

Clinical Diagnostic Reagent and Device Market in Japan: Key Findings 2009

➤ **Research Outline**

Yano Research Institute has conducted a study on the clinical diagnostic reagent and device market in Japan with following conditions.

1. Research period: May to August 2009
2. Research targets: Forty clinical diagnostic reagent and device companies in Japan (Japanese companies and overseas incorporated companies in Japan)
3. Research methodologies: Face-to-face interviews, telephone interviews and literature research

➤ **Key Findings**

◆ **FY2008 business size of clinical diagnostic reagents and devices was 737.7 billion yen**

The fiscal 2008 business size of clinical diagnostic reagents and devices of major companies in Japan was 737.7 billion yen. Among which, domestic business was 435.2 billion yen and overseas business was 302.5 billion yen. Diagnostic reagent business was 409.3 billion yen and diagnostic device business was 328.4 billion yen.

◆ **Growth is seen for influenza test kit and testing for diabetes management in FY2009**

The Japanese clinical diagnostic reagent and device market is structurally matured, however, a certain growth is expected for the next several years due to the demands for quick influenza test kit and HbA1c test for diabetes management.

◆ **FY2012 business size of clinical diagnostic reagents and devices is expected to be 811.3 billion yen with large growth of overseas business**

Current clinical diagnostic reagent and device businesses targeting overseas are conducted by only a small group of companies that sell automatic biochemical analyzers, blood cell counters and testing reagents. In the future overseas business will be strengthened for immunological testing devices and reagents as well, and the overall trend is likely to shift to attaching importance to overseas business.

➤ **Report format:**

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➤ Research Summary

1. Business Overview

The fiscal 2008 business size of clinical diagnostic reagents and devices of major companies in Japan was 737.7 billion yen based on the sales figures of major 40 companies conducting the clinical diagnostic reagent and device business in Japan. Among which, domestic business was 435.2 billion yen and overseas business was 302.5 billion yen. Overseas business represents 41 percent among the total clinical diagnostic reagent and device business. Currently the businesses largely targeting overseas are conducted by only a small group of companies that sell automatic biochemical analyzers and blood cell counters. However, many other diagnostic reagent companies in the biochemical and immunology domains also declare that they are going to place importance on overseas business and are strengthening the businesses targeting the global market.

In terms of clinical diagnostic reagents versus clinical diagnostic devices, the business size of diagnostic reagents was 409.3 billion yen and that of diagnostic devices was 328.4 billion yen. It is becoming difficult to divide them into two categories of reagents and devices year by year because diagnostic reagent companies are entering the diagnostic device market and diagnostic device companies are beginning to handle diagnostic reagents.

2. Trend Focus

In Japan specimen test easily becomes a target to reduce along with the advancement of all-inclusive payment system. Its health insurance medical technique point is reduced at each time of health insurance reimbursement revision, and the market is basically matured.

However, there are testing demands due to the aging population, governmental measures emphasizing prophylactic medicine (special checkup, cancer screening, etc.) and other unexpected factors, including several kinds of infectious diseases. As a result, the market has been slightly growing at an annual rate of 1 to 2 percent. The quantity of diagnostic testing tends to be secured even if the unit price of testing is lowered.

Recently, in particular, the test items such as diabetes management index HbA1c, heart failure detection BNP, including NT-proBNP and lipid metabolism management index LDL-C have been steadily increasing. At present quick influenza test kit is enormously sold due to the new influenza pandemic. The influenza test sector is expected to drive the increase in the total business size of clinical diagnostic reagents and devices in fiscal 2009.

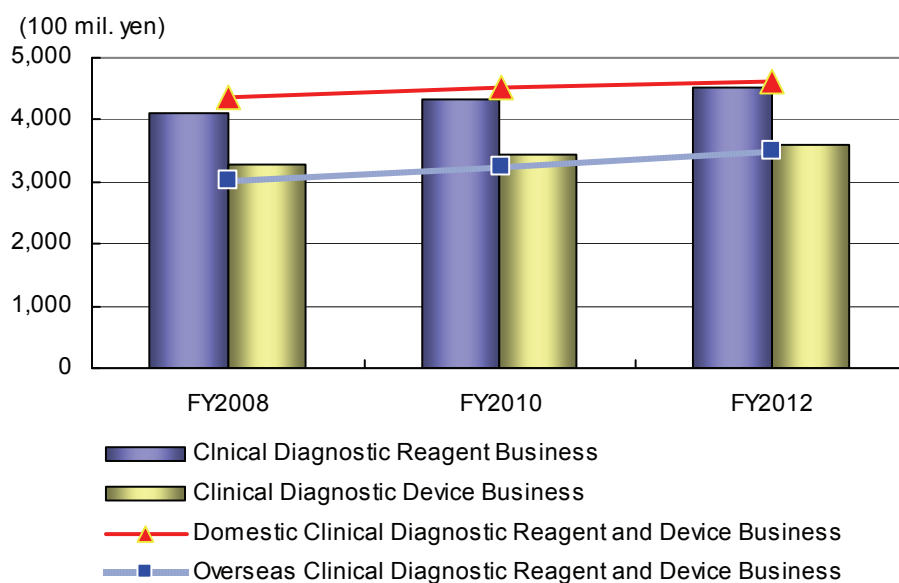
In the long term view, human genetic testing is anticipated to be paid attention along with the advancement of individualized medicine by each patient.

3. Future Prospects

In the medium term the domestic business size of clinical diagnostic reagents and devices is forecast to increase by 6.0 percent from 435.2 billion yen in fiscal 2008 to 461.3 billion yen in fiscal 2012. The overseas business size is forecast to increase by 15.7 percent from 302.5 billion yen in fiscal 2008 to 350.0 billion yen in fiscal 2012 due to the growth in emerging countries, such as China, India and Russia, in addition to the US and Europe. The total business size of clinical diagnostic reagents and devices, including those for the Japanese market and the overseas markets, is expected to expand to 811.3 billion yen in fiscal 2012.

In view of growth rate, overseas business is holding a favored position, however, domestic business would also grow steadily for the time being with the developments of additional test items. In the medium and long term overseas business will become more important. Along with the trend, mergers and acquisitions and alliances with overseas companies are expected to be more active and global strategies are to be further taken.

[Changes in Clinical Diagnostic Reagent and Device Business]



Estimated by Yano Research Institute Ltd.

[Changes in Clinical Diagnostic Reagent and Device Business by Reagent and Device]

(Unit: 100 mil. yen, %)

Reagents/Devices	FY2008	FY2010 (fcst.)	FY2012 (fcst.)	FY2010/ FY2008	FY2012/ FY2008
Clinical Diagnostic Reagent Business	4,093	4,338	4,508	106.0	110.1
Clinical Diagnostic Device Business	3,284	3,430	3,605	104.4	109.8
Total	7,377	7,768	8,113	105.3	110.0

Estimated by Yano Research Institute Ltd.

[Changes in Clinical Diagnostic Reagent and Device Business by Domestic and Overseas]

(Unit: 100 mil. yen, %)

Domestic/Overseas	FY2008	FY2010 (fcst.)	FY2012 (fcst.)	FY2010/ FY2008	FY2012/ FY2008
Domestic Clinical Diagnostic Reagent and Device Business	4,352	4,535	4,613	104.2	106.0
Overseas Clinical Diagnostic Reagent and Device Business	3,025	3,233	3,500	106.9	115.7
Total	7,377	7,768	8,113	105.3	110.0

Estimated by Yano Research Institute Ltd

* Note: Based on the sales figures of major 40 companies conducting the clinical diagnostic reagent and device business in Japan