

Sysmex Korea, HBsAg, HIV test reagent received MFDS's approval of IVD Class 4

Hepatitis B virus and AIDS infection check within 17 minutes.

On December 31st, 2014 Sysmex Korea received Ministry of Food and Drug Safety (MFDS)'s approval for a hepatitis B virus in vitro test reagent (HISCL HBsAg Assay Kit) and HIV in vitro test reagent (HIV Assay Kit). This is the first approval from MFDS for the new product in Class 4 test reagent since the Medical Appliance Act amendment in 2012.

Sysmex's immunoassay system, HISCL-Series can deliver the test results for HBsAg and HIV within 17 minutes. It is a fully automated immunochemistry analyzer which applies chemiluminescence enzyme immunoassay (CLEIA) methodology to test human body's plasma and serum.

HISCL system, which launched in Korea in December 2013, enhanced the sensitivity by adopting Sysmex's expertise and technology also among the immunology system available in Korea it enables to check the test results with the minimum quantity of specimen. This new immunology system will contribute to improve the hospital efficiency and reduce burden on patients by providing rapid and accurate test result.

HISCL system can test hepatitis marker, hormone marker, tumor marker, cardiac marker and other special parameters. Furthermore, atopic dermatitis monitoring test and hepatic fibrosis test by a blood sample (serum), not on the cell tissue, is the unique feature of HISCL system.

Sysmex Korea will take the approval of MFDS's on HBsAg and HIV test reagent as an opportunity to accelerate the immunology business in Korea, and continue to work towards the MFDS approval for other test parameters. HISCL system has already started the business in Japan and other Asia countries.

Sysmex is looking forward to provide enriched quality of life for patients by providing better service through HISCL system.