

Clinical Diagnostic Agent/Device Market in Japan: Key Research Findings 2016

◆ Research Outline

Yano Research Institute has conducted a study on the clinical diagnostic agent/device market with the following conditions:

1. Research period: August to October, 2016
2. Research targets: 40 Domestic leading companies in the business of clinical diagnostic agents and devices (Japanese companies and Japanese arms of overseas companies)
3. Research methodologies: Face-to-face interviews, survey by telephone, and literature research

◆ Key Findings

■ FY2015 Clinical Diagnostic Agent/Device Market Rose by 6.5% on a Y-o-Y Basis to Attain 1,006.7 Billion Yen

Size of the clinical diagnostic agent/device market in FY2015 (based on the sales of 40 domestic leading companies in the business of clinical diagnostic agents/devices) is estimated as 1,006.7 billion yen, a rise by 6.5% from the previous fiscal year, out of which clinic diagnostic agent business marked 589.8 billion yen, and diagnostic devices and the related business reached 416.9 billion yen. Also, the business for the domestic market attained 536.4 billion yen, while the business for overseas market reached 470.3 billion yen.

■ FY2015 Clinical Diagnostic Agents/Devices for Domestic Demands Grew by 2.3% on a Y-o-Y Basis, Showing Steady Growth

The domestic business of clinical diagnostic agent/devices in FY2015 was led by those clinical testing agents such as HbA1c (Glycated Hemoglobin) which is an indicator of diabetes, NT-proBNP used for diagnosis of heart failure or for understanding of the patient's disease, PCT for differential diagnosis of bacterial sepsis, and D-dimer for diagnosis of thrombosis. In addition, in testing using immunochromatography method, rapid testing of Group A Streptococcus and Mycoplasma antigens has been stably needed, which contributed to the market growth by 2.3% from the previous fiscal year.

■ New Moves in Clinical Examination of Microbes and Infectious diseases

With respect to examination areas, clinical examination of microbes and infectious diseases are likely to be needed stably both for urgent demands and for infection prevention. In addition to specific testing of microbes, immunity, and genes using various methods depending on use and measurement accuracy being carried out, clinical examination, which used to be time-consuming and troublesome, has come to be much easier because of apparatuses becoming smaller and automatically operated. In the future, multiplex genetic examination equipment is expected to be developed and introduced, after which collective examination of pathogenic bacteria and the like can be tested easily.

◆ Report format:

Published report: "Clinical Laboratory Test Market 2016"

Issued on: October 30, 2016

Language: Japanese

Format: 369 pages in A4 format

Price: 125,000 yen (The consumption tax shall additionally be charged for the sales in Japan.)

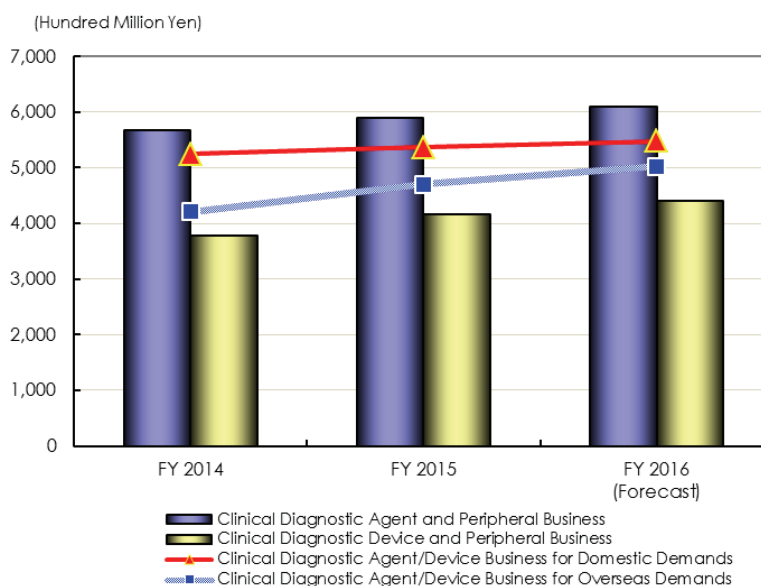
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■ **Figure 1: Transition and Forecast of Clinical Diagnostic Agent/Device Business Size**



Survey by Yano Research Institute

Notes:

1. The market size is based on the sales of 40 domestic leading companies in the business of clinical diagnostic agents/devices.
2. Forecast shows the forecast values.

■ **Table 1: Transition and Forecast of Clinical Diagnostic Agent/Device Business Size by Category**

(Hundred Million Yen)

By Business Category	FY 2014	FY 2015	FY 2016 (Forecast)		
			Y-o-Y	Y-o-Y	Y-o-Y
Clinical Diagnostic Agent Business	5,680	5,898	103.8%	6,100	103.4%
Clinical Diagnostic Device Business	3,775	4,169	110.4%	4,400	105.5%
Clinical Diagnostic Agent/Device Business Size (Total)	9,455	10,067	106.5%	10,500	104.3%

Note: based on the sales of 40 domestic leading companies in the business of clinical diagnostic agent/devices.

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■ **Table 2: Transition and Forecast of Clinical Diagnostic Agent/Device Business Size by Domestic/Overseas Demand**

(Hundred Million Yen)

Domestic/Overseas	FY 2014	FY 2015	FY 2016 (Forecast)		
			Y-o-Y	Y-o-Y	Y-o-Y
Clinical Diagnostic Agent/Device Business for Domestic Demands	5,242	5,364	102.3%	5,480	102.2%
Clinical Diagnostic Agent/Device Business for Overseas Demands	4,213	4,703	111.6%	5,020	106.7%
Clinical Diagnostic Agent/Device Business Size (Total)	9,455	10,067	106.5%	10,500	104.3%

Note: based on the sales of 40 domestic leading companies in the business of clinical diagnostic agent/devices.

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3. The market size is based on the sales of 40 domestic leading companies in the business of clinical diagnostic agents/devices.
4. Forecast shows the forecast values.