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1. Transmitted is a complete revision to Department of Veterans Affairs, Veterans Health Administration Manual M-2, "Clinical Affairs," Part VI, Pathology and Laboratory Medicine Service," Chapter 10, "Ancillary Testing," formerly entitled "Quality Control in Laboratory Services."

2. Principal policy changes are:

a. All testing sites that perform laboratory tests for patient care purposes must comply with JCAHO and CAP standards.

b. All Ancillary Testing Sites will follow the same operational and quality management standards required by the Clinical Laboratory Improvement Amendment of 1988.

c. An Ancillary Testing Coordinator shall be appointed at each VA medical center.

3. Filing Instructions

Remove pages

Insert pages

39 through 46

10-i

10-1 through 10E-1

4. RESCISSIONS: M-2, part VI, Chapter 10, "Quality Control in Laboratory Service," dated September 6, 1968, and VHA Circular 10-91-043.

for

Signed 2/5/93 by J.T. Farrar, M.D.

James W. Holsinger, Jr., M.D.  
Under Secretary for Health

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## CHAPTER 10. ANCILLARY TESTING

## 10.01 PURPOSE

This chapter establishes policy for ancillary testing for laboratory tests used for patient care purposes in all VA (Department of Veterans Affairs) medical centers and outreach functions.

## 10.02 GENERAL INFORMATION

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

b. Ancillary testing is defined as laboratory testing or services within a VA medical center or its outreach functions (clinic, et. al.) that is performed outside the physical facilities of the main clinical laboratory. (See app. 10A.)

c. All laboratory tests performed in VA medical centers and its outreach functions are of high complexity levels when they are used for patient care purposes regardless of the time required, method or analyzer used to perform the test.

## 10.03 POLICY

a. Each testing site performing laboratory testing for patient care (see app. 10A) must include specific quality management functions in its operational manual: (See subpar. 10.08c.)

b. All ancillary testing sites within VA medical centers and their outreach functions are mandated to comply with current Standards for Laboratory Accreditation of JCAHO (Joint Commission on Accreditation of Healthcare Organizations) and CAP (College of American Pathologists) regardless of scope of testing activity. NOTE: It is expected that there will be centralized coordination of all Ancillary Testing Site Programs through the VA medical center's Ancillary Testing Committee. (See par. 10.04.)

c. All ancillary testing sites are required to be inspected and fully accredited by CAP and JCAHO. The inspection of these sites, including bedside testing, will be performed during the same inspection visit for the VA medical center's main clinical laboratory. NOTE: CAP inspected ancillary testing sites are not required to undergo a second inspection by JCAHO if their ancillary testing functions have been inspected by CAP.

(1) Ancillary Testing Sites that perform tests for diagnosis, monitoring and other patient care purposes must be under the quality management oversight

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responsibility of the Chief, Pathology and Laboratory Medicine Service. NOTE: The CAP Commission on Laboratory Accreditation will not perform inspection/accreditation unless the VA medical center supports this oversight. If the Chief of Staff determines that an ancillary testing site should not be under the quality management oversight of the Chief, Pathology and Laboratory Medicine Service, the VA medical center must apply for a separate JCAHO inspection for these sites, and incur additional administrative responsibilities, preinspections and costs for this inspection.

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(2) Quality management records for all VA medical center and outreach ancillary testing sites must be maintained within the main clinical laboratory. The CAP inspector will review all centrally maintained records and visit only one or two of the ancillary sites in order to evaluate compliance with the Standards.

(3) The JCAHO implemented Decentralized (Ancillary) Testing Standards in January 1990, and requires written records and requirements for tests performed outside the main VA medical center laboratory, including identification of personnel performing testing and the responsibilities laboratory manager. (See app. 10B.) JCAHO also requires daily quality control tests and certification of current competency of testing personnel. NOTE: For VA laboratories, JCAHO maintains reciprocity with CAP, and accepts CAPs inspection and accreditation in lieu of its own inspection.

#### 10.04 ANCILLARY TESTING COMMITTEE

a. Each VA medical center will appoint an Ancillary Testing Committee for overall policy, standards development and operational quality management of ancillary testing (see app. 10C). This committee will provide medical appropriateness guidance coordination for all VA medical center outreach and home-based testing functions that are assigned to the parent medical center. (See subpar. 10.07a.)

##### (1) Membership

(a) The committee must be composed of representatives from Medical Service, Surgical Service, Ambulatory Care Service, Nursing Service, Pharmacy Service, all other services that perform ancillary testing, and the medical center's Quality Management Coordinator.

(b) The committee will be chaired by the Chief, Pathology and Laboratory Medicine Service. This position must be held by a licensed pathologist who is board certified at a minimum in clinical pathology. NOTE: This responsibility cannot be delegated to a non-pathologist. In a VA medical center with only a consultant pathologist, the consultant will chair the committee, and will be licensed and, at a minimum, board certified in clinical pathology. When it is impossible to find a qualified pathologist in remote VA locations, the chairperson may be a clinical scientist or clinician with laboratory residency training. If it is impossible to find such persons in remote locations, the chairperson may be the chief medical technologist/laboratory manager, as appointed by the Chief of Staff, or the Chief of Staff may chair the committee.

(c) The Chief, Pathology and Laboratory Medicine Service, will appoint an Ancillary Testing Coordinator as a member of the committee. (See subpar. 10.07b.) The Ancillary Testing Coordinator:

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1. Acts as a technical oversight supervisor for all ancillary testing sites for:

- a. Quality control.
- b. Records control.
- c. Proficiency testing.

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d. Inspection and accreditation for ancillary testing sites on a hospital-wide basis.

2. Oversees the safe and accurate testing of outreach function patients in the clinic and at home.

3. Develops, as part of a CQI (Continuous Quality Improvement) effort, a documentation plan for all ancillary testing sites.

4. Documents training, authorization, and annual competence evaluation for all persons in the medical center who perform capillary blood glucose testing.

(2) Responsibilities

(a) The Ancillary Testing Committee shall:

1. Develop protocols for healthcare persons performing testing for the purpose of assessing their levels of competence in testing (see app. 10B).

2. Define the clinical limits of acceptable variability for each type of test performed outside the main clinical laboratory.

3. Provide a protocol for immediate evaluation of results and actions by non-laboratory testing personnel if a test result is outside the specified range.

4. Decide which tests may be performed outside the main clinical laboratory for patient care diagnostic or monitoring purposes, which will be in the form of a written policy reviewed and approved by the VA medical center medical staff. NOTE: As new laboratory methods and testing techniques become available, the policy will be amended to reflect the needs of the medical staff, and standards will be developed for the use of newly introduced laboratory tests throughout the medical center.

5. Establish a plan to standardize methods and equipment that produce test results most commonly used by the VA medical facility medical staff in the diagnosis and monitoring of emergent and life-threatening conditions. This plan:

a. Will be based on safe and expedient delivery of quality care.

b. Will provide medical center-wide requirements to minimize duplication and/or discrepant test results, normal values, and reference ranges for test results between ancillary testing sites and the main clinical laboratory.

c. Will be centered around the main clinical laboratory's equipment configuration and methods that are used on a daily basis to report test results on the DHCP (Decentralized Hospital Computer Program).

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6. Establish, under the guidance of the Chief, Pathology and Laboratory Medicine Service, critical values ("panic" values), which will be used throughout the VA medical center and its outreach functions for notification of the patient's physician in an emergency or when an unexpected, life-threatening value is obtained in a testing site.

7. Ensure compliance with the following patient test management requirements for all ancillary testing sites.

a. Detailed written or electronic test requisition requirements to ensure accurate reporting of test results.

b. A recording system for specimens submitted that documents each step in processing and testing patient specimens to ensure that accurate test results are reported.

c. Adequate systems to report test results in a timely, accurate, and reliable manner, in addition to requirements governing the maintenance, timing and storage of test reports.

(3) Record Keeping. Good record keeping is necessary for good patient care, risk management, and to satisfy the requirements of regulatory and accrediting agencies.

(a) All ancillary testing sites will follow the same operational, quality management and record keeping standards required by the Clinical Laboratory Improvement Amendments of 1988.

(b) As a minimum, the following records must be maintained by the testing unit or the VA medical center's Ancillary Testing Coordinator and must be available for inspection at the time of visits by CAP, JCAHO, and other inspection groups.

1. Patient Test Results

a. Patient test results must include:

- (1) Patient identification.
- (2) Date and time of specimen collection.
- (3) Name of test performed.
- (4) Reference (normal) values.
- (5) Test result.
- (6) Name of analyst.
- (7) Name or location of laboratory performing the test.

b. Test results may be recorded on only in a test log in the testing unit or only in the patient chart.

(1) If recorded in the patient chart, results or frequently repeated tests, such as capillary blood glucoses or blood gases during a procedure should be

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entered on a flow sheet that clearly delineates the results as well as therapeutic interventions.

(2) It is mandatory that test results be entered into the DHCP system to facilitate integration of data and review by care givers. The Ancillary Testing Committee will determine which results, normal values and reference ranges should be in DHCP, in addition to critical results (see subpar. 10.04a.(2)(a)5.).

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2. QC (Quality Control) Records. QC records to include remedial actions taken when QC results are outside the acceptable range, must be up-to date. These records, or alternatively some other record, should indicate when reagent lots were changed and when maintenance was performed on the test system. QC records must also show evidence of review by the Ancillary Testing Site Director or Ancillary Testing On-Site Supervisor.

3. Proficiency Testing Results. Proficiency testing results to include remedial actions taken when QC results are outside the acceptable range, must be up-to-date. Proficiency testing records must also show evidence of review by the Ancillary Testing Site Director or Ancillary Testing On-Site Supervisor.

4. Instrument Maintenance Records. Instrument maintenance records showing routine maintenance including cleaning, as well as repairs or other service, must be up-to-date.

5. Instrument Calibrations. Records of Instrument calibration must be maintained and up-to date.

6. Problem log. A problem log, including remedial actions, must be maintained in the Ancillary Testing Site.

7. Authorizations. Specific authorization of each individual to perform testing including a listing of specific tests which the individual is authorized to perform, and level of supervisory review required before test results may be released. This authorization is to be signed by the Ancillary Testing Site Director.

8. Personnel Evaluations. Periodic evaluations of personnel, specifically in relation to their lab testing functions, with certification of their continuing competency to perform tests.

b. The Office of the Chief of Staff will provide the committee with the type and location of ancillary testing sites including bedside testing sites and their designated directors within the medical center. The chiefs of all clinical services that have ancillary testing sites shall provide the committee with annual estimates on the number and type of ancillary testing analyzers and methods that are used in these labs, and will update the list each time new methods and/or instruments are added or deleted.

c. In the event that there is a dispute regarding whether or not a test or group of tests performed by an ancillary testing site is considered research or medical care testing, the committee and the committee chair will adjudicate and resolve the dispute through the VA medical center's Clinical Executive Board and Chief of Staff. All disputes and their resolution will be recorded in the minutes of the Ancillary Testing Committee and/or Clinical Executive Board, specifically noting the final decision as to who will be responsible for inspection, accreditation, quality control, proficiency testing, patient



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is provided in appendix 10D. NOTE: The Committee will provide educational programs for the nursing and clinical staff regarding the need for blood glucose testing guidelines and some control on this very injury-prone and expensive activity, which may approach \$200,000 in supplies and another \$150,000 to \$2000,000 per year in labor for bedside glucose testing in major VA medical centers.

a. Only one brand of blood glucose testing meter and test strips will be used for in-house ancillary testing since there is wide variation in types of meters, techniques and technological changes and since educational efforts for patient safety will be easier to accomplish with one type of meter/strip. NOTE: Use of more than one brand has resulted in using the wrong test strips in the meter, producing erroneous results.

b. When possible, sufficient quantities of blood glucose testing strips and control solutions with the same lot number must be purchased within each VA medical center to allow consistency in-testing.

(1) The strips must be compatible with the one brand of glucose meter to be used, and only one lot number should be used in the VA medical center at one time.

(2) Two lots should be available at all times as the FDA (Food and Drug Administration) has been known to recall entire strip lots.

(3) Pathology and Laboratory Service and Pharmacy Service in each VA medical center must coordinate the change of lot numbers to assure that meters remain calibrated properly.

c. Blood glucose test strips must be stored at all times, according to the manufacturer's storage conditions for temperature and humidity, in a tightly closed container. When used in a meter, the manufacturer's recommended procedures should be followed for all test procedures and maintenance.

(1) Specifically, blood glucose test strips must never be:

(a) Cut lengthwise.

(b) Inserted in the meter backwards.

(c) Blotted improperly.

(d) Washed with tap water.

(2) Urine test strips for glucose must never be used in place of blood glucose test strips since erroneous readings could result.

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d. When used within VA medical centers or their outreach functions, blood glucose meters must be checked for calibration to a standard glucose reference and cleanliness on a regular basis under the VA medical center main laboratory's guidance. Standards for frequency of calibration will be set by the Ancillary Testing Committee, however, it should be no less than quarterly.

e. A key operator at each location where glucose meters are used must clean the meters on a daily basis and record the cleaning on the instrument maintenance log. Daily QC is, in effect a calibration check, especially if the manufacturer's control

solution, usually an aqueous material, is used. Standard glucose solutions as used in the lab are not appropriate for some meters because of matrix effects. Cross-correlation with a reference lab method using patient samples is logistically very complex to perform. The Ancillary Testing Coordinator will provide technical guidance on the correct methods to use.

f. Home Testing

(1) A choice of two different meters will be provided for home use to reduce procedural errors. Some meters are easier to read than others and some have design problems that make it difficult for patients to operate them in a safe manner.

(2) Patients using blood glucose meters or other testing meters at home must bring their meters to check them for accuracy, and calibration with a specific lot of test strips or for internal meter calibration and cleanliness, to check procedural techniques and to correlate them with the laboratory reference method.

(a) Routine maintenance (battery check/charges) and cleaning must be accomplished, as suggested by the manufacturer, when used in VA medical center ancillary testing sites.

(b) Patient education on meter maintenance and cleaning will be provided.

(c) The frequency of check/correlation should be at least quarterly for patients living far distances from a VA medical center, and more frequently for patients living in close proximity to a VA medical center.

(3) VA patients, with the exception of fee basis patients, who receive home testing devices for blood glucose testing or other tests through a VA medical center must have initial training and refresher training in their proper use provided by a qualified health care professional (such as a physician, a nurse, a pharmacist or a medical technologist). NOTE: Fee basis patients will be the responsibility of the fee basis prescriber. (See M-1, pt. I, ch. 18, subpar. 18.03(c).)

(4) When blood glucose testing materials have been provided by the VA to a patient for use at home, clinic personnel will:

(a) Be responsible for ensuring that the patient has been instructed and is proficient in:

1. Operations of the testing system; and
2. Cleaning and routine maintenance of the system.

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(b) Ensure that the test system is operating properly and that the patient is currently competent to obtain acceptable test results, during quarterly clinic visits, or at longer intervals if the clinic visits are less frequent.

(5) Encourage patients to test blood glucose levels frequently (one or more times each day for Type I patients, or as determined by the clinician) to assure that proper dosage of insulin is given.

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g. Healthcare Personnel

(1) Minimum qualifications for healthcare persons performing blood glucose testing using meters outside the main facility laboratory include, but are not limited to:

(a) Successful completion of a Diabetes Clinic or other approved in-service training program, and

(b) Random quarterly demonstration of levels of competence in blood glucose testing documented by the VA medical center Ancillary Testing Coordinator.

(2) Only healthcare persons are qualified to perform blood glucose testing. Each qualified healthcare person must perform at least one control test each shift for each meter they use, and must follow the standards established by the CAP Ancillary Testing Program and the Decentralized Laboratory Testing Guidelines of the JCAHO (app. 10B).

(3) Documentation of training, authorization to perform capillary blood glucose testing, daily quality control, and annual competence evaluation must be kept by the VA Medical Center's Pathology and Laboratory Medicine Service by the Ancillary Testing Coordinator. (See subpar 10.04a(1)c.).

h. Patient Safety Concerns

(1) To avoid patient injury and prevent adverse reactions to diabetic medications, the Ancillary Testing Committee may elect to recommend to the professional staff that the medical center no longer dispense glucose-measurement meters to monitor glucose levels of outpatients. This decision should be considered if several recurrent and significant problems surface. A safety concern exists if:

(a) Patients fail to appear for their clinic appointments and the self-administration of their medications is not physician-guided.

(b) The risk of injury increases if home glucose measurements are consistently not in agreement with glucose determinations performed by the medical center's main clinical laboratory.

(c) After investigation, it is determined that the patient and/or family members are not properly caring for the glucometer devices and the test strips, or not performing the proper periodic calibrations.

(d) Patients are found to be "skipping" medications when the glucometer readings are normal and educational efforts have little positive impact.

(2) The Ancillary Testing Committee may recommend, in lieu of home testing, that diabetic patients be monitored by the use of appropriate laboratory blood

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glucose determinations that are usually done at the time of regular outpatient clinic visits.

(a) Blood sugars may be monitored, through the Diagnostic Procedures Clinic, between clinic visits.

(b) Patients may also be monitored by Hemoglobin A1C levels, an arrangement preferable to home glucose monitoring because it is safer and achieves better glucose control with more frequent physician/dietitian contact.

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10.06 TEST MANAGEMENT

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a. Maintaining the reliability of ancillary testing is critical in the management of patients because patient care decisions are made, and action is taken immediately on the basis of test results. These tests are frequently high volume and high cost (in terms of labor expended to produce a test result), and they present a high risk to the patient because the personnel performing the tests are usually not technically trained to perform the test.

b. Test procedures, although appearing simple, are problem-prone. References in laboratory literature note that personnel without technical training using test systems developed for ancillary testing sites produce results significantly worse than results produced by fully trained laboratory technologists using the same test methods and equipment. As a result, a high level of quality management and compulsive attention to its use must be applied to ancillary testing, especially for blood glucose.

## 10.07 ANCILLARY TESTING SITE PERSONNEL

a. Ancillary Testing Site Director. The Ancillary Testing Site Director, even if not technically qualified to provide leadership for testing activities, is responsible for seeing that all requirements are carried out in accordance with applicable VA, regulatory and accreditation regulations.

(1) For each defined testing activity outside the main clinical laboratory (e.g., capillary blood glucose testing by nurses, stool occult blood testing, by house staff blood gas testing by operating room personnel, etc.), the Ancillary Testing Site Director must appoint an on-site supervisor with supervisory authority over the testing personnel.

(2) The on-site supervisor must have education, training and experience in clinical laboratory medical testing, and will have the responsibilities for:

(a) Ensuring that all requirements of CAP and JCAHO Standards and Scoring Guidelines are adhered to in the testing area.

(b) Ensuring that for all tests performed, all applicable sections of M-2, part VI are adhered to in the testing area.

(c) Ensuring that all tests performed are listed with the medical center's Ancillary Testing Coordinator in Pathology and Laboratory Medicine Service.

b. Medical Center ATC (Ancillary Testing Coordinator). Under the direction of the Chief, Pathology and Laboratory Medicine Service, the medical center ATC is a fully-qualified laboratory technologist with at least 2 years of experience in all areas of laboratory testing (see app. 10D). The Ancillary Testing Coordinator advises and assists each Ancillary Testing Site Director, supervisor and testing personnel in:

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(1) Selection of test methodologies appropriate for the clinical use of the test results. NOTE: This is critically important to ensure that there is consistency of patient test results, normal values, "panic" values and standardization of reporting of test results in DHCP.

(2) Verification of methods and test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.

(3) Enrollment and participation in a proficiency testing program commensurate with the testing services offered.

(4) Establishing a quality control program appropriate for the testing performed.

(5) Establishing acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results.

(6) Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

(7) Ensuring that all testing personnel know that patient test results are not to be reported until all corrective actions have been taken and the test system is functioning properly.

(8) Identifying training needs.

(9) Ensuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed.

(10) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to:

(a) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

(b) Monitoring the recording and reporting of test results.

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

(d) Direct observation of performance of instrument maintenance and function checks.

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

(f) Assessment of problem solving skills.

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(g) Evaluating and documenting the performance of individuals responsible for testing. NOTE: If test methodology or instrumentation changes, prior to reporting patient results, the individual's performance must be reevaluated to include the use of new test methodology or instrumentation.

c. Testing Personnel. Testing personnel are VA medical center employees who are authorized by the Ancillary Testing Site Director to perform patient testing. Their training and experience must be appropriate for the testing performed. The Ancillary

Testing Site Director is responsible for this determination and authorization. Ancillary Testing Site technical and supervisory personnel are subject to the same competency evaluations as main clinical laboratory personnel.

#### 10.08 REFERENCES

a. National Committee for Clinical Laboratory Standards NCCLS Documents C30-P ISSN 0273-3099 Ancillary (Bedside Blood Glucose) Testing in Acute and Chronic Care Facilities NCCLS, 771 East Lancaster Avenue, Villanova, PA 19085.

b. The Clinical Laboratory Improvement Amendments of 1988, Federal Register, Vol. 57, No. 40, February 28, 1992, pp. 7183-85 (Quality Assurance), 7163-72 (Quality Control), 7237-43 (Enforcement Procedures), 7146-62 (Proficiency Testing), 7162 - (Patient Test Management).

SAMPLE OF THE SCOPE OF ANCILLARY TESTING FUNCTIONS IN  
VA MEDICAL CENTERS AND OUTREACH PROGRAMS

Ancillary Testing Site	Responsible Administrative Service
1. Nuclear Medicine	Nuclear Medicine
2. Clinical Services	
a. Dialysis     Medicine	
b. Renal Function	Medicine
c. Blood Gas     Medicine or Surgery	
d. Pulmonary Function	Medicine
e. Anesthesia   Surgery	
f. Gastrointestinal	Medicine
g. Endocrine     Medicine	
h. Bone Marrow	Medicine
i. Psychotropic Drug Monitoring	Psychiatry
j. Pharmacokinetics	Pharmacology or Medicine (I.D.)
k. Toxicology    Medicine (Environmental Medicine)	
l. Sickle Cell	Medicine
m. Other _____	
3. Emergency Room	Medicine or Surgery
4. Intensive Care	
a. Medical Intensive Care Unit	Medicine
b. Surgical Intensive Care Unit	Surgery
c. Other _____	
5. Ambulatory Care	
a. Diabetes Clinic	Ambulatory Care
b. Urology Clinic	Ambulatory Care
c. Arthritis Clinic	Ambulatory Care
d. Other _____	Ambulatory Care
6. Bedside Testing	Nursing, Medicine, or Surgery
7. Resident Teaching	Medicine or Surgery
8. Mobile Clinic Ambulatory Care	

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9. Outpatient Clinic

a. Free Standing

Ambulatory Care

b. Satellite Ambulatory Care

10. Nursing Home and/or Domiciliary

Extended Care

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11. Outreach Functions

- |                                   |                                 |
|-----------------------------------|---------------------------------|
| a. Post Traumatic Stress Disorder | Psychiatry                      |
| b. Alcohol and/or Drug            | Psychiatry                      |
| c. Vietnam Veteran                | Readjustment Counseling Service |

12. Hospital Based Home Care                      Extended Care

13. Employee Health                                      Employee Health

14. Confirmatory Drug Testing                      Laboratory

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SUMMARY OF JCAHO DECENTRALIZED LABORATORY TESTING REQUIREMENTS

JCAHO (Joint Commission on Accreditation of Healthcare Organizations) requirements that follow are excerpted from "Pathology and Medical Laboratory Services" in the JCAHO Accreditation Manual for Hospitals

PA.6.4 Decentralized Laboratory Testing

PA.6.4.1 If diagnostic clinical laboratory testing for the organizations's patients is done within the organization, outside a central laboratory, then

PA.6.4.1.1 Personnel responsible for test performance and those responsible for direction/supervision of the testing activity are identified.

PA.6.4.1.2 Personnel performing tests have adequate, specific training and orientation to perform the test, and demonstrate satisfactory levels of competence.

PA.6.4.1.3 Current written policies and procedures are readily available and address

PA.6.4.1.3.1 Specimen collection;

PA.6.4.1.3.2 Specimen preservation;

PA.6.4.1.3.3 Instrument calibration;

PA.6.4.1.3.4 Quality control and remedial action;

PA.6.4.1.3.5 Equipment performance evaluation; and

PA.6.4.1.3.6 Test performance.

PA.6.4.1.4 Quality control checks are conducted on each procedure each day the procedure is performed, and identified problems are resolved; and

PA.6.4.1.5 Appropriate quality control and test records are maintained.

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ORGANIZATIONAL CHART FOR DIAGNOSTIC LABORATORY TESTING IN VA  
MEDICAL CENTERS AND OUTREACH FUNCTIONS

Appendix 10C is not available on WANG  
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SAMPLE PROTOCOL FOR WHOLE BLOOD GLUCOSE SUGGESTED CRITERIA  
FOR IN-HOUSE FINGERSTICK GLUCOSE MONITORING

1. A bedside whole blood glucose (fingerstick) test should be reserved for those patients whose clinical situation verifiably cannot permit a serum glucose test to be performed in the clinical laboratory, for example:

a. If the glucose value is such that it is less than 60 mg/dl or greater than 350 mg/dl or the patient's packed cell volume (Hematocrit) performed on the same day is less than 30 percent or greater than 50 percent, the glucose determination will be performed by the clinical laboratory on a serum sample drawn from the patient.

b. If the glucose value is suspected to be out of range of the glucometer, then a serum must should be ordered and sent to the laboratory to be performed on the patient's serum.

c. With proper quality control and quality assurance, bedside glucose monitor values are equal to serum laboratory values  $\pm$  10 to 20 percent. Therefore, serum glucose tests should be performed in the main laboratory and compared with fingerstick monitoring on a regular basis to prevent a discrepancy between the two different methods.

d. Fingerstick glucose determinations should be performed in conjunction with hematocrit determinations at the same time to prevent errors due to a high or low hematocrit values.

2. Drug interactions known to alter glucose values should be reviewed when patients are given medications which are known to elevate and/or lower blood glucose levels.

3. Serum glucose testing in conjunction with bedside glucometer testing or bedside testing alone may benefit patients with the following conditions: (This list of patient conditions is not all-inclusive and is utilized here as an example.)

\_\_\_\_\_ Patient on (TPN/Enteral Feeding) with suspected glycosuria.

\_\_\_\_\_ Patient receiving insulin infusion therapy.

\_\_\_\_\_ Patient on sliding scale insulin.

a. Fingerstick glucose determinations should be done 30 minutes before meals unless patient is on hyperalimentation which requires specific times to be designated for determinations.

b. The sliding scale approach often leads to a "roller coaster" effect with wide variations in blood glucose levels and should be avoided in most cases.

(1) \_\_\_\_\_ Patient on split/mixed regimen in whom tight control is a goal institution of tight control as defined below requires a diabetic consultation. Tight control is defined as a fasting blood sugar of less than 140 mg/dl, and 1 or 2 hour postprandial excursions of less than 200 mg/dl.

(2) \_\_\_\_\_ Patient on a new insulin regimen.

NOTE: Initial glucose testing (q.6 hr) requires daily profiles until control is established or during a period of illness.

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FUNCTIONAL RELATIONSHIP BETWEEN ANCILLARY TESTING SITE  
AND THE MAIN LABORATORY

Appendix 10E is not available on WANG  
A copy may be Xeroxed in the Under Secretary for Health's Library

Room 662, Techworld

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APPENDIX 10A

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