By Dee Rapposelli

µTASWako i30 System for AFP-L3% and DCP Testing Cleared for Use in Canada

The µTASWako i30 microfluid-based clinical immunoanalyzer (Wako Diagnostics) for serum lectin-reactive alpha-fetoprotein (AFP-L3%) and des-gamma-carboxy prothrombin (DCP) testing has recently received clearance for use in the clinical setting in Canada. The µTASWako i30 system for AFP-L3% and DCP testing, which obtained US Food and Drug Administration (FDA) clearance in February 2011 in the United States, is intended for risk assessment of hepatocellular carcinoma (HCC) in patients with chronic liver disease. The serum biomarkers can complement the use of imaging technologies in surveillance programs for earlier detection and timely treatment of HCC.

The µTASWako i30 system uses immunochemical and electrophoretic techniques to achieve rapid assay results with good sensitivity and high specificity. The device (Figure) is a bench-top automated instrument designed for ease of use in a clinical laboratory setting. Results of index tests are produced in 9 minutes, and results thereafter are produced in 2 minutes. Reagent usage is tracked using radiofrequency identification tags.

The µTASWako i30 system reports AFP-L3%, total AFP, and DCP values using reagents manufactured by Wako Diagnostics, a division of Wako Life Sciences, Inc. For more information, see www.wakodiagnostics.com.

Figure. The µTASWako i30 microfluid-based clinical immunoanalyzer.

HCV Screening Recommended for All "Baby Boomers"

All persons born between 1945 and 1965 should be screened for hepatitis C virus (HCV) infection, according to updated recommendations of the US Preventive Services Task Force (USPSTF). In a statement published online in the *Annals of Internal Medicine* on June 25, 2013, the USPSTF stated that it had updated its recommendation regarding screening for HCV infection in high-risk persons from grade D to grade B and now also recommends offering one-time screening for HCV infection to all persons born between the critical years of 1945 and 1965 (B recommendation). Prevalence data have shown that this birth cohort, labeled the Baby Boomer Generation, is at higher risk than other birth cohorts for HCV infection. Causes include exposure to tainted blood products before donor screening initiatives were in place and exposure to high-risk cultural currents related to recreational drug use and sexual experimentation. The USPSTF recommendations are aligned with those of the Centers for Disease Control and Prevention.

According to the USPSTF, the most important risk factor for HCV infection is past or current injection drug use. Other risk factors include receiving blood products prior to 1992, long-term hemodialysis, maternal HCV infection during birth, incarceration, intranasal drug use, and unregulated tattooing. Anti-HCV antibody testing followed by polymerase chain reaction testing to confirm results is the recommended screening method. Noninvasive techniques are also suggested over liver biopsy for diagnosis of fibrosis and cirrhosis. Observance of these screening recommendations is expected to have a moderate influence on the epidemiology of HCV infection, according to the USPSTF. For more information, see Moyer VA; on the behalf of the U.S. Preventive Services Task Force. Screening for hepatitis C virus infection in adults: U.S. Preventive Services Task Force Recommendation Statement [published online June 25, 2013]. *Ann Intern Med.* doi: 10.7326/0003-4819-159-5-201309030-00672.

Guidelines for the Diagnosis and Management of Achalasia Issued by the American College of Gastroenterology

The American College of Gastroenterology (ACG) has issued guidelines for diagnosis and management of achalasia, a primary esophageal motor disorder that compromises the lower esophageal sphincter and esophageal peristalsis. The primary symptom of achalasia is dysphagia. The cause of achalasia is unknown, and achalasia is considered incurable. Because patients may report substernal pain or heartburn and experience regurgitation, achalasia is often misdiagnosed as gastroesophageal reflux disease. Although uncommon, with an annual incidence of 1 in 100,000 persons, achalasia should be suspected in patients in whom an obstructive mass has been ruled out and who experience regurgitation of solids and liquids and who have failed an adequate trial of proton pump inhibitors.

The ACG recommends that esophageal motility testing be conducted to definitively diagnose achalasia in all patients suspected of having it. Supported esophagram findings should include dilation of the esophagus, a narrow esophagogastric junction that has a "bird-beak" appearance, aperistalsis, and poor emptying of barium. In patients in whom findings of motility testing are equivocal, a barium esophagram is recommended to assess esophageal emptying and esophagogastric junction morphology. Endoscopic assessment of the gastroesophageal junction and gastric cardia is recommended to rule out pseudoachalasia.

Initial therapy should consist of either graded pneumatic dilation (PD) or laparoscopic surgical myotomy with a partial fundoplication in those patients who are willing candidates for surgical intervention. The choice of initial therapy should be guided by patients' age, gender, preference, and local institutional expertise, and surgery should be performed in centers of excellence that have high-volume and proven track records for achalasia interventions. In patients who are not candidates for PD or surgical myotomy, botulinum toxin therapy is recommended. Pharmacologic therapy, such as calcium channel blockers and long-acting nitrates, is recommended for patients who are unwilling or not candidates for PD or surgical myotomy and have failed botulinum toxin therapy.

An in-depth discussion of achalasia and its recommended diagnosis and management were published in the August issue of the *American Journal of Gastroenterology.* The citation is Vaezi MF, Pandolfino JE, Vela MF. ACG clinical guideline: diagnosis and management of achalasia. *Am J Gastroenterol.* 2013;108(8):1238-1249.

FDA Lightens Up, but Just a Bit, on Regulating Fecal Transplantation

The FDA has eased up on its decision to require physicians to obtain an investigational new drug application (IND) before performing fecal microbiota transplantation to treat such conditions as *Clostridium difficile* infection. The initial decision to require an IND before performing fecal microbiota transplantation was announced during a workshop conducted by the FDA on May 2 to 3, 2013. The decision caused significant discussion among thought leaders in the field of gastroenterology who felt that it would be a significant barrier to care, particularly in patients with *C difficile* infection unresponsive to other therapeutic interventions. After further consideration, the FDA announced, some weeks later, that it would, for now, not enforce requirements to obtain INDs before a physician could perform a fecal microbiota transplantation procedure. Physicians are, however, being told that they must document informed consent about the risks and benefits of the procedure. The FDA intends to develop policies for the study and use of fecal microbiota under the IND process. It strongly encourages physicians to comply with the IND regulations and also reports eager willingness to work with sponsors interested in conducting clinical trials related to transplantation of fecal microbiota for the treatment of *C difficile* infection. For the most recent FDA industry-guidance information on this, see http://www.regulations.gov/#!documentDetail;D=FDA-2013-D-0811-0002.