

All of us at the Danbury Hospital Laboratory would like to begin the New Year by thanking all our customers for choosing Danbury Hospital Laboratory. In the coming year, we will continue to fulfill our pledge to provide the highest quality laboratory services to physicians, patients and the community.

We wish you a New Year filled with health, happiness and prosperity.

APTIMA Genprobe System Replaces PACE Genprobe System

Laura Ross, MS, MT (ASCP)

The Microbiology section of the Danbury Hospital Laboratory is pleased to announce the conversion from the PACE Genprobe system to the APTIMA Genprobe system for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* by amplified DNA technology.

- The change in methodology will improve detection of these pathogens. In addition to cervical and urethral swab samples, testing can also be performed on urine and ThinPrep transport media. The implementation date for APTIMA is December 28, 2009. Please note that if you still have PACE Genprobe collection kits, we can accept those for testing in the APTIMA system until current supplies are depleted.
- APTIMA collection kits and instructions are now available from the Microbiology section at 203-739-7305 or by calling Laboratory Client Service-Marketing Coordinator Sandra Smith at 203-739-7800.
- Please contact the Microbiology section at 203-739-7305 or Dr. Jessica Dodge, Medical Director of Microbiology, at 203-739-7034 with any questions or concerns.

New Reference Range for Serum Sodium

We have adjusted our reference range for serum sodium due to a recalibration of our sodium assay by the manufacturer. The new reference range for serum sodium is 135-145 mmol/L and this will be reflected in our laboratory reports. Note that the reference ranges for whole blood sodium and urine sodium are not affected.

ADA Revises Diabetes Standards to Include Use of HbA_{1c} for Diagnosis

Salvador F. Sena, Ph.D., DABCC. Medical Director, Clinical Chemistry and Point-of-Care Testing

In its annual update to “Standards of Medical Care in Diabetes”⁽¹⁾, the American Diabetes Association now endorses the HbA_{1c} assay (A1C) as one of four options for diagnosing and screening for diabetes.

The current (2010) ADA criteria for the diagnosis of diabetes are as follows:

- **HbA_{1c} ≥6.5%:** The test should be performed in a laboratory using a method that is National Glycohemoglobin Standardization Program (NGSP) certified and standardized to the Diabetes Control and Complications Trial (DCCT) assay.
- **Fasting plasma glucose (FPG) ≥126 mg/dL:** Fasting is defined as no caloric intake for at least 8 h.
- **2-h glucose ≥200 mg/dL** during an oral glucose tolerance test (OGTT): The test should be performed as described by the World Health Organization using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water.
- **Random glucose ≥200 mg/dL** in a patient with classic symptoms of hyperglycemia or hyperglycemic crisis.

In addition to using A1C to diagnose diabetes, a HbA_{1c} range of 5.7-6.4% has been added as a category of “increased risk for future diabetes” in addition to impaired fasting glucose (FPG 100-125 mg/dL) and impaired glucose tolerance (2-h glucose 140-199 mg/dL). [Note: the section of the Standards previously titled “Diagnosis of pre-diabetes” has been renamed “Categories of increased risk for diabetes”.]

The evidence, logic and rationale given by the ADA to support the inclusion of A1C as a screening and diagnostic test for diabetes and for using a cut point of ≥6.5% are:

- The standardization of A1C assays has been vastly improved.
- An International Expert Committee, after an extensive review of established and emerging epidemiological evidence, has recommended the use of the A1C test to diagnose diabetes.⁽²⁾
- The diagnostic cut point of 6.5% is associated with an inflection point for retinopathy prevalence, as are the diagnostic thresholds for fasting glucose and 2-h glucose.
- There is an inherent logic to using a more chronic versus an acute marker of dysglycemia, particularly since A1C is already widely familiar to clinicians as a marker of glycemetic control.
- A1C has several advantages to fasting glucose, including greater convenience since fasting is not required, evidence to suggest greater preanalytical stability, and less day-to-day perturbations during periods of stress and illness.

The A1C assay methodology used in the Danbury Hospital laboratory is high-performance liquid chromatography (HPLC) on the Bio-Rad Variant II Turbo system. This assay is NGSP-certified and standardized to the DCCT assay. Regarding point-of-care A1C assays, the ADA Standards state that these assays are not sufficiently accurate at this time to be used for the diagnosis of diabetes. Use of these assays should be restricted to monitoring glycemetic control in already diagnosed diabetic patients.

The ADA 2010 Standards may be found at

http://care.diabetesjournals.org/content/33/Supplement_1.toc.

ADA Revises Diabetes Standards (Con't)

References

1. Diabetes Care 2010;33: Supplement 1.
2. International Expert Committee. International Expert Committee report on the role of the A1C assay in the diagnosis of diabetes. Diabetes Care 2009; 32:1327–1334.

Ionized Calcium No Longer Included with PTH

In response to feedback from our clients, orders for PTH (parathyroid hormone) will no longer automatically include an ionized calcium test. We will not collect a separate tube and perform an ionized calcium test when PTH is ordered unless ionized calcium is explicitly ordered. If an ionized (or total) calcium test is desired with PTH, please order this test separately on the requisition or in CPOE. This change will be reflected in the next revision of our paper requisitions.

Reminders:

When **Stat Testing** is requested, please refer patients to the Specimen Collection Facility at 79 Sandpit Rd, Germantown. Appointments for specimen collection may be made by calling 203-749-5742.

P2Y12, a new test performed at Danbury Hospital Laboratory, is used to determine patient response to Plavix® and Effient®. The test can only be collected in-house for inpatients or at our Patient Service Center at 79 Sandpit Rd. The time of collection must be included on the label when the specimen is collected. For further information regarding this test, please refer to *Technically Speaking* issue, Vol. 3, No 9.