

Sound Bites . . .

Decrease Platelet Dose at FUMC

The FUMC Transfusion Committee recommended a decrease in platelet pool size from 6 to 5 based on increased platelet yield and reduced donor exposure. Five pre-storage leukoreduced platelet concentrates provide a yield of 4.0×10^{11} platelets which is equal to six bedside filtered platelet concentrates.

EDTA Tube Now Standard for Blood Bank Testing

In conjunction with implementation of gel technology for antibody screening at all sites, purple (EDTA) tubes are now preferred for collection of blood bank testing.

Conversion to Frozen Plasma

As recommended by the FUMC Transfusion Committee, fresh frozen plasma (frozen within 8 hours) has been replaced with frozen plasma (frozen within 24 hours) at FUMC.

New *H pylori* Fecal Antigen Test Specimen Requirements

Place formed or liquid feces in sterile, screw cap container. Feces in transport media or swabs in preservatives are not acceptable. Testing is performed 3 times/week; results are reported within 2 days. Performance results have not been established for watery, diarrheal stools.

New Qualitative D-Dimer Specimen Requirements

SimpliRED will initially be offered as a pilot for FUMC ED only. Collect 2.7 mL in a light blue tube. Testing will be performed 24 h/d; turnaround time is 1 hour.

Standardized Testing for Diagnosis of Diabetes Mellitus

Confirm by repeat testing on a 2nd day:

- Symptoms plus random glucose ≥ 200 mg/dL
- Fasting glucose ≥ 126 mg/dL
- 2 hour glucose ≥ 200 mg/dL post 75 g glucose load

OGTT is not recommended; if performed, collect fasting and 2 hour specimens only. Do not collect urine.

Lab Focus

New *H pylori* Fecal Antigen Test

Patricia Ferrieri, MD, Medical Director

Infection with *Helicobacter pylori* may lead to chronic gastritis and predispose to gastric and duodenal ulcers. Infection with *H pylori* is very common and has been estimated to occur in 40-50% of the population in developed countries and 80-90% of the population in developing regions. Several techniques, both invasive and non-invasive have been utilized to diagnose *H pylori* infection. The urea breath test is based on the detection of labeled carbon dioxide in expired air as a result of urease production by *H pylori*. Serological tests are based on the detection of a specific anti-*H pylori* response, mostly by IgG antibodies in a patient's serum.

Among the invasive techniques used for diagnosis of *H pylori* infection is endoscopic biopsy of the antrum or corpus of the stomach with detection of *H pylori* by specialized stains such as Giemsa, culture and rapid urease test. Non-invasive methods are preferred when endoscopic evaluation is not necessary to rule out a malignancy. Serologic approaches detect the host's immune response to the infection, but do not permit a physician to distinguish current active infection from a past infection. In addition, the antibody titer does not decrease sufficiently after therapy for accurate prediction of eradication of the organism.

The basis for diagnosing *H pylori* infection by **fecal antigen test** is the finding that the organism can be isolated from feces by culture technique; however, culture is not a sensitive method for detecting the presence of the organism in fecal samples. Recent literature confirms that there is fecal shedding of *H pylori* in infected individuals, and that the organism can also be found in vomitus and saliva. Polymerase chain reaction (PCR) has been used in research studies for detecting *H pylori* in clinical specimens, but PCR cannot distinguish between DNA from viable cells versus non-viable organisms.

The laboratory currently offers breath testing, rapid urease testing on endoscopic biopsies, culture of tissue, and antibody

testing. The new non-invasive fecal antigen test, an enzyme immunoassay, was approved by the FDA for both primary diagnosis and evaluating eradication of infection with *H pylori*. Studies in the literature have revealed that the *H pylori* fecal antigen test had similar sensitivity and specificity to PCR. Another large multi-center European diagnostic trial in adults revealed that the fecal antigen test had equivalent sensitivity and specificity to the urea breath test for both primary diagnosis and monitoring eradication. The fecal antigen test has a sensitivity of 94-96% and a specificity of 92-96%.

It is likely that the fecal antigen test will be a superior substitute for the antibody test in both the diagnosis and treatment of patients with peptic ulcer disease and chronic gastritis associated with *H pylori*.

New Qualitative D-Dimer

Nigel Key, MD, UMPhysicians

A **pilot** will begin March 6 with the FUMC ED to evaluate a new qualitative D-dimer assay, SimpliRED. Because elevated D-dimer levels are associated with many diseases, the test is not specific for venous thromboembolism (VTE). However, with a high sensitivity and negative predictive value, D-dimer is useful to exclude the diagnosis of VTE if used with other radiologic evaluation. It is most appropriate in the outpatient setting where comorbid conditions that elevate D-dimer are less common.

In deep vein thrombosis (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.

In pulmonary embolism (PE), due to limited data, recommendations are premature. A negative D-dimer in conjunction with a negative CUS and nondiagnostic (low or intermediate probability) ventilation perfusion (V/Q) lung scan may preclude the need for serial noninvasive testing (e.g., CUS). This combination may also obviate the need for pulmonary angiography, when the clinical probability of PE is rated as low or intermediate.

ADA Revised Criteria: Diabetes Mellitus Diagnosis and Testing

Michael Steffes, MD, PhD, Priscilla Bormann, CLS, and Chris Senn, CLS

Fairview Laboratories has standardized diagnostic glucose testing based on the recommendations of an International Expert Committee, working under the sponsorship of the American Diabetes Association, (Diabetes Care 20: 1183-1197, 1997).

Revised Criteria for Diagnosis of Diabetes Mellitus

Note: In the absence of unequivocal hyperglycemia with acute metabolic decompensation, criteria should be confirmed by repeat testing on a different day.

1. Symptoms of diabetes (polyuria, polydipsia, and unexplained weight loss) plus a random (i.e., any time of day without regard to the last meal) plasma/serum glucose level ≥ 200 mg/dL.
or
2. Fasting plasma/serum glucose (FPG) level ≥ 126 mg/dL after a minimum 8-hour fast.
or
3. 2-hour post glucose challenge plasma/serum glucose level ≥ 200 mg/dL after an appropriate oral glucose load. The oral glucose tolerance test (OGTT) should be performed as described below.

Oral Glucose Load: 75 g glucose dissolved in water
 Fasting Glucose: ≥ 126 mg/dL
 2 Hour Glucose: ≥ 200 mg/dL
The protocol does not include urine collection for glucose.

This differs from the World Health Organization (WHO) standards (Diabetes Mellitus, Technical Report Series 727, WHO, Geneva 1985), in using 126 mg/dL as the upper limit for a fasting glucose.

The OGTT is not recommended for routine clinical use. Disadvantages of the OGTT are: inconvenient for health care givers and patients; more costly and time-consuming than the FPG, less reproducible than the FPG.

Screening and Diagnosis Scheme for Gestational Diabetes Mellitus

Screening for Gestational Diabetes Mellitus (GDM) may not be necessary in pregnant women who meet all of the following criteria: <25 years of age, normal body weight, no first-degree relative with diabetes, and not Hispanic, Native American, Asian, or African-American.

Plasma/Serum Glucose	50 g Load Screening Test	100 g Load Diagnostic Test
Fasting	-	105 mg/dL
1 hour	140 mg/dL	190 mg/dL
2 hour	-	165 mg/dL
3 hour	-	145 mg/dL

The 100 g diagnostic test is performed on patients with a positive screening test. Diagnosis of GDM requires any two of the four glucose values meet or exceed the values indicated.

Fairview Laboratories
 Box 198, University Campus
 420 Delaware St. S.E.
 Minneapolis, MN 55455
 Comments: csenn1@fairview.org

ADDRESS CORRECTION REQUESTED

Criteria for Testing for Diabetes in Asymptomatic, Undiagnosed Individuals

Individuals with diabetes often have the disease for 7-10 years before being diagnosed, leaving them with an advanced case of disease, more serious disease sequelae, and greater costs for medical treatment. The CDC estimates 16 million Americans have diabetes, but at least 5 million of these remain undiagnosed.

1. Consider testing for diabetes in all individuals at 45 years and above and, if normal, repeat at 3-year intervals.
2. Consider testing at a younger age or more frequently if:
 - obese ($>120\%$ desirable body weight or BMI >27 kg/m²)
 - first-degree relative with diabetes mellitus
 - high-risk ethnic population
 - delivered a baby >9 lb. or diagnosed with GDM
 - hypertensive ($>140/90$ mm Hg)
 - HDL cholesterol >35 mg/dL and/or triglyceride >250 mg/dL
 - impaired glucose tolerance or impaired fasting glucose on previous testing

The diagnosis of diabetes mellitus using HbA_{1c} has not been recommended, because the HbA_{1c} test is not standardized. However, HbA_{1c} is clearly indicated for measuring therapeutic efficacy.

Impaired Glucose Tolerance (IGT) & Impaired Fasting Glucose (IFG)

The terms IGT and IFG refer to metabolic stages intermediate between normal glucose homeostasis and diabetes mellitus. IFG includes individuals with fasting plasma/serum glucose levels >110 mg/dL but <126 mg/dL. A fasting glucose concentration of 110 mg/dL has been chosen as the upper limit of "normal." Although somewhat arbitrary, it is near the level above which acute phase insulin secretion is lost in response to intravenous administration of glucose and is associated with a progressively greater risk of developing micro- and macrovascular complications. IGT refers to an OGTT with only one abnormal value, insufficient for diagnosis of diabetes mellitus.

In the absence of pregnancy, IFT and IGT are not clinical entities in their own right but rather risk factors for the future development of diabetes mellitus and/or cardiovascular disease.

Etiologic Classification of Diabetes Mellitus

- Type 1 diabetes mellitus* (b-cell destruction usually leading to absolute insulin deficiency)
- Type 2 diabetes mellitus* (may range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with insulin resistance)
- Other specific types of diabetes mellitus (rare causes)
- Gestational diabetes mellitus (GDM)

**Patients with any form of diabetes may require insulin treatment at some stage of their disease. Therefore the use of insulin does not serve to classify the patient.*

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