

Clinical Diagnostic Assay/Device Market in Japan: Key Research Findings 2017

◆ Research Outline

Yano Research Institute has conducted a study on the business size of enterprises in the clinical diagnostic agent/device market with the following conditions:

1. Research period: August to October, 2017
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

■ FY2016 Clinical Diagnostic Agent/Device Market Rose Slightly by 0.9% on a Y-o-Y Basis to Attain 1,015.9 Billion Yen

Size of the clinical diagnostic agent/device market in FY2016 (based on the sales of 40 domestic leading companies in the business of clinical diagnostic agents/devices) is estimated to have risen slightly by 0.9% from the previous fiscal year to attain 1,015.9 billion yen, out of which clinic diagnostic agent business marked 607.8 billion yen, and diagnostic devices and the related business 408.1 billion yen. On the other hand, out of the entire market size, the sales for the domestic market reached 543.9 billion yen, and for overseas market 472.0 billion yen.

■ Market Size of Clinical Diagnostic Agents/Devices for Domestic Demands in FY2016 Grew by 1.4% on a Y-o-Y Basis

Among the clinical diagnostic agent/devices market (based on the sales mentioned above) for the domestic business in FY2016, clinical testing agents such as NT-proBNP used for diagnosis of heart failure or for understanding of the patient's disease, PCT for differential diagnosis of bacterial sepsis, D-dimer for diagnosis of thrombosis, and HCV RNA quantification assay for hepatitis C, as well as test drugs for osteoporosis have shown stable sales to contributed to the market growth by 1.4% from the previous fiscal year.

■ POCT(Point Of Care Testing) Attracts Attention for Promising Marketability and as a Development Theme

An immunochromatography test, a representative method of POCT, has begun expanding its market shown by well acceptance of rapid testing kit of influenza as well as of Group A Streptococcus, Mycoplasma antigens, and etc. On the other hand, in the field of respiratory infection, methods of detecting genes of pathogenic bacteria in a short time are about to be established. By introducing some devices to enable multiplex assays to simultaneously detect multiple pathogens easily, there is a possibility of such POCT market with different dimension from immunochromatography to be formed.

◆ Report Format:

Published report: "Clinical Laboratory Test Market 2017"

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Format: 343 pages in A4 format

Price: 150,000 yen (The consumption tax shall additionally be charged for the sales in Japan.)

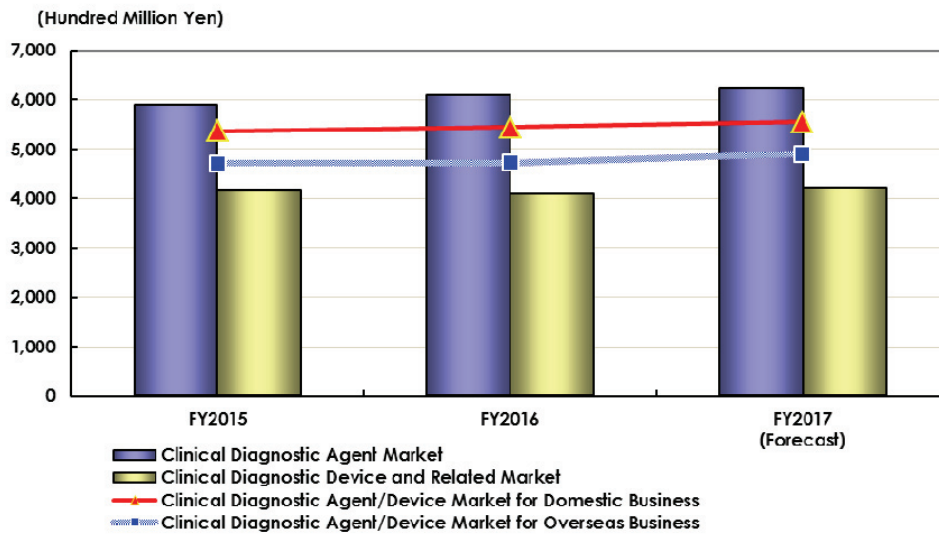
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■ **Figure 1: Transition and Forecast of Clinical Diagnostic Agent/Device Business Size**



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 Market Size by Category**

(Hundred Million Yen)

Market Category (Agent or Device)	FY2015	FY2016	FY2017 (Forecast)		
			Y-o-Y	Y-o-Y	Y-o-Y
Clinical Diagnostic Agent Market	5,898	6,078	103.1%	6,240	102.7%
Clinical Diagnostic Device and Related Market	4,169	4,081	97.9%	4,210	103.2%
Clinical Diagnostic Agent/Device Market Size (Total)	10,067	10,159	100.9%	10,450	102.9%

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

Notes:

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.

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

(Hundred Million Yen)

Market for Domestic/Overseas Business	FY2015	FY2016	FY2017 (Forecast)		
			Y-o-Y	Y-o-Y	Y-o-Y
Clinical Diagnostic Agent/Device Market for Domestic Business	5,364	5,439	101.4%	5,550	102.0%
Clinical Diagnostic Agent/Device Market for Overseas Business	4,703	4,720	100.4%	4,900	103.8%
Clinical Diagnostic Agent/Device Market Size (Total)	10,067	10,159	100.9%	10,450	102.9%

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

Notes:

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