

## Press Release - March 1st, 2011

### Announcing 510(k) Clearance of a New Microfluidic-based IVD Test System, the $\mu$ TASWako™ i30 Immunoanalyzer, and AFP-L3 and DCP Assays for Liver Cancer Risk Assessment.

Richmond, VA, March 1st, 2011—Wako Diagnostics, a division of Wako Chemicals USA, has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) to market the  $\mu$ TASWako i30 instrument with alpha-fetoprotein L3 (AFP-L3) and des-gamma-carboxy prothrombin (DCP) in vitro diagnostic (IVD) tests in the USA. The AFP-L3 and DCP assays are intended for use by healthcare professionals as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC).

“Wako is very pleased to receive 510(k) clearance for these assays using microfluidic technology,” said Peter Panfili Ph.D., General Manager, Wako Diagnostics. “We expect that the adoption of these biomarkers into HCC surveillance programs will complement the use of imaging technologies to bring about the desired earlier detection and treatment of liver cancer.”

HCC, primary liver cancer, is currently the fastest growing cause of cancer-related death in the USA. It has been demonstrated that HCC surveillance programs for at-risk patients improves applicability of curative therapies. Incorporating these biomarkers as additional surveillance tools will improve the chance of detecting early stage HCC and improve patient outcomes.

Microfluidics has enabled miniaturization and integration of key analyzer processes for the  $\mu$ TASWako i30: sampling, mixing, separation, and detection on microfluidic chips. The system uses immunochemical and electrophoretic techniques to achieve rapid, accurate, precise and sensitive assay results.

As a bench top automated instrument, the  $\mu$ TASWako i30 is designed for efficiency and ease of use in a clinical chemistry setting. Up to six analytes may be selected per patient sample with the first result reported in nine minutes. With automated calibration and quality control, the  $\mu$ TASWako i30 requires minimal setup time. Reagent usage is tracked using radio frequency identification (RFID) tags.

The  $\mu$ TASWako i30 reports AFP-L3%, total AFP, and DCP values using Wako’s unique reagents. This IVD test system is available to hospital laboratories, reference laboratories and tertiary care centers. Wako is the only company that offers 510(k)-cleared AFP-L3 and DCP assays for IVD use.

#### About Wako Diagnostics

Wako Diagnostics, a division of Wako Chemicals USA, headquartered in Richmond, VA, is a solely owned subsidiary of Wako Pure Chemicals, with headquarters in Osaka, Japan. Wako Pure Chemicals offers a comprehensive range of reagents for both clinical and research laboratories, as well as specialty chemicals. More information may be obtained at [www.wakodiagnostics.com](http://www.wakodiagnostics.com).

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$\mu$ TASWako® i30