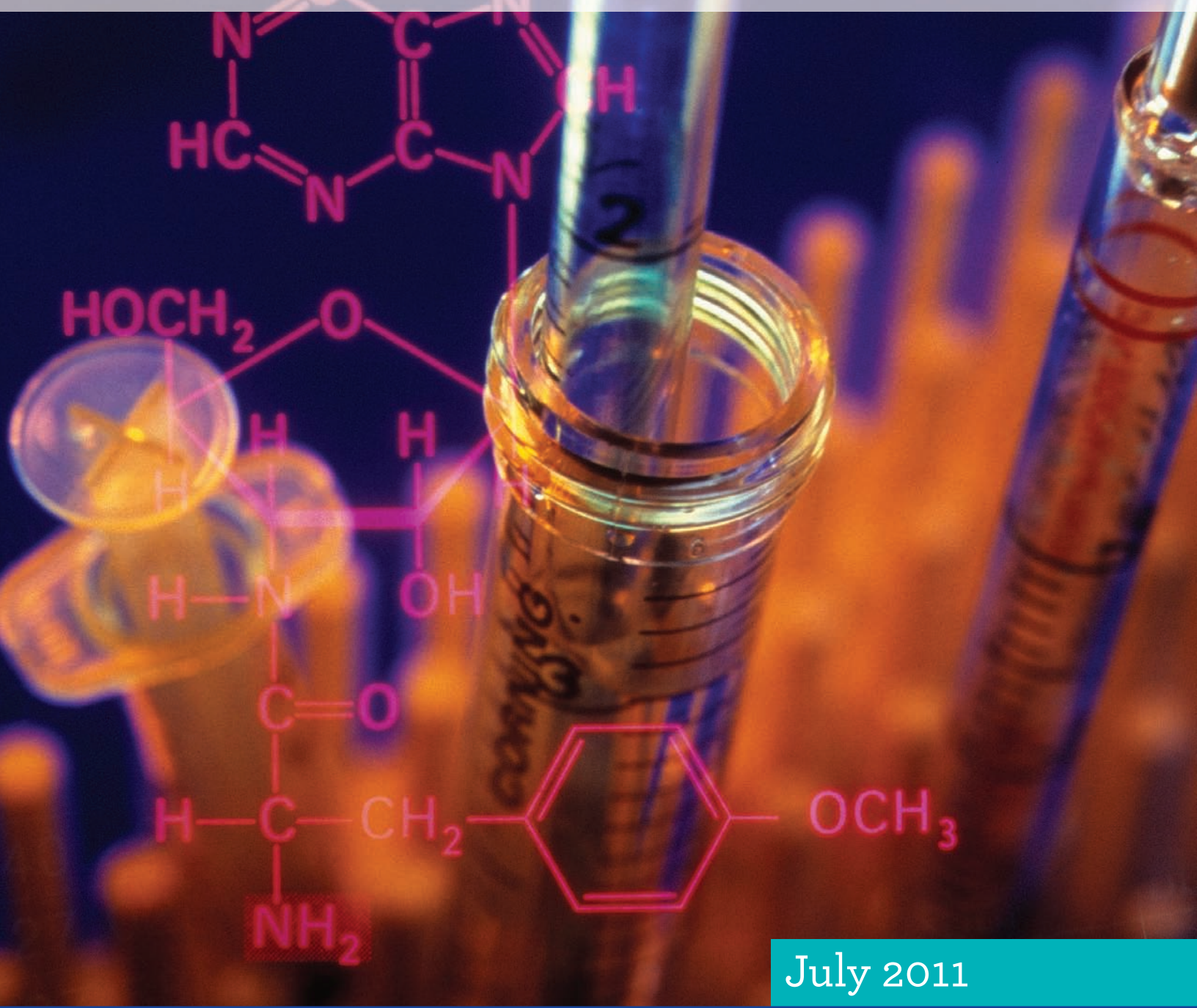


Lab Updates

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July 2011

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UMassMemorial

Laboratories

Changes in Growth Hormone (GH)

GH IS A POLYPEPTIDE (191 amino acids) originating in the anterior pituitary. Its metabolic effects are primarily anabolic. It promotes protein conservation and engages a wide range of mechanisms for protein synthesis. It also enhances glucose transport and facilitates the buildup of glycogen stores. GH is useful in the diagnosis and treatment of various forms of inappropriate growth hormone secretion. It is increased in, pituitary gigantism, acromegaly, Laron dwarfism (defective GH receptor), ectopic GH secretion (neoplasm of stomach and lung), malnutrition, renal failure, cirrhosis, stress, exercise, prolonged fasting, uncontrolled diabetes mellitus, anorexia nervosa. GH can be decreased in pituitary dwarfism, hypopituitarism and adrenocortical hyperfunction.

GH concentration in circulation is highly variable and is regulated by several physiologic factors such as age, body composition, nutrition, stress, and sleep. GH levels vary throughout the day, making it difficult to define a reference range or to judge an individual's status based on single determination.

The heterogeneity of GH assay results from different laboratories is a serious problem in using published consensus criteria for diagnosis and monitoring treatment of GH-related diseases. The main reasons for the discrepancies between results are associated with the heterogeneity of GH molecules in circulation, the presence of a GHBP interfering with assays, the use



Photo: Kevin Vance

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of different assay designs involving monoclonal or polyclonal antibodies, and the availability of different standard preparations to calibrate GH assays. International efforts to harmonize GH assays have led to the recommendation that GH assay results be reported only in mass units of the new IRP 98/574.

Effective July 1, 2011, GH testing is standardized to recombinant second IRP 98/574. When comparing results with old standardization (pituitary derived preparation (80/505) a shift to lower values (up to 20%) is observed reflecting this change. We recommend for patients undergoing serial measurements, baseline values should be reestablished. There are no changes in specimen requirements and reference range.

If you have questions, comments or suggestions, please contact:

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Non-Invasive Test for the Diagnosis of *Helicobacter pylori* (*H. pylori*) Infection (UBT)



H. pylori are bacteria that can infect the stomach or duodenum. It infects more than half the global population, causing peptic ulcer disease and chronic gastritis. It is also strongly associated with gastric malignancies. It is also classified by WHO as a Group 1 Carcinogen. *H. pylori* is transmissible, and is spread from person to person through fecal-to-oral or oral-to-oral routes. Accurate detection of *H. pylori* is the first step toward curing stomach and intestinal ulcers, and preventing the development of more serious gastrointestinal problems. *H. pylori* infection can be diagnosed by invasive techniques (endoscopy with biopsies for histology, culture and rapid urease test) and non-invasive techniques (serology, the ^{13}C -Urea breath test and the stool antigen test).

The American College of Gastroenterology guidelines recommend the urea breath test (UBT) as the “best non-endoscopic test for documenting *H. pylori* infection.” This is the preferred method of diagnosing *H. pylori* among non-invasive methods in pre and post treatment settings. *H. pylori* produces urease, an enzyme that splits urea in to ammonia and carbon dioxide. The UBT is based on the principle that urease activity is present in the stomach of individuals infected with *H. pylori*. Patients ingest urea labeled with either ^{13}C or ^{14}C . Hydrolysis of urea occurs within the mucus layer and

results in the production of labeled CO_2 . The CO_2 diffuses in to epithelial blood vessels and, within a few minutes, the isotopic CO_2 appears in the subject’s breath. Labeled urea is usually given to the patient with a test meal to delay gastric emptying and increase contact time with the mucosa. After ingestion of the urea, breath samples are collected for up to 20 min by exhaling in to a CO_2 trapping agent (hyamine).

^{13}C is a naturally occurring stable isotope and therefore no nuclear regulatory concerns and the test can be used in children and pregnant women. These tests have very high sensitivity and specificity. The advantage of UBT is that it is a global assessment of *H. pylori* content of the stomach. By convention, the UBT should not be conducted until 4 weeks after *H. pylori* antibacterial therapy to allow any residual bacteria to increase to a number sufficient for detection. A negative result does not rule out the possibility of *H. pylori* infection. Antimicrobials, proton pump inhibitors, bismuth preparations are known to suppress *H. pylori*. Premature POST-DOSE breath collection time can lead to a false negative diagnosis for the patient. A false positive test may occur due to urease associated with other gastric spiral organisms observed in humans such as *H. heilmannii* and in patients who have achlorhydria.

UBT test is performed at UMass Memorial Laboratories using UBiT-IR 300-Infrared Spectrophotometer. **Please call Customer Service at 800-476-4431 to order the breath kit.**

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This publication is made possible by Kevin Vance, Senior Director, Business Development and Marketing, Kevin.vance@umassmemorial.org

Cystic Fibrosis Testing Update



We are pleased to announce that the UMass Memorial Molecular Diagnostics Laboratory will be offering testing for the cystic fibrosis [R74W+R1070W+D1270N] and [R74W+V201M+D1270N] complex mutation alleles starting August 6, 2011.

This test provides clarification as to whether a D1270N variant, when detected, occurs by itself and is benign, or whether it is a part of a complex CFTR mutation allele [R74W+R1070W+D1270N] (1) or [R74W+V201M+D1270N](2).

D1270N was previously reported as one of the rare mutations associated with cystic fibrosis, as well as in men with congenital absence of the vas deferens (CBAVD). However, it is currently thought that D1270N by itself is a benign variant since

D1270N is detected with an unexpectedly high frequency among carriers as compared with CF patients. Nevertheless, the D1270N was reported to be causative of CF or CBAVD when associated with mutations R1070W or V201M, respectively.

This test will be orderable individually or as part of extended CFTR testing (mnemonic: CF3ADD). This test will be re-reflexed from the current CF test (41 CF mutations and intron 8 poly T) for patients with a D1270N variant identified.

Methodology: Polymerase chain reaction amplification followed by extension reaction and fragment analysis using MALDI-TOF mass spectrometry.

References:

1. de Prada Merino *J Cyst Fibros.* 2010;9(6):447-9.
2. Claustres M et al. *BMC Medical Genetics* 2004,5:19.

