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Sysmex gets FDA nod for XN hematology analyzers

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Sysmex America announces FDA clearance of XN-series hematology analyzers

Singapore: Sysmex America, and Sysmex, Kobe, Japan, announced that the US FDA has cleared the Sysmex XN-Series Hematology Analyzers. Sysmex previously received a Medical Device License for the analyzers from Health Canada. The XN-Series enables laboratories of any size to implement advanced clinical parameters, including an all-new fluorescent platelet channel for Immature Platelet Fraction (IPF) to aid in the differential diagnosis of thrombocytopenia.

"The FDA clearance of the Sysmex XN-Series Hematology Analyzers puts Sysmex at the forefront of 'accountable care' by enabling clinical laboratories to contribute to the overall efficiency and productivity of their hospitals. Advanced clinical parameters, now available to virtually any clinical laboratory regardless of throughput, have potential to impact treatment guidelines, care pathways, and patient flow.

This has broad implications on the healthcare industry, especially considering much of a patient's medical record is comprised of laboratory results," said Mr John Kershaw, president and CEO, Sysmex America.

The design intent for the Sysmex XN-Series Hematology Analyzers is to enable clinical laboratories to withstand future medical technologists shortages; and the ability to keep up with workload demands and testing complexity that may accompany an aging population. This breakthrough concept known as Silent Design provides a simplified system of operation and user interface based on careful study of laboratory processes, the relationship between the operator and the analyzer and how people work.

Sysmex, Kobe, Japan, was awarded the Good Design Gold Award in October 2011 from Japan's Ministry of Economy, Trade and Industry for its in vitro diagnostic system employing the company's new Silent Design concept.