JAMES E VAN ZANDT VA MEDICAL CENTER
ALTOONA, PENNSYLVANIA

MEDICAL CENTER MEMORANDUM (MCM) 11L-04
AUGUST 2012

ANCILLARY TESTING

1. **PURPOSE**: To establish the guidelines, procedures, and personnel requirements for performing and maintaining an ancillary testing program in compliance with the College of American Pathologists (CAP), The Joint Commission, and the Department of Veterans Affairs regulations.

2. **SUMMARY OF MAJOR CHANGES**: Updating to include Altoona Veterans Affairs Medical Center (VAMC) and Community Based Outpatient Clinic (CBOC) International Normalized Ratio (INR) testing and expanding cleaning procedure. Modify the format so each ancillary test is a separate attachment.

3. **POLICY**:

a. Only approved ancillary tests are to be performed at this medical center. All ancillary tests must be approved and validated by a laboratory method.

b. Oversight of the ancillary testing program is the responsibility of the Chief, Pathology and Laboratory Medicine Service, in conjunction with the Ancillary Testing Coordinator.

c. When patients/residents are in a VA inpatient, Community Living Center (CLC), or ambulatory care setting, they may not perform self-testing, unless in a learning situation under nurses' supervision.

d. Ancillary blood glucose testing, Ancillary Urine Pregnancy Screen Testing at the CBOC, Ancillary INR testing at VAMC and CBOC's, and blood gas analysis are the only laboratory tests authorized to be performed outside the main laboratory area. See Attachments A, B, and C for Ancillary Blood Glucose Testing, Ancillary Urine Pregnancy Screen Testing at the CBOC, Ancillary INR testing at VAMC and CBOC's . Blood gas analysis is addressed in MCM 11M-27, Respiratory Care Services.

e. All ancillary tests will be performed only with a written provider order. Glucose testing may be done if a patient/resident is presenting with symptoms of hypoglycemia per protocol.

4. **DEFINITIONS**:

a. **Laboratory test** is defined as a diagnostic or monitoring procedure on a human specimen to determine specific information for patient/resident care, the prevention of disease, and to detect the impairment of health status.

b. **Ancillary testing** is defined as diagnostic laboratory testing performed outside the physical facilities of the main clinical laboratory by non-laboratory personnel.

c. **Proficiency testing** is defined as a method of demonstrating clinical competency.

d. **Confirmatory testing** is defined as laboratory testing performed in the main laboratory.

5. **RESPONSIBILITIES**:

a. **Chief of Staff** has overall responsibility for assuring compliance with this policy.

b. **Chief, Pathology and Laboratory Medicine Service** is responsible for the overall administration of the ancillary testing program.

c. **Ancillary Testing Coordinator (ATC)**, who is a registered medical technologist representative from the Pathology and Laboratory Medicine Service, is responsible for the overall management of ancillary testing. The Ancillary Testing Coordinator will monitor quality control, quality assurance, maintenance review, records control, preparation for inspection and accreditation of ancillary testing sites, and will assist in operator proficiency evaluation. The Ancillary Testing Coordinator monitors clinical competency through the proficiency testing program from College of American Pathologists.

d. **Supervisors and service chiefs** have overall responsibility for adherence to the ancillary testing program policy and procedures. They will serve as contact persons for resolution of any incidents of non-compliance or proficiency testing issues.

e. **Nurse managers** serve as liaisons between the Ancillary Testing Coordinator and certified operators in their units. The nurse managers are responsible for informing the Ancillary Testing Coordinator of any test site problems that may occur and assisting the Ancillary Testing Coordinator in the scheduling of proficiency testing. They are to oversee inventory control and all manufacturer required maintenance, and also oversees proper cleaning and disinfection of equipment.

f. **Certified instructor** is the individual who has received extensive technical training by a company representative, or at a company facility, in the performance of the ancillary test. The certified instructor will provide training of testing personnel in instrument operation and policy and procedure of the ancillary testing program. They will also participate in the evaluation and documentation of clinical competency.

g. **Certified operator** is defined as an individual who has successfully participated in the certification program presented by a certified instructor. Only certified operators will be authorized to perform ancillary INR testing on patients/residents in the CBOC's.

h. **Supervisory Medical Technologist** provides support to the ancillary testing program.

i. **Pathology & Laboratory Medicine Service staff** distributes all testing strips, quality control, reagents and test kit to all testing sites.

j. **Staff provider** is responsible for ordering, interpreting, and prescribing therapies.

k. **Logistics Section** is responsible for supplying lancets.

l. **Education Service** is responsible for the training of student nurses and new nurses and assisting with annual reviews of testing personnel. In conjunction with the Ancillary Testing Coordinator, Education will train new nursing personnel and evaluate clinical competency through the proficiency testing program.

m. **Pharmacy Service** is responsible for scheduling ancillary INR patient appointments, performing testing at the Altoona VAMC, interpreting the results and prescribing therapies for patients.

6. **PROCEDURES**:

a. Certification:

(1) Authorization to perform ancillary testing in this facility will be limited to those health care personnel who have satisfied the certification requirements. These requirements include participation in an in-service training program by a certified instructor and demonstration of clinical competency.

(2) Continued certification will be contingent upon successful recovery and interpretation of control data, adherence to policy and procedures. The ATC will notify Patient/Nursing Services and Pharmacy Service (for INR) of any issues related to staff compliance.

(a) Successful recovery and interpretation of control data is to be performed no less than once per year.

(b) Adherence to policy and procedure is continuous.

(3) Ancillary Blood Glucose, CBOC Point of Care (POC) Urine Pregnancy Screen Testing, and Ancillary INR Testing certification will be renewed annually, or more frequently if indicated by unacceptable performance on quality control, proficiency

testing, or lack of compliance to policy and procedure compliance. If retraining is indicated, it will be performed by the nurse educator or designee.

(a) Quality management and performance improvement will cover seven basic areas: quality control, maintenance, proficiency testing, record reviewing, reporting results, confirmatory testing, and on-site visits.

1. The following records are kept in the laboratory: Initial instrument verification, to include accuracy, precision, and linearity checks.

2. Training.

a. Initial training documentation from the nurse educator or designee will be filed in the laboratory and a copy maintained by the employee.

b. A list of current trained testing personnel, including certification expiration date, will be distributed by Education Service.

(4) On-site visits:

(a) The Ancillary Testing Coordinator will conduct on-site visits at least once per year for all clinical areas and each CBOC location where testing is performed.

(b) The Ancillary Testing Coordinator will observe and review all activities, including quality control, critical value reports, proficiency tests, data documentation, and the competencies of operators.

(c) The Ancillary Testing Coordinator will provide written reports to the Chief, Pathology and Laboratory Medicine Service to document on-site visit activities and give recommendations for improvements, if necessary.

7. **REFERENCES**:

a. Pathology and Laboratory Medicine Service Policies, VHA Handbook 1106.01, October 6, 2008

b. Accu-chek Inform System Operators Manual, Roche Diagnostic 2006

c. Roche Coaguchek XS Plus and XS System Operators Manual Roche Diagnostic 2007

8. **RESCISSION**: MCM 11L-04, Ancillary Testing, dated April 2012.

9. **REISSUE DATE**: Three years from date of MCM

10. **FOLLOW-UP RESPONSIBILITY**: Chief, Pathology & Laboratory Medicine Service

5. MCM 11L-04, Ancillary Testing

William H. Mills
Director

Distribution: E

6. MCM 11L-04, Ancillary Testing

Attachment A

Ancillary Blood Glucose Testing

Procedure:

Quality Control for blood glucose:

(a) A Level 1 and Level 2 control external controls is supplied by Pathology and Laboratory Medicine Service in ready to use form. Each level has an assigned acceptable range established by the manufacturer. The results will be reviewed by the Ancillary Testing Coordinator on a monthly basis and any discrepancies will be communicated to the Education Service for remedial education if warranted.

(b) Each control value must be evaluated for acceptability by the operator. If results are within range, patient/resident testing may proceed. If results are not within range, the instrument prohibits patient/resident testing until quality control results are acceptable.

(c) Quality control must be performed once each day on each instrument in the unit and CBOC before patient/resident testing may proceed.

Instrument Maintenance:

Instrument Maintenance: Routine maintenance and cleaning will be performed at the test site by the operator, as specified by the manufacturer's guidelines. The meters must be cleaned with PDI® super-sani cloth germicidal disposable wipes (PURPLE TOP WIPES) after each patient/resident test is performed. The two minute dwell time must be observed. These procedures will be outlined in the policy and procedure handbook located at each testing site. The Ancillary Testing Coordinator will assist in any in-depth maintenance, troubleshooting, or repair. The Ancillary Testing Coordinator will perform a monthly inspection of testing sites located within the medical center and annually at the CBOC's.

(a) Proficiency testing will be performed on a random rotating basis.

Reporting Glucose Results:

(a) Reference range for normal healthy adults in a fasting state is 70 milligrams/deciliters (mg/dl) to 100 mg/dl.

(b) Critical (panic) values: If a patient/resident result is less than 50 or greater than 400, the test must be repeated. If, after a repeat assay, the critical value is confirmed, the provider must be notified. The provider, at his/her discretion, may confirm the assay by laboratory analysis. Critical values reporting will follow MCM 11-18, Reporting of Critical and Abnormal Values.

(c) Any time a non-numerical result is obtained and confirmed by repeat analysis, the provider must be notified, and the assay must be confirmed by laboratory analysis.

(d) Whole blood glucose values of 200 mg/dl and above are affected by extremes in hematocrit. A hematocrit greater than (>) 55% can lower the glucose result by as much as 15 percent (%), while a hematocrit less than (<) 30% may increase the glucose results by as much as 10%.

(e) Critical value must be documented in patient's/resident's electronic medical record. Provider's name, test result, date, and communication time will be included in the documentation. The ATC reviews these and submits a monthly report.

Confirmatory glucose testing:

(a) If results are greater than 600 mg/dl and repeat with 600 mg/dl or higher, an order for STAT serum glucose must be obtained from a provider for confirmation.

(b) If results are less than 10 mg/dl and repeat with 10 mg/dl or lower an order for a STAT serum glucose must be obtained from a provider for confirmation.

Proficiency Testing:

Each certified operator must participate in proficiency testing as defined by regulatory and accrediting agencies. The proficiency testing program used at this medical center is a survey provided by the College of American Pathologists (CAP). This is a commercially prepared survey specimen that is received by the laboratory and distributed assay. The assay results are returned to the College of American Pathologists, who evaluates and determines the acceptability of the results. In the case of unacceptable performance on proficiency testing, the retraining will be performed by Education Service.

Competency and Evaluation:

(a) Quality Control (QC) for blood glucose – two levels of QC material are performed at least once per year by all testing personnel. Nursing will forward a spreadsheet with the names and dates performed to ATC for inclusion into the Remote Automated Laboratory Systems (RALS) system. For all new hires, during the first year, competency will be assessed by performing successfully two levels of QC at least semiannually. Records of this will be kept by the ATC.

(b) CAP performance samples for blood glucose are also used for competency – five unknown specimens provided by the CAP will be performed by testing personnel every 12 – 18 months. These specimens will be rotated among the staff and the Blood Glucose meters three times per year. Lab will evaluate CAP results and maintain records. A copy will be forwarded for Associate Director for Patient/Nursing Services for record keeping also.

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Supply Acquisition:

(a) Test strips and quality control materials for ancillary glucose testing will be provided by Pathology and Laboratory Medicine Service.

(b) Lancets will be obtained by Sterile Processing Services (SPS).

(c) Replacement meters may be obtained from the ATC.

Attachment B

Ancillary Urine Pregnancy Testing

Procedure:

Quality Control for urine pregnancy testing:

(a) Internal quality controls are performed when patient testing is performed.

(b) Two levels of external quality control and a known positive and negative patient/resident will be performed on new lot shipments.

(c) Each control value must be evaluated for acceptability by the testing personnel. If results are within range, patient testing may proceed. If results are not within range, the pregnancy kit is discarded and a new one is used.

Reporting Pregnancy Test Results:

(a) Reference ranges for healthy non-pregnant women is negative.

(b) Results are documented in the patient electronic medical record.

Confirmatory Urine Pregnancy Testing:

If results are positive, an order for a serum quantitative Beta HCG test must be obtained from a provider for confirmation.

Proficiency Testing:

(a) Each certified operator must participate in proficiency testing as defined by regulatory and accrediting agencies. The proficiency testing program used at this medical center is a survey provided by the College of American Pathologists. This is a commercially prepared survey specimen that is received by the laboratory and distributed to various sites for assay. The assay results are returned to the College of American Pathologists, who evaluates and determines the acceptability of the results. In the case of unacceptable performance on proficiency testing, the retraining will be performed by Education Service.

(b) Proficiency testing will be performed on a random rotating basis.

Competency and Evaluation:

CAP performance samples for urine pregnancy testing – five unknown specimens provided by the CAP will be performed by testing personnel every 12 – 18 months. These specimens will be rotated among the staff three times per year. Lab will evaluate

CAP results and maintain records. A copy will be forwarded for Associate Director for Patient/Nursing Services for record keeping also.

Supply Acquisition:

(a) Test kits and controls will be provided by the Pathology and Laboratory Medicine Service and be stored at the CBOC in the lab area.

Attachment C

Ancillary International Normalized Ratio (INR) Testing

Procedure:

There are two types of meters used for INR testing. One meter will be used at Altoona site and the other meter will be used at the CBOC's.

Quality control for INR testing:

(a) Both types of meters perform built in QC tests independently. The quality control function is incorporated into the test strip. There are two levels of QC run with each patient test. If the QC test fails, the meter displays a QC error message and will prohibit patient testing until QC is acceptable.

(b) Level 1 and level 2 external controls are performed once a month on the meters used at the Altoona site. Each level has an assigned acceptable range established by the manufacturer. Testing is performed, reviewed and documented by the ATC.

Instrument Maintenance:

Routine maintenance and cleaning will be performed at the test site by the operator, as specified by the manufacturer guidelines. The meters must be cleaned with PDI® sani-cloth bleach germicidal disposable wipes (ORANGE TOP WIPES) after each patient test is performed. Four minute dwell time must be observed. These procedures are outlined in the policy and procedure handbook located at each testing site. The ATC will assist in any in-depth maintenance, troubleshooting, or repair. The ATC will perform a monthly inspection of testing sites located within the medical center and annually at the CBOC's.

Reporting INR Results:

(a) Reference range of INR: 0.8-1.2.

(b) Critical (panic) values: If a patient INR result is greater than (>)4.0, the test will be repeated. If it is still > 4.0, the Clinical Pharmacist must be notified and the test must be confirmed by a laboratory INR assay (venipuncture).

(c) Results that, in the Clinical Pharmacist judgment, appear to be inconsistent with patient therapy should be viewed as questionable and the test should be repeated.

(d) Critical values must be documented in the patient's electronic record. Provider's name, test result, date, and communication time should be available to identify in the documentation. The ATC reviews these and submits a monthly report.

(e) In Altoona VAMC, patient results will be downloaded electronically into the patient's chart.

(f) In the CBOC's, nursing staff will enter patient's results in a nursing template and the Pharm D will meet with the patient via telehealth and address the test results and dosing therapies.

Confirmatory Testing:

(a) If results are > 4.0, an order for a laboratory PT/INR test must be obtained from the Clinical Pharmacist for confirmation.

(b) Due to linearity limits of the test meter which is 0.8-8, if results are > 8.0, an order for a STAT laboratory PT/INR test must be obtained from the Clinical Pharmacist for confirmation.

(c) Due to linearity limits of the test meter which is 0.8-8, if results are <0.8, an order for a STAT laboratory PT/INR test must be obtained from the Clinical Pharmacist for confirmation.

Proficiency testing:

(a) Each certified operator must participate in proficiency testing as defined by regulatory and accrediting agencies. The proficiency testing program used at this medical center is a survey provided by the College of American Pathologists. This is a commercially prepared survey specimen that is received by the laboratory and distributed to various sites for assay. The assay results are returned to the College of American Pathologists, who evaluates and determines the acceptability of the results. In the case of unacceptable performance on proficiency testing, the retraining will be performed by nurse educator or designee.

(b) Proficiency testing will be performed on a random rotating basis.

Competency and Evaluation:

(a) CAP performance samples for INR – five unknown specimens for Altoona VAMC meters and three unknown specimens for the CBOC meter provided by the CAP will be performed by testing personnel every 12 – 18 months. These specimens will be rotated among the staff and the INR meters three times per year. Lab will evaluate CAP results and maintain records. A copy will be forwarded to Associate Director for Patient/Nursing Services and Pharmacy Service for record keeping also.

Supply Acquisition:

(a) Test strips will be provided by Pathology and Laboratory Medicine Service

(b) Lancets will be obtained by Supply/Distribution.

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(c) Replacement meters will be obtained from the ATC.

(d) Supplies will be stored at room temperature at a monitored area.