Lab Focus

A Newsletter for Fairview Health Services Clinical Laboratories

Revised ADA Criteria for Gestational Diabetes

**Low Risk:** Screening for Gestational Diabetes Mellitus (GDM) is not necessary for pregnant women who meet all of the following criteria:

- <25 years of age;
- Normal body weight;
- No family history, i.e., first-degree relative with diabetes;
- No history of abnormal glucose metabolism or poor obstetric outcomes;
- Not a member of an ethnic/racial group with a high prevalence of diabetes, e.g., Hispanic, Native American, Asian American, African American, or Pacific Islander.

**High Risk:** Women at high risk of GDM, i.e., marked obesity, personal history of GDM, glycosuria, or a strong family history of diabetes, should undergo testing (see below) as soon as feasible. If found not to have GDM at initial screening, the patient should be retested at 24-28 weeks of gestation.

**Average Risk:** Women with average risk of GDM should undergo testing (see below) at 24-28 weeks of gestation.

**Biochemistry:**

Two or more values must meet or exceed for a positive diagnosis. Perform in the morning after an overnight fast of 8-14 h and after at least 3 days of unrestricted diet (2150g carbohydrate/d) and unlimited physical activity. The subject should remain seated and not smoke throughout the test.

**Blood Components:**

HCFA Final Rule on Prospective Payment System for Hospital Outpatient Services

The Health Care Financing Administration’s (HCFA) final rule establishing a prospective payment system (PPS) for hospital outpatient services created new Ambulatory Payment Classification (APC) groups for blood components with substantially increased payments.

The agency raised payments for many blood services to more accurately reflect the actual cost, recognizing the costs of recently developed blood safety tests. HCFA created additional blood-related APCs to accurately account for diverse products, by adding HCFA Common Procedure Coding System (HCPCS) codes.

HCFA clarified that these products and services will be reimbursed at 100% of the designated payment. This is a correction to the original proposed rule, which would have provided only 50% reimbursement for multiple blood related services offered during the same outpatient visit.

Plasma products appear to be excluded in that they will be part of the “transitional pass-through” outlined in the Balanced Budget Refinement Act (BBRA) of 1999. This allows payments to be based on cost for one to two years, until HCFA has appropriate billing information.

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*Michael Steffes, MD, PhD, UMPH* *Physicians*  
1 Diabetes Care, 23:S4-S19, Jan 2000.
FAQ’s: Point of Care Testing & JCAHO

Who licenses point of care testing (POCT)?
POCT at each site is covered under the corresponding laboratory’s Clinical Laboratory Improvement Amendments (CLIA) license.

Who accredits POCT?
Within the laboratory, POCT is inspected and accredited by the College of American Pathologists (CAP). It is also covered during the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) accreditation process.

What is meant by “waived testing?”
HCFA identified eight tests as waived in 1992. Currently, there are 45 waived “analytes” and hundreds of different tests and kits. Although CLIA has no defined regulatory standards for these tests, the manufacturer’s instructions must be followed exactly. In addition, hospitals and/or clinics seeking accreditation from another certifying body, e.g., JCAHO or CAP, must meet the standards of the accrediting organization. Point of care testing currently includes both waived (e.g., hemoccult) and moderately complex (e.g., activated clotting time) testing; both waived and moderately complex testing must follow Fairview protocols established in compliance with CAP and JCAHO regulations.

What is required for physicians performing fecal and gastric occult blood tests in an accredited organization?
JCAHO does not require an initial orientation or ongoing competence assessment for physicians performing these tests unless the organization requires it. The individual responsible for waived testing activity, i.e., the laboratory, should make this determination. In addition, quality control policy should assure that these tests can be performed properly. At a minimum, procedures should assure that reagents and strips are stored properly and are not outdated. Physicians performing testing should follow the policy adopted by the organization.

Kathy Hansen, Operations Director
F-UMC Laboratory Services

F-UMC, U Campus
Quantitative D-Dimer to Replace FDP

Effective Nov. 1, a new quantitative D-Dimer method will replace Fibrinogen/Fibrin Degradation Products (FDP) and current D-Dimer assays (including Simpli-RED). The new quantitative D-Dimer will be offered 24 hours/day. Elevated FDP is a marker of both fibrinolysis and fibrinogenolysis. As such, the assay lacks specificity. Its primary clinical application has been in the diagnosis of disseminated intravascular coagulation (DIC). D-dimer is a specific marker of the breakdown of a cross-linked fibrin clot (i.e., fibrinolysis), and an indirect marker of clot formation. Most D-Dimer assays are more sensitive to circulating fibrin degradation products than FDP assays. Depending on the circumstances, this may be viewed as advantageous or disadvantageous. However, many hospitals have discontinued FDP, citing the higher specificity of D-Dimer which may make the FDP assay redundant. A clear advantage of D-dimer assays is that unlike FDP, they can be performed on standard coagulation laboratory (citrated/blue top) samples.

Elevated levels of D-dimer are present in a wide variety of disorders known to be associated with activation of coagulation:
- Pre-DIC conditions and DIC;
- Sickle cell disease;
- Pregnancy, higher if complicated;
- Renal diseases;
- Arterial thrombosis;
- Venous thromboembolism (VTE), including deep vein thrombosis (DVT) and pulmonary embolism (PE).

With a high sensitivity and negative predictive value for DVT, a negative D-dimer in conjunction with a negative venous compression ultrasonography (CUS) reliably excludes the diagnosis of DVT, obviating the need for serial CUS testing.

Nigel Key, MD, UMPhysicians

F-UMC
Specimen Labeling

In order to promote patient safety, the specimen labeling policy was recently standardized on both F-UMC campuses. Because of the medical-legal decisions made by physicians based on laboratory results, it is imperative physicians are informed of specimen quality issues. Although there was concern whether this would be a physician dissatisfier, some physicians have promoted an even more stringent “zero tolerance” policy.

Specimen Labeling

1. Assure correct identification of the patient by checking the patient’s wristband for name and identification number prior to collection and labeling. For outpatients, ask the patient to state name and birthdate.
2. Label the container (not transport bag) at patient’s side at time of collection. Include the patient’s full name and identification number on the label(s). If the specimen is from the Blood Bank, also include on the label the date and initials of the person collecting the specimen.

Unlabeled/Mislabeled Specimen Policy

1. If the specimen cannot be recycled, the patient’s physician seeks approval for testing from the charge Clinical Laboratory Scientist (CLS).
2. If identification of a mislabeled specimen is clearly traceable, the specimen is approved for testing.
3. Unlabeled specimens are generally not approved for testing unless the specimen is:
   - Arrest specimen;
   - Arterial puncture, cerebral spinal fluid (CSF), or other invasively collected specimen;
   - Outpatient specimen (including Home Health).
3. When a specimen is approved for testing, an incident form is signed by the physician before results are reported. Exception: The form is signed following an arrest or if a community physician is not on site.
4. If a mislabeled/unlabeled specimen is not approved for testing, the patient’s attending physician may contact the laboratory medical director.

John Eckfeldt, MD, PhD
Medical Director, F-UMC

F-UMC
Myoglobin & CK MB To Be Discontinued

Effective Nov. 15, CK MB and myoglobin testing will no longer be performed at F-UMC. F-UMC Emergency physicians, cardiologists, and pathologists have concluded that myoglobin adds little to making a correct diagnosis of AMI. The test has proven to be potentially detrimental. Not only is it quite frequently positive without cardiac disease, as