

Press Release - February 1, 2007

WakoUSA Reports the 510(k) Clearance of
des-gamma-carboxy prothrombin (DCP) Test for HCC Risk Assessment

Richmond, VA, February 1, 2007—WakoUSA, a leading provider of diagnostic reagents and instruments, today reported the FDA's 510(k) clearance of a des-gamma-carboxy prothrombin (DCP), also known as the protein induced by vitamin K absence-II (PIVKA-II), in vitro diagnostic test system. DCP is often expressed by hepatocellular carcinoma (HCC) tumors, and is used by hepatologists and gastroenterologists as a tool to assess patient risk for the development of HCC within the high risk patient population that suffers from chronic liver disease such as cirrhosis.

Liver cirrhosis can be caused by chronic viral hepatitis B (HBV) and C (HCV) infections, as well as alcohol abuse and diabetes. The number of cirrhosis patients in the US is increasing at the rate of about 5% per year. Patients that suffer from liver cirrhosis are at an elevated risk for the development of HCC, which is now the third largest cause of cancer death in the US. Hepatologists and gastroenterologists use a variety of biomarkers and imaging techniques to monitor these high risk patients. Abnormally high levels of serum DCP is often associated with the future development of HCC in this patient population. DCP, when used in conjunction with the complementary biomarkers AFP and AFP-L3%, provide the physician with a simple set of biomarker tests that will help hepatologists and gastroenterologists to find HCC earlier, and improve long term patient outcomes.

DCP, total AFP, and AFP-L3% values are reported using unique Wako's reagents that are coupled with Wako's LiBASys instrument. Reagents and instrumentation are offered by Wako directly to clinical laboratories in the US.

About WakoUSA

WakoUSA, headquartered in Richmond, VA, is a solely owned subsidiary of Wako Pure Chemicals, with headquarters in Osaka, Japan. Wako offers a full range of reagents for both clinical and research laboratories worldwide. Wako has also recently added specialty instrumentation to its extensive clinical diagnostic product line. More information may be obtained at www.wakodiagnosics.com.

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