

July 9, 2020
Sysmex Corporation

Sysmex Launches New Products in the Hemostasis Field: Automated Blood Coagulation Analyzers CN-6500/CN-3500

- Using Chemiluminescence Enzyme Immunoassay to Enhance Testing Workflow Efficiency -

Sysmex Corporation (HQ: Kobe, Japan; Chairman and CEO: Hisashi Ietsugu) announces the July 2020 launch of new products in the hemostasis field: the Automated Blood Coagulation Analyzers CN-6500/CN-3500. These new offerings from Sysmex come with a measuring unit using the chemiluminescence enzyme immunoassay methodology (CLEIA), which we cultivated in our Automated Immunoassay Systems HISCL™-5000/HISCL™-800 (HISCL™), on top of the unique features of the Automated Blood Coagulation Analyzers CN-6000/CN-3000, making it possible to measure blood coagulation testing parameters, including molecular markers for blood coagulation with a single device.

Hemostasis, a type of testing that helps determine the ability of the blood to coagulate and dissolve clots, is used when diagnosing and treating hemorrhagic diseases, such as hemophilia, and thrombotic diseases, such as myocardial and cerebral infarction.

In recent years, changing lifestyle habits and the aging of the population have led to an increase in thrombotic diseases. Also, new blood preparations have been developed to enhance quality of life (QOL) in the face of hemorrhagic disease. Against this backdrop, the field of hemostasis has seen more diverse demands for early-stage diagnosis and appropriate treatment of such conditions, and the compound average growth rate of the global hemostasis market is estimated at 5.3%.

While the demand for greater diversity in testing and prompt provision of test results to physicians is on the rise, hemostasis is typically performed by using multiple instruments with different measurement principles, such as immunoassay systems and platelet aggregation analyzers, in addition to blood coagulation analyzers, to measure different parameters. This not only adds to the complexity of the testing workflow, but also requires lengthy waits before test results become available to determine the disease state and provide appropriate medical care, posing challenges in healthcare settings.

In July 2020, Sysmex will launch its Automated Blood Coagulation Analyzers CN-6500/CN-3500 in Japan. These integrated analyzers incorporate features of their predecessors the CN-6000/CN-3000, such as high levels of productivity, reliability, operability, and serviceability, and come with a measuring unit using CLEIA, a measuring principle developed with HISCL™. As a result, our new blood coagulation analyzers allow for flexible measurements in response to a broad range of test orders in the fields of thrombosis and hemostasis, such as molecular markers for blood coagulation measured with CLEIA, in addition to the blood coagulation and platelet aggregation parameters that can be measured by the CN-6000/CN-3000, realizing an efficient testing workflow in a way that caters to real needs in healthcare settings.

When linked with our proven network solution Caresphere™, the CN-6500/CN-3500 will allow users to easily and remotely monitor and analyze the number of samples processed, the amount of remaining reagents and other consumables, and the quality control status, as well as the status of the entire lab, thus increasing the efficiency of their day-to-day tasks.

To further enhance efficiency and quality in the field of hemostasis, after their launch in Japan we will expedite the regulatory approval acquisition process in other countries to successively introduce the CN-6500/CN-3500 to overseas markets.

Going forward, we will seek to offer new values by promoting the development of reagents for hemostasis and immunochemistry using CLEIA.

New Product Overview

Name (Medical Device Marketing Authorization Number):

Automated Blood Coagulation Analyzer CN-6500 (28B1X10014000057)

Automated Blood Coagulation Analyzer CN-3500 (28B1X10014000058)

Target facilities: Medium- and large-scale hospitals and commercial labs,

as well as other facilities

Launch: Japan: August 2020; Outside Japan: to be launched successively
in individual countries after regulatory approval

New Product Photo



Measurable Parameters for New Product (at launch in Japan)

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|----------------------------|--|
| Clotting: | PT, APTT, Fbg, extrinsic coagulation factors (II, V, VII, X), Intrinsic coagulation factors (VIII, IX, XI, XII) |
| Chromogenic: | FVIII, FIX, FXIII, AT, PC, Plg, α2-PI |
| Turbidimetric immunoassay: | FDP, D-dimer, FM, vWF:Ag |
| Aggregation: | vWF:RCO, ADP, collagen, epinephrine |
| CLEIA: | TAT, PIC, TM, tPAI • C |

References

December 18, 2018 press release entitled "Sysmex Launches New Products in the Hemostasis Field: Automated Blood Coagulation Analyzers CN-6000 and CN-3000 -Making Testing Even More Efficient and of Higher Quality through Higher Levels of Productivity, Reliability, and Operability-"

<https://www.sysmex.co.jp/en/news/2018/181218.html>

April 5, 2018 press release entitled "Sysmex Launches Caresphere,™ a New Network Solution -Supporting the Intelligent Use of Information for the Healthcare of the Future, Where the Use of Information is Accelerating-"

<https://www.sysmex.co.jp/en/news/2018/180405.html>

March 18, 2019 press release entitled "Sysmex Launches Caresphere™ LWS, a Laboratory Information System -Further Enhancing Clinical Testing Efficiency through a New Caresphere™ Solution-"

<https://www.sysmex.co.jp/en/news/2019/190318.html>

September 19, 2019 press release entitled "Sysmex Launches Caresphere™ QM, an Operational Support System for Testing Quality Management -Realizing the Operation of High-Quality Clinical Laboratories through our New Caresphere™ Solution-"

<https://www.sysmex.co.jp/en/news/2019/190919.html>