

## Press Release - July 29th, 2013

### Wako Diagnostics granted Medical Device Licences from Health Canada for the $\mu$ TASWako<sup>®</sup> i30 Immunoanalyzer, and AFP-L3 and DCP Assays for Liver Cancer Risk Assessment

Mountain View CA, July 29th, 2013—Wako Diagnostics, a division of Wako Life Sciences, Inc., was issued three Class III Medical Device Licences by Health Canada on April 23, 2013 to market the  $\mu$ TASWako i30 instrument with serum biomarkers lectin-reactive alpha-fetoprotein (AFP-L3) and des-gamma-carboxy prothrombin (DCP) tests for clinical use in Canada. The AFP-L3 and DCP tests are intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment.

"We are very pleased to have been granted these licences by Health Canada," said Shinji Satomura, Ph.D., President, Wako Life Sciences, Inc. "Wako Life Sciences, Inc. is committed to the improvement of patient care by making important tests such as AFP-L3 and DCP available to the medical community. With the rising incidence of HCC in Canada and worldwide, it is a great milestone now being able to also bring these HCC risk assessment biomarkers to the Canadian market." The AFP-L3 and DCP tests obtained FDA clearance for in vitro diagnostic use in February 2011 and are currently offered at most major Reference Laboratories in the U.S.A. The tests are also available for clinical use in Japan, South Korea and the European community.

HCC is the third leading cause of cancer related deaths worldwide and the incidence is rising. In Canada, liver cancer is one of the cancers with increasing incidence and mortality. The availability of the serum biomarkers in Canada will provide physicians with screening tests to help stratify chronic liver disease patients who are at high risk for HCC. The biomarkers can complement the use of imaging technologies in surveillance programs for earlier detection and timely treatment of HCC.

#### **About $\mu$ TASWako i30**

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 laboratory setting under the direction of healthcare professionals. With the features of automated calibration and quality control, the  $\mu$ TASWako i30 requires minimal setup time. The first test result is obtained swiftly in nine (9) minutes from starting the measurement; results thereafter are 2 minutes each. Reagent usage is tracked using radiofrequency identification (RFID) tags. The  $\mu$ TASWako i30 reports AFP-L3%, total AFP, and DCP values using Wako manufactured quality reagents. More information on how to order or acquire the tests can be obtained by contacting Wako Diagnostics.

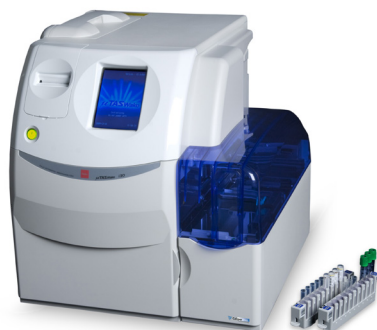
#### **About Wako Diagnostics**

Wako Diagnostics, a division of Wako Life Sciences, Inc., headquartered in Mountain View, CA, is a solely owned subsidiary of Wako Pure Chemical Industries, Ltd., with headquarters in Osaka, Japan. Wako Pure Chemical Industries, Ltd. offers a comprehensive range of reagents for both clinical and research laboratories, as well as specialty chemicals. More information can be obtained at [www.wakodiagnosics.com](http://www.wakodiagnosics.com).

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$\mu$ TASWako<sup>®</sup> i30

