D.12 ANCILLARY BLOOD GLUCOSE TESTING POLICY

I. PURPOSE: To establish policies, procedures and requirements for performing and maintaining the Ancillary Blood Glucose Testing (ABGT) program in compliance with The Joint Commission (TJC) standards, College of American Pathologists (CAP) standards and Department of Veterans Affairs, Veterans Health Administration Handbook 1106.1, *Pathology and Laboratory Medicine Service Procedures*, paragraph 8, "*Ancillary Testing*".

II. POLICY:

A. ABGT is performed outside the physical facilities of the main clinical laboratory.

B. All ancillary test sites must comply with current standards for laboratory accreditation, including TJC, CAP and CLIA '88. Ancillary test sites are inspected and accredited by TJC and CAP.

C. Finger stick glucose testing is intended for patients whose clinical situation warrants close supervision of their blood glucose levels.

D. For glucose values beyond the measurable range of the glucose meter (< 10 mg/dL [LO] or > 600 mg/dL [HI]), a serum glucose must be ordered and sent to the main clinical laboratory for confirmatory testing.

E. If the hematocrit is < 20% or > 55%, results obtained from the glucose meter are unreliable; a serum glucose must be sent to the main clinical laboratory for analysis.

F. Unless otherwise requested by a physician, finger stick glucose determinations should be done 30 minutes before meals. If the patient is on hyperalimentation, specific times for glucose testing will be per physician order.

G. Ancillary test sites fall under the responsibility of the Lead Pathologist, Pathology & Laboratory Medicine Service (P&LMS) for quality management oversight

H. Quality management records for all ancillary test sites are maintained within the main clinical laboratory. The Ancillary Testing Coordinator or Program Director monitors the Quality Control (QC), Quality Assurance (QA) and maintenance documentation for all glucose meters.

III. RESPONSIBILITIES:

A. Program Director: The Lead Pathologist, P&LMS, or designee is responsible for the overall quality management of the ABGT program.

B. Ancillary Testing Coordinator (ATC) is responsible for:

1. Instructing new testing personnel during orientation. Nurse Education works with the ATC to instruct new personnel in policies, procedures and QC.
2. Providing technical oversight for all ancillary testing sites.
3. Evaluating instrumentation and implementing all test procedures.
4. Monitoring QC, QA, maintenance, and training of authorized individuals, and retention of all such information.
5. Retaining all QC, QA, maintenance and information related to authorization of individuals in the clinical laboratory.
6. Supplying QC materials and glucose meters.

C. Ancillary Testing Site Supervisors are Nurse Managers at each ancillary site, who:

1. Assure all qualified personnel are trained and authorized to perform ABGT.
2. Take and document corrective action for non-compliance and/or deficiencies.
3. Appoint a ward preceptor (designated trainer) who assists in the training of policies and procedures, and in evaluation and documentation of competency.

D. Authorized Operators are individuals who have been properly trained and are responsible for performing ABGT. They:

1. Perform and document patient tests and quality control.
2. Perform and document instrument maintenance.
3. Participate in a proficiency testing program.
4. Apply universal precautions at all times. Gloves must be worn during testing and changed between patients.
5. Maintain compliance by running both levels of controls (low and high) at least once per year.

IV. PROCEDURES

A. Authorization:

1. ABGT is limited to those individuals who have satisfied certification requirements. These requirements include:
    a. Participation in a training program,
    b. Completion of a written test,
    c. Demonstration of clinical competency.
2. Continued authorization requires a satisfactory QC and proficiency record, along with adherence to procedures.
3. Authorization is renewed annually (or sooner, if indicated by performance) via demonstration of clinical competence through routine QC monitors.
4. Individuals not complying with policies or procedures are removed from the list of authorized personnel.
5. Reinstatement occurs only after additional training and demonstration of clinical competence. The reinstatement form is signed and submitted to the ATC.

B. Quality Assurance: Quality Assurance Logs: Each meter has its own permanent log that is retained for the life of the instrument. The log is located in the laboratory and includes the following information:
1. Initial instrument verification, including accuracy, precision and linearity.
2. QC collected from each meter; data is stored on a hard drive for future reference.
3. Maintenance/service records.
4. Training documentation.

C. Quality Control:

1. All authorized operators must participate in the QC program.
2. Control material consists of low and high-level solutions.
3. Each instrument has a daily QC check using both levels of control.
4. Control values are logged into the instrument and include the following information: date, time, operator's initials, reagent strip data (lot number, expiration date and code number), and control lot data (lot numbers and expiration dates for each level of control).
5. Each control value is evaluated for acceptability. If the results are not within the expected range, the instrument automatically flags "control out of range". Corrective action must be documented.
6. Both control levels are run whenever a new package of reagent strips is opened, or whenever a meter's performance is in question.
7. Each operator must run both levels of control at least once yearly to maintain compliance.

8. If unopened, controls are good until the expiration date on the package. After opening, they a good for 3 months from the date they are put into use. The vials are labeled with the date they are opened.

D. Proficiency Testing (PT):

1. Authorized individuals must randomly participate in the PT program. PT is performed three times a year, and successful completion is required in order to perform ABGT.
2. If a test site shows a pattern of unacceptable results on QC and/or proficiency testing, that site will have their meters checked and replaced, if needed.
3. If a pattern of unacceptable performance continues, the test site may have their meters removed and ABGT privileges suspended.

E. Patient Testing:

1. All patients are positively identified by full name and social security number.
2. A drop of blood obtained by a self-retracting and auto-disabling single use finger stick device; is dropped on the Accu-Chek Inform test strip, and the test is performed according to procedure.
3. Patient results are recorded on a flow chart or sheet and include:
    a. Patient identification
    b. Date and time of specimen collection
    c. Name of test performed
    d. Test result
    e. Name of analyst
    f. Name or location of where test is performed.
4. When the glucometer is set at the charging base unit, results automatically upload every 10 minutes into VISTA. Results with wrong patient identification numbers, wrong location, are held and reviewed by the ATC. After review and correction, data is released and uploaded to VISTA.
5. Infection control policies are followed at all times.
6. Patient Self-Testing: Patients are in a VA inpatient or ambulatory care setting may <u>not</u> perform self-testing, except when self-testing is required as part of a patient education program. Results from patient self-testing may <u>not</u> be utilized for patient diagnosis or treatment. Laboratory personnel must be available to participate in patient education.

F. Maintenance:

1. Each site supervisor is responsible for ensuring meters are cleaned as needed. <u>Use of protective gloves is required.</u>
2. Clean the Accu-Chek Inform meter after each usage with approved disinfected and document as such.
3. After use in an isolation room, the meter must be immediately cleaned and documented in the meter.

G. Supply Acquisition

1. Accu-Chek Inform test strips and finger stick lancets are supplied by Supply Service.
2. Control material, batteries and replacement meters may be obtained from the ATC, x65771.

H. Results Reporting:

Reference range for normal healthy adults:

Fasting…….	70-115 mg/dL
2 hr after a meal…	<145 mg/dL

Critical Values: Any value < 50 mg/dL or greater than 450 mg/dL should be repeated or confirmed by the chemistry laboratory via a serum glucose. A confirmed or repeat value of < 10 mg/dL (LO) or > 600 mg/dL (HI) requires sending a serum sample to the laboratory for a serum glucose. Critical Value reporting procedures are followed (see Critical Results Procedure for more information).

I. Guidelines for Ordering Finger stick Testing

1. Bedside glucose testing is generally recommended in the following situations:
    a. Patient on TPN/enteral feeding with suspected glycosuria
    b. Patient receiving insulin infusion therapy
    c. Patient on sliding scale insulin
    d. Patient on split/mixed regimen for tight control
    e. Patient on a new insulin regimen

2. If the test is ordered four times a day, it must be renewed after 72 hr.

V. REFERENCES

- The Joint Commission Standards
- CAP Inspection Checklist – Ancillary Testing 2008.
- NCCLS Document C30-P, Vol. 9, No 7 and C30-T, Vol. 11, No 8
- Accu-Chek Inform System Operator's Manual 2002
- Department of Veterans Affairs Handbook 1106.1, October 6, 2008.

VI. FOLLOW-UP RESPONSIBILITY:

- Lead Pathologist, Pathology & Laboratory Medicine, (518) 626-5708