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Hitachi High-Technologies Develops Automated Platform Technology for Molecular Diagnostics

Hitachi High-Technologies Corporation (TOKYO:8036) has developed an automated platform technology for molecular diagnostic .

The global market for molecular testing is growing rapidly at rate of 11% annually, and is expected to grow from 4.0 billion US dollars in 2009 to more than 5.4 billion US dollars accounting for 10% of worldwide In Vitro Diagnostic market in 2012. In Japan, use of molecular testing is on the rise to detect infectious diseases such as hepatitis, sexually transmitted diseases, and influenza.

Molecular testing, which uses nucleic acids extracted from human samples to detect and identify pathogen, provides high sensitivity over traditional testing methods, in particular the conventional immunological testing method. However, molecular test operation has not been processed efficiently since it requires complex and time-consuming manual procedures such as pre-analytical processing of samples, dissolution and mixing of reagents. Therefore there has been customers' requirement for molecular diagnostic instrument that provides automation in eliminating complex, time-consuming, and labor-intensive procedures, which results in improving quality of tests.

In order to meet the customers' requirement, Hitachi High-Technologies has developed molecular diagnostic platform technology that automates these complex procedures. The overarching concept for the platform is to provide a system compatible with various types of nucleic acids amplification protocols, realize sophisticated level of automation with random access function for different assays testing simultaneously, and continuous loading of samples, reagent and consumables like clinical chemistry analyzer. Random access and continuous loading functions will be at the mainstream of molecular diagnostic testing going forward, and are expected to contribute greatly to reduce both labor-intensive works and time to result under routine operation in hospital laboratories.

The concept behind the newly developed platform technology is outlined below.

(1) Molecular Diagnostic Instrument Platform Compatible with Various Types of Nucleic Acid Amplification Protocols

Conventional molecular diagnostic testing requires dedicated instrument designed for each amplification protocol. Hitachi High-Technologies' new platform technology is compatible with various types of nucleic acids amplification protocols, offering a high degree of versatility.

(2) Total Automation from Pre-Analytical Processing to Amplification and Detection Processes

After the extracted sample is loaded, all processes are fully automated—from pre-analytical processing of reaction solutions to amplification and detection.

Hitachi High-Technologies' highly reliable automation technology enables to eliminate manual processes and realize outstanding performance.

(3) Random Access Function

Since conventional molecular testing is processed by batch due to inflexibility of instrument, only one type of assay can be tested at once.

Hitachi High-Technologies' new platform is equipped with Random Access function capable of different assay testing simultaneously at random. This is achieved by uniquely designed carousel-type detector that allows for multiple fluorescence measurements simultaneously.

(4) Continuous Loading Function

Operators can load/unload samples, reagents, consumables and waste even while analysis is in process. Hitachi High-Technologies' new platform features a highly functional, easy-to-access layout in which all operations are performed from the front side of the instrument.

Hitachi High-Technologies has developed molecular diagnostic instrument platform technology, ahead of the competition, by utilizing the technologies established from laboratory automation experiences, in particular clinical chemistry analyzers. The Company will unveil information about the prototype at the Molecular Medicine Tri-Conference 2010 to be held from Wednesday, February 3 in San Francisco, USA. (<http://www.tri-conference.com/>)

Hitachi High-Technologies aims to bring it to the research market in fiscal 2011 at the start using developed platform technology.



Outlook of Automated Platform (Prototype)

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