *Pneumocystis carinii* provisionally remains in the Parasitology subspecialty although examinations for this agent may also be conducted in

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Anatomic Pathology and the agent is potentially reclassifiable as a fungal agent. This convention is merely to conform with current PT formulations.

(d) The detection and identification of parasites in tissue sections will be under the purview of the surgical pathologist, following the histopathology procedures outlined in Chapter 6.

(e) In all cases, testing sites that perform Microbiology tests will follow quality improvement polices and standards in Chapter 2.

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(2) Accessioning and Examination of Specimens. Specimens shall be accessioned and examined for conformance to specimen requirements (see Ch. 2), with specimen rejection documented and the report of rejection, with reason included, retained as an official laboratory report; records are to be disposed of in accordance with VHA's RCS 10-1.

(3) Microbiology Reports and Retention of Specimens

(a) Requirements for Microbiology reports, with work documentation included, shall follow policies established in Chapter 2.

(b) Specimen, preservation, and retention requirements will follow the policies described in Chapter 2.

(4) TQI in Microbiology. An overall program in TQI will be established in each Microbiology testing site with a program of PT and quality control.

(a) The Microbiology testing site must engage in formal quality assurance studies, investigations and interventions that seek to identify problems in utilization, in specimens and their transport, analytical testing, and in the distribution, or effective utilization, of test results.

(b) These studies must be documented and reported to the TQI committees of the laboratory and medical center for review and approval.

(c) Different laboratories are subject to different sets of problems; therefore, these elements of quality improvement shall be individualized to the needs of each VA medical center.

(d) VA expert consultant microbiologists, named by the Director, Pathology and Laboratory Medicine Service, VA Central Office, will share with other VA laboratories, TQI Programs as examples that may be useful for incorporation into facility laboratory testing site settings.

(e) Successful quality improvement programs fully meet the requirements of the JCAHO and CAP Laboratory Accreditation Programs.

(f) All Microbiology Laboratory testing sites and their subsections will be inspected by CAP.

(5) PT in Microbiology. The PT Program employed by the Microbiology testing site must provide challenges in each of the subcategories of microbiology for which the laboratory testing site currently performs detection, isolation, and/or identification. The extent of the service in the subspeciality will determine what the program content of the PT shall involve. The frequency of testing and the number of challenges per test sequence shall, at a minimum, conform as follows:

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(a) Approved PT Programs include those that are administered by national accreditation bodies. Unapproved programs will not be accepted for utilization by VA laboratories.

(b) In order to pass a proficiency test, the Microbiology testing site must score at least 80 percent correct for each of the tests in the subspecialty. When a testing site fails to achieve the 80 percent pass rate, it may elect to consult with the VA expert consultant on those items in which it has failed. Such a consultant will provide outside

perspective, training, suggestions, and/or procedural changes that will allow the laboratory to improve its performance.

(c) When the laboratory has failed twice in a row in a subspecialty, such a consult is mandatory. The consulting VA expert microbiologist will introduce changes to assist the laboratory in improving its performance. The consulting VA expert microbiologist advises the Director, Pathology and Laboratory Medicine Service, VA Central Office, regarding the continuing of testing by the involved laboratory microbiology subspecialty.

(d) The Chief, Microbiology, will appoint a qualified technologist to assume the responsibility to:

1. Ensure that all PT procedures are carried out based on protocols established by CAP and JCAHO.

2. Ensure that answers are reported within the established time limits.

3. Ensure that appropriate corrective actions are taken for any unacceptable performance by the testing site.

4. Establish and evaluate quality improvement monitors.

5. Recommend appropriate corrective actions and follow up to ensure that all out-of-control practices included in the monitors are brought back in control.

6. To provide and maintain up-to-date accurate records of all these proceedings.

(6) Quality Control in Microbiology. The design of each VA medical center's Quality Control Program depends upon the laboratory's complexity level, mode of operation and unique needs. Written procedures must specify the appropriate quality control steps for media, reagents and devices.

(a) Documentation. Quality control limits must be established and clearly recorded. All quality control activities must be documented. There must be evidence of review of this documentation at least on a monthly basis, with details of intervention activities, both short-term and long-term, relevant to the problems encountered.

1. When quality control measurement parameters fall outside these limits, there must be specific instructions about the restrictions on test results, i.e., reporting, notification of supervisor, or other appropriate responses.

2. Quality control records shall be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

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3. Preventive maintenance records shall be maintained beyond the life of the applicable instrument; records are to be disposed of in accordance with VHA's RCS 10-1.

(b) Media

1. Media must be checked for:

a. Sterility,

- b. Growth support, or inhibition of, relevant microbiota; and
- c. Biochemical reactions critical to their applications.

2. Alternatively, the laboratory may employ and document the manufacturer's control checks of media performance if the package insert specifies that these control checks meet the NCCLS standards for media quality control, and if they document the physical characteristics of the media are not evidently compromised.

(c) Stains. Stains must be checked each day of use, unless otherwise specified, for intended reactivity. Fluorescent antibody stains are checked with positive and negative controls each time of use, unless otherwise specified.

(d) Reagents, Tests and Systems

1. The laboratory must check each lot and/or shipment for positive and negative reactivity, as well as graded reactivity if applicable.

2. FDA-approved microbiology devices are subject to the quality control checks specified in the package insert.

(e) Reference Collection and Reference Materials The laboratory must have an in-house and on-the-bench, reference collection suitable for performance of its tasks. The bacteriology laboratory shall have the latest edition of M100-S3, Performance Standards for Antimicrobial Susceptibility Testing, published by NCCLS, (see subpar. 4.12y), and at least one of the general clinical microbiology manuals, e.g., Clinical Microbiology Procedures Handbook or Manual of Clinical Microbiology (American Society for Microbiology), Koneman et al, Color Atlas and Textbook of Diagnostic Microbiology (Lippincott), Baron, et. al., Bailey and Scott's Diagnostic Microbiology (Mosby) or Diagnostic Procedures for Bacterial Infections (American Public Health Association)).

(f) Checks

1. Each day of use, the laboratory will check for positive and negative reactivity with control organisms: Catalase, coagulase, beta-lactamase, oxidase, gene probes.

2. Each week of use, the laboratory will check gram and acid-fast stains, bacitracin, optochin, ONPG and X, V and XV reagents for positive and negative reactivity with relevant organisms.

3. Each month of use, the laboratory will check antisera for reactivity with relevant organisms or antigens.

(g) Antimicrobial Susceptibility. Antimicrobial susceptibility testing methods will conform to the most recent guidelines of NCCLS. The selection of antibiotics for testing and reporting shall conform, with exceptions to the NCCLS guidelines being documented and the reasons given.

1. The laboratory will utilize reference strains of control organisms obtained directly from the American Type Culture Collection (ATCC), or a commercial source, so that the strain number can be verified.

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2. New lots of media, discs, or testing systems, will be checked for performance parameters according to the NCCLS guidelines or manufacturer's specifications before, or concurrent with, initial use.

3. Appropriate control organisms will be employed each day of use for an antimicrobial susceptibility test, with reporting limited to those antimicrobials that are within control limits.

4. Maintenance of control strains shall involve the freezing of newly obtained control strains in multiple individual containers at time of receipt so that no strain is subcultured continuously for greater than 6 weeks. This is done to avoid genetic drift and sub-selection of altered clonal varieties.

(h) Aerobic Actinomycetes. For identification of aerobic actinomycetes, each time of use, hydrolysis agars shall be checked with negative and positive organisms. Partial acid fast stains must be checked with sputum seeded with positive (*Nocardia* grown on 7H11, in skim milk or other acid-fast promoting medium) and negative (*Streptomyces*) organisms.

b. Mycobacteriology. The laboratory must have an in-house and on-the-bench reference collection suitable for its level of service. The Mycobacteriology Laboratory must have the latest edition of the Manual of Clinical Microbiology (American Society for Microbiology), or its equivalent, and the latest edition of the relevant Centers for Disease Control Mycobacteriology Handbook, Public Health Mycobacteriology; A Guide for the Level III Laboratory or Procedures for the Isolation and Identification of Mycobacteria. NOTE: Both are available from the Department of Health and Human Services, U.S. Government Printing Office.

(1) Each day of use, the laboratory must check all reagents and media used for identification with at least one acid-fast organism that produces a positive reaction, and with an acid-fast organism that produces a negative reaction, and an uninoculated medium or reagent control when appropriate.

(2) Each day of use, the laboratory must check fluorochrome and general acid-fast stains for positive reactivity. Where low level contamination of water supplies used for stain and rinse fluids is a problem, e.g., fluorochrome stains, the laboratory must employ appropriate negative controls, or use filtered water (0.2 um filters), in the staining process.

(3) Each time susceptibility tests are done on mycobacteria, the laboratory must check the procedure and reagents with a strain of mycobacterium that is susceptible to all the antimycobacterial agents tested.

(4) Control cultures should consist of ATCC Type Strains of each species used, e.g., *Mycobacterium tuberculosis* ATCC 27294, *Mycobacterium intracellulare* ATCC 13950, and *Mycobacterium gordonae* ATCC 14470.

c. Mycology. The laboratory must have an in-house and on-the-bench reference collection suitable for its level of service. For the routine

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mycology laboratory, a minimal requirement is the most recent edition of the Manual of Clinical Microbiology, (American Society for Microbiology), or its equivalent.

(1) Each day of use, the laboratory that uses auxanographic media for nitrate assimilation must check the nitrate reagent with a peptone control. Each time of use

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Calcufluor stains, Trichophyton agars, hair penetration samples and germ tube tests shall be checked with a positive control.

(2) Each week (or time, if less frequent than weekly) of use, the laboratory must check other reagents used with biochemical tests for mycological identification with an organism that produces a positive reaction.

(3) Each day of use the laboratory shall test each drug for performance in antimicrobial susceptibility tests, using an organism(s) that will ensure the reactivity of the antimicrobial agent, using established control limits that are applied according to a prescribed report/do not report scheme.

d. Parasitology

(1) Parasitology is a subspecialty within clinical microbiology that is included under the broader speciality of clinical pathology. VA medical centers will provide parasitology services at one, or more, of three levels of activity depending on the VA medical center's level of training and expertise in parasitology:

(a) Level one. Processing of specimens only, providing for means of preservation and appropriate packaging for shipment to a reference laboratory;

(b) Level two. Procedures for determining by direct microscopic examination the presence or absence of parasites in fresh clinical materials including transparency tape pinworm preparations and specimens preserved in polyvinyl alcohol (PVA), sodium acetate formalin (SAF), merthiolate-iodine-formalin (MIF), or equivalent;

(c) Level three. Complete identification of parasites using concentration techniques and/or permanent stained smears of fecal specimens, and the detection of circulating parasites in stained blood films, and detecting parasites in extraintestinal specimens including sputum, urine, body fluids, and in-touch preparation of tissue biopsies.

NOTE: The detection and identification of parasites in tissue section will be under the purview of the surgical pathologist following the histopathology procedures outlined in Chapter 6.

(2) The section Chief of the Microbiology Laboratory, will:

(a) Be responsible for the overall supervision of all practices and procedures used in the parasitology laboratory.

(b) Serve as the final arbitrator for the identification of any parasitic forms that are in doubt or controversial.

(c) Be responsible for the certification and documentation of all credentials of the professional and technical staff.

(d) Be responsible for seeing that programs for quality control are in effect at all times.

(e) Ensure appropriate quality assurance monitors are in place.

(f) Ensure that standards are met.

(g) Ensure that appropriate corrective actions taken.

(3) Standards for parasitology are in accordance with those published in the current edition of the Accreditation Manual for Hospitals, by JCAHO. The VA medical center must maintain a mandated centralized contract with CAP for regularly scheduled inspection of all laboratory services to ensure continuing accreditation of microbiology services including the parasitology subsection.

(4) Requirements for accessioning and examination of specimen reporting of results include:

(a) All parasitology specimens submitted to the laboratory must be properly identified with legible information as to:

1. Name of patient;
2. Patient's Social Security Number (SSN);
3. Hospital identification number;
4. In-hospital location (or address if an outpatient);
5. Name and address of the referring physician;
6. Time of collection; and
7. Any pertinent clinical information that may require techniques other than those normally used.

(b) Specimens should be rejected if:

1. Visibly contaminated with any chemicals (for example, barium, oils or medications), or other materials that may compromise or confuse the detection and/or identification of parasitic forms.
2. Any specimens that are submitted in inappropriate, or leaky containers.
3. Any specimens which have dried out, or begun to putrefy, because of delay in shipping and lack of proper preservation.

(c) The receipt of each specimen will be accurately documented, on arrival in the laboratory, including the exact time of receipt, to determine if all specifications for acceptance are met according to established laboratory practices. NOTE: Any specimens sent to another laboratory for specialized or medicolegal examination, both its identity and the chain of custody must be preserved.

(d) Under the supervision of the Microbiology Supervisor and Microbiology Section Chief, routine parasitology preparations may be read, interpreted and reported by medical technologists with at least 1 year of specialized training in parasitology, and/or academically trained parasitologists with degrees.

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(e) The Microbiology Section Chief will be responsible for consulting with the physician submitting the case on any results that may:

1. Be potentially misinterpreted.

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2. Have epidemiological importance as to potential modes of infection and precautions for human to human transfer.

3. Impact on patient management and therapy.

(f) Diagnostic reports will be written and/or entered into the DHCP, depending on the time required by the requesting physician and DHCP service submitting the specimen, but will be no more than 48 hours after receiving the sample.

1. These reports will be made a permanent part of the patient's medical record.

2. Copies of all reports will be maintained in the Microbiology Section of the laboratory for a period of time consistent with the requirements in chapter 2.

(5) Quality Improvement in Parasitology

(a) Quality improvement in parasitology is defined as the systematic mechanism and program that ensures quality care through accuracy in the detection and/or recovery of parasitic forms from clinical specimens. A key element in such programs is continuing systematic independent review of parasitology specimens, which encompasses both external and internal aspects.

(b) Internal aspects of quality control include practices by which all positive results are checked by a qualified second observer in the same laboratory, and that any examinations made during off-hour shifts be checked by the microbiology supervisor, parasitologist, or other qualified designee, on the following day. Quality assurance monitors that disclose any problems or inconsistencies in parasitology practice must lead to documented immediate and appropriate internal corrective actions.

(c) The laboratory must have an in-house and on-the-bench reference collection suitable for its level of service. For the routine Parasitology Laboratory, a minimal requirement would be :

1. The most recent edition of the Manual of Clinical Microbiology (American Society for Microbiology), or its equivalent;

2. A clinical parasitology book, such as Garcia and Bruckner's Diagnostic Medical Parasitology; and

3. An atlas such as Ash and Orihel's American Society of Clinical Pathologists.

NOTE: Laboratories identifying arthropods should have suitable compendia.

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NOTE: Additional teaching and reference materials, such as slides or photographs and gross specimens should also be maintained appropriate to the level of service of the laboratory.

(d) The laboratory must calibrate and use an ocular micrometer for determining the size of ova and parasites. Size charts of parasites should be available at the microscope.

(e) Each week, or time of use, if less frequent than weekly, the laboratory must check permanent stains using a fecal sample control that will demonstrate staining characteristics.

(f) Each time of use, the laboratory must employ appropriate positive and negative controls for the acid-fast staining of cryptosporidium. Similarly, positive and negative controls must be employed for fluorescent antibody staining and enzyme immunoassay for the detection of Cryptosporidium sp, Giardia lamblia, Pneumocystis carinii and other relevant organisms.

(g) Each time of use, the laboratory must screen blood films (thin and thick) for microfilaria, using the low power objective.

(h) Where applicable, the laboratory shall document the specific gravity and force requirements relevant to effective concentration of fecal parasites.

(i) External quality control aspects are focused primarily on mandated participation in professional PT Programs, such as that conducted by CAP.

1. The parasitology laboratory must perform at least three testing events annually at evenly spaced intervals, with each event including at least five samples for analysis, both containing and devoid of parasitic forms.

a. An annual program must include samples that contain parasites that are commonly encountered in the United States, as well as those that have potential for being introduced into the United States. Other important pathogens as they may be emerging at any given time must also be periodically included in the program.

b. An approved external PT Program must furnish HHS each calendar year with a description of samples that it plans to include in its annual program no later than 6 months before each calendar year. Samples must include both specimens and PVA fixed specimens as well as blood smears, as appropriate for a particular parasite. Following are examples of the types of specimens that might be included in an approved program:

- (1) Entamoeba histolytica,
- (2) Entamoeba coli,
- (3) Iodamoeba butschlii,
- (4) Endolimax nana,
- (5) Blastocystis hominis,
- (6) Giardia lamblia,
- (8) Chilomastix mesnelii,
- (9) Dientamoeba fragilis,
- (10) Cryptosporidium species,

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- (11) *Isospora belli*,
- (12) *Ascaris lumbricoides*,
- (13) Hookworms,

- (14) *Strongyloides stercoralis*,
- (15) *Trichuris trichura*,
- (16) *Enterobius vermicularis*,
- (17) *Taenia solium*/*Taenia saginata*,
- (18) *Hymenolepis nana*/*Hymenolepis diminuta*,
- (19) *Diphyllobothrium latum*,
- (20) *Dipylidium caninum*,
- (21) *Fasciola hepatica*/*Fasciolopsis buskii*,
- (22) *Clonorchis sinensis*,
- (23) *Paragonimus westermani*,
- (24) *Schistosoma mansoni*/*Schistosoma haematobium*,
- (25) *Plasmodium falciparum*/*Plasmodium vivax*,
- (26) *Leishmania* species,
- (27) *Trypanosoma cruzi*,
- (28) *Wuchereria bancrofti*/*Brugia malayi*, and
- (29) *Toxoplasma gondii*.

2. The PT samples received from the external PT Program must be examined by the laboratory in the same manner as it tests patient specimens, by personnel who routinely perform the test on patient samples.

NOTE: Personal interlaboratory communications with other laboratories participating in the same PT Program pertaining to any current results must be avoided. Samples or portions of samples will not be sent to another laboratory for analysis.

3. The external PT Program selected by the parasitology testing site must be sensitive and specific enough to determine the reportable parasites. It may elect to determine the minimum number of parasites that are to be identified in a given sample before they are reported. Parasites found in rare numbers in the referee laboratories will not be scored toward a laboratory's performance if the findings are neutral. NOTE: Referee laboratories are external laboratories set up by the external PT Program that provide the expert consultants to select the PT materials.

a. To determine the acceptability of laboratory performance, an overall testing event scores of at least 80 percent must be attained.

b. The criterion for acceptable performance for qualitative parasitology examinations is the presence or absence of a parasite(s). However, since laboratories may incorrectly

report the presence of parasites in addition to the correctly identified principal parasite(s), any such error will be appropriately reflected in the final event score (i.e., if one parasite is recognized but an additional one reported that is not present, a 5 percent to 10 percent deduction may be applied to the final score depending on the nature of the situation.

4. Failure to achieve a satisfactory overall testing event score for two consecutive testing events or two out of three consecutive testing events is considered unsuccessful performance.

a. In such event, appropriate training of the personnel involved and the technical assistance necessary to correct problems associated with a PT failure will be provided by the Chief, Pathology and Laboratory Medicine Service.

b. All remedial action taken will be appropriately documented and maintained in the laboratory from the date of participation; records are to be disposed of in accordance with VHA's RCS 10-1.

e. Virology

(1) The laboratory must have an in-house and on-the-bench reference collection suitable for its level of service. For the routine virology laboratory, a minimal requirement would be:

(a) The most recent edition of the Manual of Clinical Microbiology (American Society for Microbiology), or its equivalent;

(b) A clinical virology book, such as Spector and Lancz's Clinical Virology Manual, or Hsiung's Diagnostic Virology; and

(c) A general text such as Belshe's Textbook of Human Virology.

(2) The laboratory must have available host systems for the isolation of viruses and test methods for the identification of viruses that cover the entire range of viruses etiologically related to clinical diseases for which services are offered.

(3) The laboratory must maintain records that reflect the systems used and the reactions observed.

(4) In tests for the identification of viruses, the laboratory must simultaneously culture uninoculated cells, or cell substrate controls as a negative control to detect erroneous identification results. Positive controls must be employed where stains, hemagglutination or antigenic identification is performed.

(5) The reporting of the results of viral tests should reflect the scope of testing conducted.

(a) For example, where permissive host cells, or detection tests, were limited to the detection of Herpes simplex virus (HSV), the results should state, "No HSV detected."

(b) If a broader spectrum of viral agents were sought, but some common viral agents were not detectable with the methods used, the report should so indicate. For example,

"cerebrospinal fluid (CSF) culture negative for common seasonal agents of aseptic meningitis. If other viral agents are suspected, consult the laboratory for additional test modalities."

(6) The laboratory must ensure that specimen procurement and transport are suitable to the agents sought by:

- (a) Providing advance instructions,
- (b) Rejecting inappropriate specimens, and
- (c) Conducting relevant studies in quality assurance.

4.06 HEMATOLOGY

Hematology is the study of the cellular elements in the blood which is comprised of both routine and special components. Each VA medical center Pathology and Laboratory Medicine Service will provide a Hematology section that is properly equipped to provide services including, but not limited to, specimen reception, and reporting timely and accurate results. All equipment used in connection with these services will be properly maintained according to manufacturer's and accrediting body regulations.

a. Personnel

(1) The Chief, Pathology and Laboratory Medicine Service, is responsible for:

(a) The professional and technical aspects of Hematology including receiving, processing, and reporting results.

(b) Certification and documentation of all credentials of the hematology professional medical and technical staff.

(2) A board-certified pathologist will be responsible for all hematology services. The pathologist may delegate selected responsibilities to a registered medical technologist who has a minimum of 3 years experience in the speciality of hematology, or a specialist in hematology certified by a national certification agency.

b. Standards. Standards for hematology will be established in accordance with those published in the current edition of Accreditation Manuals for Hospitals by JCAHO. CAP conducts regularly scheduled inspections of all Pathology and Laboratory Services to ensure continuing accreditation. All testing sites that perform hematology tests will follow policies and standards in Chapter 2, in addition to policies in this chapter.

c. Specimen Handling. The laboratory must have available written policies and procedures for each of the following, if applicable:

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- (1) Preparation of patients,
- (2) Specimen collection,
- (3) Specimen labeling,
- (4) Specimen preservation,

- (5) Conditions for specimen transportation, and
- (6) Extention of blood films after a differential smear and count (see App. 2B).
 - d. Patient Identification. Written policies and procedures must ensure positive identification and optimum integrity of the patient specimens from the time the specimens are collected, or received as a referral specimen, until testing has been completed and the results reported.
 - e. Referral Specimens. If the laboratory accepts a referral specimen, written instructions must be available to clients.
 - f. Oral Explanation. Oral explanation of instructions to patients for specimen collection, including patient preparation, may be used as a supplement to written instructions, where applicable.
 - g. Test Requisitions. The laboratory will perform tests only at the written or electronic request of an authorized person. Oral requests for laboratory tests are permitted.
 - (1) Records of test requisition, must be retained and must be available to the laboratory at the time of testing, and available for inspecting groups upon request; records are to be disposed of in accordance with VHA's RCS 10-1.
 - (2) The laboratory must ensure that the requisition or test authorization includes:
 - (a) The patient's name, Social Security Number, and medical center identification number.
 - (b) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for utilizing the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person, to enable the reporting of imminent life threatening laboratory results or panic values.
 - (c) The name(s) of test(s) to be performed.
 - (d) The date and time of specimen collection and receipt in the laboratory.
 - (e) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results.
 - h. Patient Test Management. Each laboratory must employ and maintain a system that provides for:
 - (1) Proper reporting of results,

- (2) Communication between laboratory and clinical staff,
- (3) Retrieval of test results promptly by clinical and laboratory staff,
and
- (4) Systems for detection of reporting errors.

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i. Reporting

(1) The laboratory report must be sent promptly to the authorized person, the individual responsible for using the test results, or the laboratory, that initially requested the test.

(a) The original report, or an exact duplicate of each test report, including final and preliminary reports, must be retained by the testing laboratory; records are to be disposed of in accordance with VHA's RCS 10-1.

(b) This information must be maintained as part of the patient's chart, or medical record, which must be readily available to the laboratory and to inspection groups upon request.

(2) The laboratory must have adequate systems in place to report results in a timely, accurate, reliable and confidential manner, ensuring patient confidentiality throughout those parts of the testing process under laboratory control.

(3) The test report must indicate:

(a) The name and address of the laboratory location at which the test was performed.

(b) The test performed.

(c) The test result.

(d) The units of measurements, if applicable.

(4) The laboratory must indicate on the test report any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

(5) Pertinent "reference" or "normal" ranges, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests, or the individual responsible for utilizing the test results.

(6) The results, or transcripts of laboratory tests, or examinations, must be released only to authorized persons, or the individual responsible for utilizing the test results.

(7) The laboratory must develop and follow written procedures for reporting imminent life threatening laboratory results or "panic values." The laboratory must immediately alert the individual, or entity requesting the test, or the individual responsible for utilizing the test results, when any test result indicates an imminent life threatening condition.

(8) Information that may affect the interpretation of test results, such as test interferences, must be provided upon request.

(9) Pertinent updates on testing information must be provided to clients whenever changes occur that affect the test results, or the interpretation of test results.

(10) The original report, or exact duplicates of test reports, must be maintained by the laboratory in a manner that permits ready identification and timely accessibility.

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(11) Storage of the test results in DHCP is mandatory.

j. Records. The laboratory must maintain a record system to ensure reliable identification of patient specimens as they are processed and tested to ensure that accurate test results are reported.

(1) These records must identify the personnel performing the testing procedure.

(2) Records of patient testing, including, if applicable, instrument printouts, must be retained and include the same elements as noted in chapter 2, as well as:

(a) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability; and

(b) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s), to ensure proper identification and accurate reporting of patient test results.

NOTE: Records are to be disposed of in accordance with VHA's RCS 10-1.

k. Referral of Specimens. A laboratory must refer specimens for testing only to a laboratory possessing a valid certificate authorizing the performance of testing in the speciality, or subspecialty of service for the level of complexity, in which the referred test is categorized.

(1) The referring laboratory must not revise results or information directly related to the interpretation of results provided by the testing laboratory.

(2) The referring laboratory may permit each testing laboratory to send the test result directly to the authorized person who initially requested the test.

(3) The referring laboratory must retain, or be able to produce an exact duplicate of, each testing laboratory's request.

(4) The authorized person who requests a test must be able to determine the name and address of each laboratory location at which a test was performed.

1. Method Performance Specifications

(1) Prior to reporting patient test results, the laboratory must verify or establish, for each method, the performance specifications for the following performance characteristics:

(a) Accuracy;

(b) Precision;

- (c) Analytical sensitivity and specificity to include interfering substances;
- (d) The reportable range of patient test results;
- (e) The reference range(s) (normal values); and
- (f) Any other performance characteristic required for test performance.

(2) A laboratory that introduces any new procedure for patient testing method (instrument, kit, or test system developed in-house or) cleared by the FDA must demonstrate that, prior to reporting patient test results, it can obtain the performance specifications for accuracy, precision, and reportable range of patient test results, comparable to those established by the manufacturer. The laboratory must verify that the manufacturer's reference range is appropriate for the laboratory's patient population.

(3) Based upon the performance specifications verified or established in accordance with this chapter, the laboratory must establish calibration and control procedures for patient testing as required by this chapter.

(4) The laboratory must have documentation of the verification or establishment of all applicable test performance specifications.

m. Quality Control. The laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method.

(1) The laboratory must comply with the applicable requirements in chapter 2.

(2) All quality control activities must be documented and records of all quality control activities must be maintained; records are to be disposed of in accordance with VHA's RCS 10-1.

(3) For automated hematology testing systems the laboratory must include two levels of control for each 8 hours of operation.

(4) Cell counts performed manually using a hemocytometer must be tested in duplicate for each 8 hours of operation.

(5) For each method that is developed in-house, or is a modification of the manufacturer's test procedure, the laboratory must:

(a) Evaluate instrument and reagent stability and operator variance in determining the number, type, and frequency of testing calibration or control materials.

(b) Establish criteria for acceptability used to monitor test performance assuring a run of patient specimen(s). NOTE: A run is an interval within which the accuracy and precision of a testing system is expected to be stable, but cannot be greater than 24 hours.

(c) For each procedure, the laboratory must monitor test performance using calibration materials, or control materials, or a combination of both.

1. For qualitative tests:

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a. The laboratory must include a positive and negative control with each run of patient specimens.

b. The laboratory must include at least two samples of different concentrations of either calibration materials, control materials, or a combination thereof, with the frequency determined in (b), but not less frequently than once each run of patient specimens.

2. If calibration materials and control materials are not available, the laboratory must have an alternative mechanism to ensure the validity of patient test results, specifically utilizing qualified, certified, experienced technologists.

3. Control samples must be tested in the same manner as patient specimens.

4. When calibration or control materials are used, statistical parameters (e.g., mean and standard deviation) for each lot number of calibration material, and each lot of control material, must be determined through repetitive testing.

5. The purpose of using controls is to establish the accuracy of testing. The stated values of an assayed control material may be used as the target values provided the stated values correspond to the methodology and instrumentation employed by the laboratory, and are verified by the laboratory.

6. Statistical parameters for unassayed materials must be established by the laboratory, over time, through concurrent testing with calibration materials or controls having previously determined statistical parameters.

7. Control results must meet the laboratory's criteria for acceptability prior to reporting patient test results.

n. Reagent and Supply Quality Checks

(1) The laboratory must check each batch or shipment of reagents, antisera and identification systems (system using two or more substrates) when prepared, or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

(2) After each day of use (unless otherwise specified in this document), the laboratory must test staining materials for intended reactivity to ensure predictable staining characteristics.

(3) Remedial actions taken to correct conditions that fail to meet criteria specified in subparagraph 4.06(c)(1), must be documented.

(4) Reagents, solutions, culture media, control materials, calibration materials and other supplies, as appropriate, must be labeled to indicate:

- (a) Identity and, when significant, titer, strength, or concentration;
- (b) Recommended storage requirements;
- (c) Preparation and expiration date; and
- (d) Other pertinent information required for proper use.

(4) Reagents, solutions, control material, calibration materials and other supplies must be prepared, stored, and handled in a manner to ensure that:

(a) Reagents, solutions, controls, calibration materials and other supplies are not used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

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1. The laboratory must comply with the FDA product dating requirements of 21 Code of Federal Regulations (CFR) 610.53 for blood products and other biologicals, and labeling requirements, as cited in 21 CFR 809.10 for all other in vitro diagnostics.

2. Any exception to the product dating requirements in 21 CFR 610.53 will be granted by the FDA in the form of an amendment of the product license, in accordance with 21 CFR 610.53(d).

3. All exceptions must be documented by the laboratory.

(b) Components of reagent kits of different lot numbers are not interchanged unless otherwise specified by the manufacturer.

o. Patient Test Management

(1) Policies and procedures must be established by the laboratory and applied, as necessary, to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.

(2) The laboratory must document all remedial action taken when:

(a) Test systems do not meet the laboratory's established performance specifications, as determined in this section including, but are not limited to, equipment, or methodologies, that perform outside of established operating parameters, or performance specifications.

(b) Patient test values are outside of the laboratory's reportable range of patient test results.

(c) Results of control and calibration materials fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run, or since the last acceptable test run, must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the remedial action necessary to ensure the reporting of accurate and reliable patient test results.

(d) The laboratory cannot report patient test results within its established time frames. The laboratory must determine, based on the urgency of the patient test(s) requested, the need to notify the appropriate individual of delayed testing.

(e) Errors in the reported patient test results are detected; then the laboratory must:

1. Promptly notify the authorized person ordering, or the individual utilizing the test results, of reporting errors.

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2. Issue corrected reports promptly to the authorized person ordering the test, or the individual utilizing the test results.

3. Maintain exact duplicates of the original report, as well as the corrected report; records are to be disposed of in accordance with VHA's RCS 10-1.

p. Facilities, Equipment, Supplies, Environmental and Safety Requirements. The laboratory must provide the space and environmental conditions necessary for effective test performance.

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(1) The laboratory must be constructed, arranged, and maintained to ensure space, ventilation, and utilities necessary for conducting all phases of testing, which are:

- (a) Pre-analytic (pre-testing);
- (b) Analytic (testing); and
- (c) Post-analytic (post-testing).

(2) Safety precautions must be established, posted, and observed to ensure protection from physical hazards and biohazardous materials.

(3) The laboratory must utilize test methods, equipment, instrumentation, reagents, materials, and supplies that provide accurate and reliable test results and test reports.

(4) Test methodologies and equipment must be selected, and testing performed in a manner that provide test results within the laboratory's stated performance specifications for each test method, (See subpar. 4.06m.)

(5) The laboratory must have appropriate and sufficient equipment and instruments, reagents, materials, and supplies for the type and volume of testing performed, and for the maintenance of quality during the pre-analytic, analytic, and post-analytic phases of testing.

(6) The laboratory must define criteria for conditions essential to the proper storage of reagents and specimens.

(7) These conditions include, if applicable:

- (a) Water quality;
- (b) Temperature;
- (c) Humidity; and

(d) Protection of equipment and instrumentation from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

q. Procedure Manual

(1) Laboratory personnel must follow the written procedure manual for the performance of all analytical methods used by the laboratory; this manual must be readily available in the testing area. NOTE: Textbooks may be used as supplements to these written descriptions but may not be used in lieu of the laboratory's written procedures for testing or examining specimens.

(2) The procedure manual must include:

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- (a) Requirements for specimen collection and processing;
- (b) Criteria for specimen rejection;
- (c) Procedures for microscope examination, including the detection of inadequately prepared slides;

(d) Step-by-step performance of the procedure, including test calculations and interpretation of results;

(e) Preparation of slides, solutions, calibrators, controls, reagent stains and other materials used in testing;

(f) Calibration and calibration verification procedures;

(g) The reportable range for patient test results as established or verified in this chapter;

(h) Control procedures;

(i) Remedial action to be taken when calibration or control results fail to meet the laboratory's criteria for acceptability;

(j) Limitations in methodologies, including interfering substances;

(k) Reference range (normal values);

(l) A protocol for imminent life-threatening laboratory results or "panic values;"

(m) Pertinent literature references;

(n) Appropriate criteria for specimen storage including criteria for specimen preservation to ensure specimen integrity until testing is completed;

(o) The laboratory's system for reporting patient results;

(p) Description of the course of action to be taken in the event that a test system becomes inoperable; and

(q) Criteria for the referral of specimens including procedures for specimen submission and handling as described in subparagraph 4.06d.

(3) Manufacturers' package inserts or operator manuals may be used, when applicable, as supplements to written procedures in the Hematology procedure manual. The manufacturer must be contacted by the Chief, Hematology, or Supervisor of Hematology, if instructions are not provided for methods and/or equipment.

(4) Procedures must be approved, signed, and dated by the Chief, Hematology Laboratory.

(5) Procedures must be re-approved, signed and dated if the Chief, Hematology Laboratory changes.

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(6) Each change in a procedure must be approved, signed and dated by the current Chief, Hematology Laboratory.

(7) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance.

(8) After a procedure has been discontinued the records must be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

r. Calibration and Verification. Calibration and verification is the process of assaying calibration materials in same manner as patient samples to confirm that the calibration of the instrument, kit, or test system, has remained stable throughout the laboratory's reportable range for patient test results. The reportable range is the range of test result values over which the relationship between the instrument, kit, or test system's, measurement response is shown to be valid.

(1) Calibration and calibration verification procedures are required to substantiate the continued accuracy of the test method throughout the laboratory's reportable range for patient test results. Calibration and calibration verification must be performed and documented as required in this section, unless otherwise specified in Chapter 2.

(2) For laboratory test procedures that are performed using instruments, kits, or test systems, that have been cleared by the FDA, the laboratory must, at a minimum, follow the manufacturer's instructions for calibration and calibration verification procedures using calibration materials specified by the manufacturer.

(3) For each method that is developed in-house, and is a modification of the manufacturer's test procedure, or is an instrument, kit, or test system, that has not been cleared by the FDA, the laboratory must:

(a) Perform calibration procedures at a minimum, in accordance with manufacturer's instructions, if provided, using calibration materials provided, or specified, as appropriate, and with at least the frequency recommended by the manufacturer.

(b) Set limits for calibrations, and the frequency of calibration if manufacturer's instructions are not provided using calibration materials appropriate for the methodology. If possible, the calibrator will be traceable to a reference method or reference material of known value.

s. Equipment Maintenance and Function Checks. The laboratory must perform equipment maintenance and function checks that include electronic, mechanical and operational checks as follows:

(1) Maintenance of equipment, instruments, and test systems

(a) For manufacturers' equipment, instruments or test systems cleared by the FDA, the laboratory must:

1. Perform maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

2. Document all maintenance performed.

(b) For equipment, instruments, or test systems not cleared by FDA, or equipment, instruments, or test systems that have been modified, or developed in-house, the laboratory must:

1. Establish a maintenance protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

2. Perform maintenance with at least the frequency specified in Chapter 2; and

3. Document all maintenance performed.

(2) Function checks of equipment, instruments, and test systems

(a) For manufacturers' equipment, instruments, or test systems cleared by the FDA, the laboratory must:

1. Perform function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer; and

2. Document all function checks performed.

(b) For equipment, instruments, or test systems, not cleared by FDA, or equipment, instruments, or test systems, that have been modified or developed in-house, the laboratory must:

1. Define a function check protocol that ensures equipment, instrument, and test system performance necessary for accurate and reliable test results and test result reporting;

2. Perform function checks including background or baseline checks specified in Chapter 2. Function checks must be within the laboratory's established limits before patient testing is conducted; and

3. Document all function checks performed.

t. PT. Each Hematology Laboratory must enroll in a PT Program. The PT standards and the acceptability of PT Program are addressed in Chapter 2. The laboratory must test the samples in the same manner as patients' specimens.

4.07 COAGULATION AND SPECIAL COAGULATION

Each VA medical center's Pathology and Laboratory Medicine Service will provide services, or access to diagnostic and monitoring testing services, for coagulation disorders that will serve the needs of the VA medical center's patient case type and mix. Tests should be of a quantitative nature and quality control parameters will be appropriately applied.

a. Accessioning and Examination of Specimens. Specimens will be accessioned and examined for conformance to specimen requirements, with specimen rejection documented and the report of rejection, with reasons, included in the DHCP report.

b. Reports and Retention of Specimens. Reports will be retained in the VA medical centers DHCP. Specimens are saved in a fashion that best meets the needs of the laboratory, for example, refrigeration of all excess blood until completion of the analysis and for at least 24 hours after verification of results.

c. Use of Specimens for Scientific/Research Purposes. Specimens that are submitted for analytical testing shall not be used for research purposes unless the research protocol has been subjected to the scrutiny of and approval of the medical center's review board.

d. TQI. An overall program in quality improvement will be established in each coagulation laboratory testing site with a program of PT and quality control described in subparagraphs 4.07 e and f.

(1) The laboratory must follow all policies and standards prescribed in Chapter 2, in identifying problems in:

- (a) Laboratory utilization,
- (b) Specimens and their transport,
- (c) Analytical testing, or
- (d) Distribution or effective utilization of test results.

(2) These studies must be documented and reported to the laboratory's TQI committee and of the medical center's TQI committee for review and approval.

(3) Different laboratories are subject to different sets of problems; therefore, these elements of quality improvement shall be individualized to the needs of the VA medical center's.

(4) VA consultants named by the Director, Pathology and Laboratory Medicine Service, VA Central Office, will share with other VA laboratories their TQI Programs as examples that may be useful for incorporation in other laboratory settings.

(5) Successful quality improvement is a program that fully meets the requirements of JCAHO and CAP laboratory accreditation programs.

e. PT in Hematology/Coagulation. The PT Program employed by the Hematology/Coagulation testing site must provide challenges for assays which the laboratory currently performs.

(1) There will be at least three testing events at approximate equal intervals per year. There will be at least five samples per event.

(2) Approved PT Programs include those that are approved by national accreditation bodies. Unapproved programs will not be accepted for utilization by VA laboratories.

(3) In order to pass a PT, the Hematology/Coagulation testing site must determine the correct response for each analyte by the distance of the response from the target value.

(a) The correct response must be determined by using either fixed criteria based on the percentage difference from the target value or the number of SD the response differs from the target value.

(b) The criteria for acceptable performance are:

CRITERIA FOR ACCEPTABLE PERFORMANCE

<u>1.</u> Platelet Count	Peer group mean +/- 3SD or 25 percent, whichever is less
<u>2.</u> Fibrinogen	Peer group mean +/- 3SD or 20 percent, whichever is greater
<u>3.</u> Partial Thromboplastin Time	Peer group mean +/- 3SD or 15 percent, whichever is greater
<u>4.</u> Prothrombin Time	Peer group mean +/- 3SD or 15 percent, whichever is greater

NOTE: (Peer group mean and Target value may be synonymous terms)

(4) When a Hematology/Coagulation testing site fails to achieve the 80 percent pass rate, it may elect to consult with the VA expert consultant on those items in which it has failed. Such a consult will provide outside perspective training, suggestions, and/or procedural changes that will allow the laboratory to improve its performance.

(5) When a Hematology/Coagulation testing site has failed twice in a row, such a consult is mandatory. The consultant will introduce changes that will assist the laboratory in improving its performance. The consulting VA expert advises the Director, Pathology and Laboratory Medicine Service, VA Central Office, regarding the continuance of testing by the involved laboratory.

f. Quality Control in Coagulation. The design of each VA medical center's quality control program depends upon the laboratory's complexity level, mode of operation and unique needs.

(1) Written procedures will specify the appropriate quality control steps for reagents and devices.

(2) Quality control limits must be established and clearly recorded.

(3) When quality control measurement parameters fall outside these limits, there must be specific instructions about the restrictions on test results reporting, notification of supervisor, or other appropriate responses.

(4) All quality control activities must be documented. There must be evidence of review of this documentation at least on a monthly basis, with details of intervention activities, both short-term and long-term, relevant to the problems encountered.

(5) Quality control records shall be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

(6) Preventive maintenance records shall be maintained beyond the life of the applicable instrument; records are to be disposed of in accordance with VHA's RCS 10-1.

4.08 DIAGNOSTIC IMMUNOLOGY

a. The speciality of diagnostic immunology includes the subspecialities of syphilis serology and general immunology. General immunology can be further subdivided into

infectious disease serology and non-infectious disease serology.

(1) All VA medical centers will provide diagnostic immunology services that will serve their needs in regards to patient case type and mix.

(2) All testing sites that perform tests must utilize the policies and standards in Chapter 2, in addition to the policies and standards in this chapter.

b. Syphilis Serology

(1) It is the policy of VHA to standardize serologic testing for syphilis.

(a) All VA medical center diagnostic immunology laboratories performing serologic tests for syphilis on serum and/or spinal fluid will use the methods accepted as standard by HHS, Public Health Service (PHS). These methods are published in the current edition of Manual of Tests for Syphilis published by APHA American Public Health Association (APHA).

(b) They consist of:

1. Non-treponemal antibody screening tests Rapid Plasma Reagin (RPR), and Venereal Disease Research Laboratory (VDRL), etc.; and

2. Confirmatory anti-treponemal antibody tests Fluorescent Treponemal Antibody-Absorbed (FTA-ABS), and Microhemagglutination - Treponema pallidum (MHA-TP).

NOTE: The VDRL slide test is still the only approved test for use with spinal fluid.

(2) At the request of those facilities that do not perform confirmatory syphilis testing locally, the VA Reference Laboratory for Selected Serologic Studies at the VA Medical Center, Lexington, KY, will perform the MHA-TP test for confirmation of positive non-treponemal tests. These tests will be conducted in accordance with techniques outlined in the current edition of Manual of Tests for Syphilis.

(3) All VA medical centers will conform to the policy of their State health departments in reporting of positive seroreactors.

(4) Diagnostic immunology laboratories performing serologic tests for syphilis will perform and document all appropriate quality control activities.

(a) Equipment, glassware, reagents, controls, and techniques must conform to manufacturer's specifications.

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(b) A positive serum control of known titer or controls of graded reactivity, including a negative control, must be run concurrently with patient specimens.

(c) Test results may not be reported unless the predetermined reactivity of the controls is observed.

(d) Records of quality control activities must be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

(5) Diagnostic immunology laboratories that perform syphilis serology must be enrolled in a national proficiency testing program that provides at least three challenges a year consisting of five specimens in each challenge. NOTE: Corrective action for unacceptable test performance must be documented and maintained; records are to be disposed of in accordance with VHA's RCS 10-1.

c. General Immunology. General Immunology consists of infectious disease and non-infectious disease serologic testing.

(1) Infectious disease serology includes many tests, ranging from serologic techniques for infectious mononucleosis to Western blot testing for Human Immunodeficiency Virus (HIV) antibody detection.

(a) Either antigen or antibodies may be detected.

(b) Non-infectious disease immunologic testing includes tests for detection of auto-immune antibodies and measuring immunoglobulin levels as well as complement components.

(2) VA medical center laboratories and testing sites performing serologic tests in general immunology must perform and document all applicable quality control activities.

(a) A positive serum control, or controls of graded reactivity including a negative control, must be run concurrently with patient specimens.

(b) Controls must be employed that evaluate all phases of the test system (e.g., for complement fixation testing; antigen, complement, buffer, erythrocyte, hemolysin, serum) to ensure that the test system is functioning properly, and if positive and negative controls are not working properly.

(c) Test results may not be reported unless the predetermined reactivity of the controls is observed.

(d) Records of all quality control activities must be retained; records are to be disposed of in accordance with VHA's RCS 10-1.

(3) Laboratories performing general immunology procedures must be enrolled in a PT Program that provides at least three challenges per year consisting of five specimens.

(a) The program must also evaluate test performance, and list criteria for acceptable performance for both qualitative and quantitative testing.

(b) Corrective action for unacceptable test performance must be documented and maintained; records are to be disposed of in accordance with VHA's RCS 10-1.

4.09 FLOW CYTOMETRY

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a. Flow Cytometry analysis is a specialized service available at a limited number of VA medical centers.

(1) The VA medical center will provide this service if a section of Flow Cytometry is established with:

- (a) Appropriate equipment,
- (b) Specimen handling and processing procedures, and
- (c) Adequately trained personnel.

(2) The section of Flow Cytometry will be under the direction of a board-certified pathologist, or certified, qualified, experienced clinical pathologist, or doctoral scientist.

(3) Flow Cytometry procedure manuals shall be in conformance with current NCCLS, GP-2 guidelines.

(a) A current manual of procedures will be available in the Flow Cytometry section at all times.

(b) All flow cytometry testing sites will follow the policies in chapter 2, in addition to the policies and standards in this chapter.

(4) The Flow Cytometry section must satisfy guidelines for general laboratory safety (see Ch. 15).

(5) All samples must be handled using universal precautions.

b. Inspection and Accreditation. The Chief, Pathology and Laboratory Services of each VA medical center providing a Flow Cytometry service is mandated to apply for institutional membership and participate in the laboratory accreditation program of CAP.

c. Responsibilities

(1) The Chief, Flow Cytometry, must:

(a) Have knowledge and expertise in Flow Cytometry to ensure acceptable practices in VA medical centers.

(b) Be responsible for the overall operation and administration of the Flow Cytometry Section.

(2) The Supervisor of Flow Cytometry, must:

(a) Be responsible for day-to-day supervision of the laboratory operation, testing and reporting of results.

(b) Be accessible to provide on-site, telephone, or electronic consultation, to resolve technical problems.

(c) Ensure that the appropriate policies and procedures are followed, adequate records are maintained and training of personnel are conducted.

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d. Quality Improvement

(1) The Chief, Flow Cytometry Section, must establish a quality improvement program to:

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(a) Monitor, evaluate the quality, appropriateness and effectiveness of test results for patient care, and

(b) Resolve any identified problems.

(2) The Flow Cytometry section will:

(a) Comply with NCCLS specific guidelines. Procedure manuals must conform to NCCLS GP2-A-2, "Clinical Laboratory Procedure Manuals," (see subpar. 4.12 n); and

(b) Participate in an approved PT Program. NOTE: Currently approved PT Programs include the CAP survey and PT Program offered by selected vendors of flow cytometry reagents.

(3) There will be established criteria for sample acceptance and rejection.

(4) The procedure for labeling and identification of specimens must be written in the section's procedure manual.

e. General Flow Cytometry Practices

(1) Quality Control

(a) The section of Flow Cytometry will ensure that all aspects of clinical testing from specimen acquisition to the reporting of results are properly controlled and evaluated.

(b) The process of quality control must include the following:

(1) Alignment, calibration and compensation of the cytometer;

(2) Positive and negative controls;

(3) Antibody quality control;

(4) Specimen handling and preparation; and

(5) Differentials and lymphocyte gating.

(c) When applicable, the Flow Cytometry section will establish its own database to define the distribution within a normal population of cells for each marker.

(d) Quality control procedures that fail to meet the criteria specified must be corrected. Remedial actions taken will be documented and reviewed by the Chief, Flow Cytometry, and supervisor.

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(e) Biological control materials must be used to identify cells with abnormal stem lines (aneuploid DNA (deoxribonucleic acid) content). These controls may be normal human cells or nucleated red cells of chicken or trout.

(f) A standard quality control procedure must be established for purification, staining and instrument analysis. When applicable, the laboratory must maintain its own database for every assay performed and ensure that the daily assays fall within two standard deviations from the mean.

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(g) Depending on the anticoagulant used, the sample must be analyzed within an acceptable time frame, to be established by the Chief, Flow Cytometry Section.

(h) The quality control procedure must evaluate the sensitivity and specificity of staining.

(i) Each new lot of monoclonal and/or polyclonal reagent must be compared in parallel to the lot currently in use for sensitivity and specificity.

(2) Patient Specimen Identification. There will be a specimen identification system in use to identify all specimens processed and reported.

(3) Collection and Preservation of Specimens. Acid citrate dextrose (ACD), ethylene diamine tetracetic acid (EDTA), or Heparin anticoagulant may be used. Samples must be transported and stored at room temperature (18 degrees Centigrade to 25 degrees Centigrade).

(4) Safety. It is advisable that samples be fixed with paraformaldehyde after staining to avoid contamination of the cytometer with infectious agents.

(5) PT

(a) The section of Flow Cytometry will participate in approved PT Programs. NOTE: Currently, the CAP survey and selected programs from vendors of flow cytometry reagents are the major programs offered.

(b) Results that vary by greater than two standard deviations from the mean, must be evaluated for extralaboratory and intralaboratory problems.

(6) Reporting of Results

(a) All results must be reported to authorized clinical staff in a timely fashion, after they have been verified by the Flow Cytometry Supervisor and certified by the Chief, Flow Cytometry.

(b) Reports on DNA measurements should include a description of the staining procedure and DNA proliferative status. The DNA index should be calculated with reference to human cells.

(c) A normal range should be included for comparison purposes, on the test report form. All results will be placed in the patient's chart, and duplicate copies will be available and easily retrievable as determined by each facility's degree of internal networking with DHCP.

(d) A summary of results should follow all analyses, such as percent antibody positivity, interpretation, and diagnosis.

4.10 CLINICAL CYTOGENETICS SERVICES

Cytogenetics is a branch of clinical genetics and deals with the study of chromosomes. Within VA, due to the highly specialized nature of the subject, the cytogenetics laboratory functions as a reference laboratory. It is a part of the Pathology and Laboratory Medicine Service and the Chief, Pathology and Laboratory Service, is responsible for maintaining high standards of quality in delivery of cytogenetic services.

a. A cytogenetic study may be indicated for a number of clinical conditions; therefore, the laboratory must be staffed with individuals who have a broad knowledge of clinical genetics.

(1) The cytogenetics laboratory must be directed by a individual with a minimum of an M.D. or Ph.D. Degree and 2 years of fellowship in clinical cytogenetics in a center accredited for such training by American Board of Medical Genetics (ABMG).

(a) The Chief, Cytogenetics Laboratory, is responsible for the professional and technical aspects of the cytogenetics services and will be responsible for the final reporting of all test results.

(b) The Chief, Cytogenetics Laboratory, must be competent in interpreting and communicating the results to the appropriate health care professionals who are directly involved in patient management.

(2) The cytogenetic technologists must have minimum of B.S. Degree in biological sciences at entry level with eventual certification by the National Certification Agency in clinical cytogenetics.

b. Standards

(1) The laboratory must take part in the PT Program given jointly by CAP and American Society of Human Genetics (ASHG).

(2) The laboratory will follow policies and standards as prescribed in Chapter 2, in addition to policies in this chapter and guidelines of CAP and JCAHO.

(3) The cytogenetics laboratory within the VA system will follow all safety and biological hazard regulations stipulated in Chapter 15.

(4) Cytogenetic technologists will receive complete training in handling biological specimen and hazardous chemicals that may be in use in the laboratory.

(5) Clinical follow-up is an important aspect of the service; therefore, the type of tests undertaken must be limited to the areas where such communication and follow-up can be accomplished.

c. Accessioning, Test Performance and Reporting Test Results

(1) Accessioning

(a) Every sample received in the laboratory must have a clinical information sheet with:

1. Patient's name,

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2. SSN,
3. Sample type,
4. Date and time of sample collection,

5. Type of study requested, and

6. Tentative diagnosis with a brief background of clinical condition.

(b) Each specimen received is immediately clocked in, and a laboratory number is assigned (unique to each sample), and accessed into the log book. The sample is identified by patient name and lab number throughout the procedure and in all related paperwork such as the laboratory patient folder.

(c) The quality and quantity of the specimen is recorded along with any unusual observations such as condition of the sample on receipt.

(d) The type and number of cultures initiated must be recorded on the culture record sheet and in the clinical information sheet.

(2) Test Performance

(a) Cultures must be initiated in parallel using two different batches of media, and must be incubated in two separate incubators.

1. To prevent cross contamination of samples, only one sample should be handled at a time while initiating the cultures.

2. While harvesting, care must be taken to prevent cross contamination by keeping each culture tube in a separate rack, and using a separate pipette for each case.

3. While making slides only one culture must be handled at a time.

4. All slides of one culture must be removed from the hot plate and labeled before proceeding.

(b) Each culture type must be verified for quality and mitotic index so that appropriate steps may be taken such as processing the back up culture.

(c) Any unusual problem encountered during the processing, or if a test has resulted in failure (such as no metaphases or poor quality of metaphases), it must be brought to the attention of the Chief, Cytogenetics Laboratory, by the technologists as soon as possible so that:

1. A concerted effort may be made to overcome the problem, or

2. A early failure results may be communicated to the referring physician.

(d) All cytogenetic studies must be carried out using banding technique.

(e) A minimum of 20 metaphases must be analyzed for every case. Additional cells may have to be examined depending upon the reason for the study, and as may be warranted by the clinical information.

(f) A minimum of two karyotypes must be prepared for each case (or each cell line when more than one cell line is part of the karyotype).

(3) Reporting Test Results

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(a) All final reports must:

1. Carry a brief summary of the results, and

2. Have a cytogenetic interpretation of the results following the latest edition of International System for Human Cytogenetic Nomenclature (ISCN).
NOTE: The latest supplement nomenclature must be used for cancer cytogenetics.

(b) A clinical correlation of the cytogenetic results should be made whenever possible and it must be in line with the current literature data. In the event a test has failed, every effort must be made to determine the cause of failure, and the test failure and cause documented.

(c) A final report must be generated for failure reports. NOTE: In certain cases a brief recommendation should be part of the report for further management of the patient.

d. Storage of Slides, Karyotypes and Patient Folder

(a) A minimum of two slides must be stored for each study in a dust-free container at room temperature.

(b) All laboratory folders containing patient information, analysis sheet, slides and the karyotypes must be retained for 7 years and the final report for 25 years. The film strips related to the metaphases used for karyotyping must be part of this folder.

(c) In laboratories that are using an automated karyotyping system, a minimum of two karyotypes must be saved, and archived, to enable retrieval at any time.

(d) The laboratory will dispose any or all documents related to the test according to VA's RCS, as administered by Medical Administration Service.

e. Use of Tissue for Scientific/Research Purposes. Tissue sent for cytogenetic tests may not be used for research purposes. However, tissue may be used for additional procedures as deemed necessary to aid in the interpretation of the results.

f. Quality Improvement

(1) The Cytogenetics Laboratory will participate in the quality improvement program implemented by the Chief of Pathology and Laboratory Medicine Service.

(a) This includes assessment of the turn-around time of test results for a minimum of 30 consecutive cases. This must be done at least once in each calendar year.

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(b) The appropriateness of ordering of tests must be monitored by the Chief, Cytogenetics Laboratory, on a monthly basis and corrective measures, if needed, must be taken immediately.

(2) The cytogenetics laboratory must participate in the PTs given by CAP and ASHG.

(3) The Chief, Cytogenetics Laboratory, and the technologists must participate in continuing education activities, and all such activities must be documented by the Chief, Cytogenetics Laboratory.

g. Internal Quality Control and Remedial Actions. The laboratory must implement internal quality control which includes: the determination of the adequacy of the

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patient's sample for testing in relation to the study requested; sufficient clinical information to allow interpretation of the results; and proper sample collection procedures.

(1) The accuracy of test performance must be evaluated on a daily basis to ensure that appropriate culture, harvest and staining procedures have been followed to gain complete information for the type of study requested. If a certain study is not routinely done in the laboratory (such as fragile X-ray study which must be done only in laboratories that have sufficient experience with internal positive controls), such information must be passed on to the referring physician prior to sampling.

(2) Cultures must be initiated in parallel using two different types of media or two different batches of media and maintained in two separate incubators. Every new batch of media must be tested for sterility and cell growth by running parallel cultures using old versus new media.

(3) The quality of metaphases and banding resolution obtained should be monitored to maintain high standards of the test. Laboratory procedures must be reviewed frequently and the procedure manual must be updated accordingly.

(4) The Chief, Cytogenetics Laboratory, must review each case with at least two completed karyotypes for each test, or cell line, before writing the report. Each case must be discussed thoroughly with the technologist handling the case and any ambiguous findings must be resolved to the best of ability.

(5) The final typed report must be reviewed by one of the senior technologists and by the Chief, Cytogenetics Laboratory, for possible clerical, or other errors. In the event a error is identified after mailing the final report, an amended report must be generated as soon as possible. The final report and amended report must be made part of the patient folder.

(6) All failure cases must be documented separately and must have a final report. The cause of test failure should be determined whenever possible.

(a) If the test failure has occurred as a result of technical error, such incidents must be documented and discussed with the respective technologists to prevent recurrence.

(b) If the failure is due to the sample quality or quantity, the Chief, Cytogenetics Laboratory, must discuss the problem with the referring physician.

(7) Remedial actions must be taken, as needed, and evidence of these actions evident in recorded documentation.

4.11 URINALYSIS

a. All VA Pathology and Laboratory Medicine Services will provide urinalysis services for diagnostic and monitoring purposes.

(1) Urinalysis consists of both a chemical and microscopic examination.

(a) Both the chemical (dip-stick) component and microscopic examination components of the urinalysis will be subject to quality control, PT and patient test management requirements.

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(b) The microscopic portion of the urinalysis will be performed and interpreted by certified medical laboratory personnel, or physicians with training in urine microscopy.

(2) The standards and requirements of JCAHO and CAP must be followed. Inspection accreditation and PT are required.

(a) Quality control testing, patient test management, personnel assessment for color-blindness and all other TQI policies and standards as noted in chapter 2, must be followed in addition to policies and standards in this chapter.

(b) These requirements are applicable to urine testing in all locations within the medical center, its clinics and remote locations, regardless of the complexity of other tests done at the same location.

b. PT. Participation in JCAHO inspection and CAP's nationally-accredited PT Program is required for each urinalysis test site in the medical center.

c. Patient Test Management. The following are required in each testing site:

(1) Test records. A log of testing including the name of each patient tested, date and time of specimen collection, quality control test results, patient test results and the name of the individual who performed each test will be kept at each testing location.

(2) Test reports. The test result must be reported in accordance with requirements in chapter 2, and the result must be maintained; records are to be disposed of in accordance with VHA's RCS 10-1.

d. Quality Control. The following are required in each testing site:

(1) Reagents. The date of opening each container of reagents (dip-sticks) shall be marked on the container. Reagents shall not be used after their expiration date.

(2) Procedure Manual. A procedure manual containing current information on correct testing procedures and written in the format recommended in NCCLS approved guideline, GP2-A2, "Clinical Laboratory Procedure Manuals," will be available at each testing location.

(3) Frequency of Quality Control Testing. Quality control tests must be performed at least once on each shift in which testing is performed, and must be documented in the same log that records patient test reports.

(4) Personal Performing Quality Control Testing. The person who performs the test on patient specimens will perform the quality control test at least once on each shift in which the testing is performed.

(5) Scope of Quality Control Testing. Urine dip-stick one level of abnormal control material will be used for each test, or batch of tests.

(6) Urine Microscopic Examination. Microscopic findings of each test result will be compared with dip-stick results and documented in a log book.

(7) Urine Pregnancy or Ovulation. For tests by dip-stick, one level of abnormal control material will be used for each test, or batch of tests.

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(8) Documentation of Quality Control Results and Remedial Actions. Quality control results, their analysis and review, and remedial actions, if any, must be documented for each urinalysis testing location:

- (a) In the VA medical center's main clinical laboratory.
- (b) Each ancillary testing site in the medical center.
- (c) Each medical center's outreach sites.

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