

## Bridge Report EIKEN CHEMICAL (4549)

 President Tetsuya Teramoto	Company	EIKEN CHEMICAL CO., LTD.	 <b>EIKEN CHEMICAL CO., LTD.</b>
	Code No.	4549	
	Exchange	Tokyo Stock Exchange, First Section	
	Industry	Pharmaceuticals (manufacturing)	
	President	Tetsuya Teramoto	
	HQ Address	Yamaguchi building 7, 4-19-9, Taito, Taoto-ku, Tokyo 〒110-8408	
	Business Description	Major manufacturer of clinical diagnostics. Its immunochemical fecal occult blood test reagents occupies over 50% share of the domestic market. It is strengthening its molecular genetics. It is actively promoting license business.	
	Year-end	End of March	
	URL	<a href="http://www.eiken.co.jp/en/">http://www.eiken.co.jp/en/</a>	

### — Stock Information —

Share price	Number of shares issued (excluding treasury shares)		Total market cap	ROE (Actual)	Trading unit
1,815 Yen	18,192,890 Shares		33,020 million yen	10.9%	100 shares
DPS (Est.)	Dividend yield (Est.)	EPS (Est.)	PER (Est.)	BPS (Actual)	PBR (Actual)
30.00 Yen	1.7%	94.54 Yen	19.2 times	1,294.26 Yen	1.4 times

\*Share price is as of the end of October 31. The number of shares issued is from the latest financial settlement report (excluding treasury shares from the number of shares issued). ROE and BPS are based on actual results at the end of the first term.

### — Business Performance Trends —

(Unit: Million yen, Yen)

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
March 2010 (actual)	26,841	1,902	2,011	1,214	66.87	25.00
March 2011 (actual)	27,562	2,709	2,775	1,672	92.06	30.00
March 2012 (actual)	27,702	2,363	2,543	1,460	80.38	30.00
March 2013 (actual)	28,645	2,548	2,812	2,453	134.98	35.00
March 2014 (estimate)	29,760	2,690	2,700	1,720	94.54	30.00

\*The figures for the fiscal year ending March 2014 are based on the estimates made by EIKEN CHEMICAL.

We would like to introduce EIKEN CHEMICAL CO., LTD., a Tokyo Stock Exchange, Section 1, in the Bridge Report.

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## Key Points

•EIKEN CHEMICAL is a general manufacturer of clinical diagnostics, including immunological and serological, microbiological, clinical chemistry, urine analysis and molecular genetics. It offers many products that occupy high market share including immunochemical fecal occult blood test reagents that occupy about 57% of the domestic share. Its unique gene amplification technology, “LAMP”, is highly recognized world-wide. With the fecal occult blood tests and LAMP, EIKEN is aiming to grow into a global corporation.

•Net sales of the first half of fiscal year (FY) 2014 was 15,000 million yen, up 2.9% year-on-year. In Japan, its major product, fecal occult blood test reagents, was in good demand. As for the overseas sales, on the other hand, although the sales in Europe and Asia showed steady growth, the income in North America decreased due to inventory adjustment. Overall, as a result of reduction in cost rate and controlling selling, general and administrative expenses, the profit margin increased. The operating income increased by double-digit percentages. The sales and profit were more than the estimate for the first half. Same as the previous term, interim dividends of 15 yen/share were distributed.

•There is no change in the estimates for FY 2014. The domestic market is expected to grow steadily. Due to recovery of overseas sales, the income will slightly increase. The operating income will also increase. The total annual dividends are expected to be 30 yen/share, including year-end dividends of 15 yen/share.

•Due to poor sales in North America, the total overseas sales decreased. However, overall sales exceeded the sales and profit estimates announced at the beginning of the fiscal year, and the business performance shows steady improvement. There are new buyers of the fecal occult blood test reagents and their sales are expanding in Europe and Asia. EIKEN’s excellent immunochemical method, as opposed to the conventional chemical method, is also gradually penetrating the market, and its future expansion is highly anticipated. Their progress of global expansion during this fiscal year, including acquisition of WHO recommendation for the tuberculosis test with LAMP, should be closely monitored.

## 1. Company Overview

EIKEN CHEMICAL is a general manufacturer of clinical diagnostics, including immunological and serological, microbiological, clinical chemistry, urine analysis and molecular genetics. It also develops and sells medical devices. It offers many products that occupy high market share including fecal occult blood test reagents that occupy about 57% of the domestic share. Its unique gene amplification technology, “LAMP”, is highly recognized in the world. With the fecal occult blood tests and LAMP, EIKEN is aiming to become a global corporation.

### 【History】

1939	Establishment of Koa Kagakukogyo Co., Ltd. Initiation of the manufacturing and sales of nourishing food article.
1949	Powdered agar for the detection of bacteria, the first product of the field, was successfully commercialized in Japan.
1961	Establishment of Clinical Laboratory Division. Initiation of R&D of clinical diagnostics.
1969	Company name was changed to EIKEN CHEMICAL CO., LTD. in recognition of its 30th anniversary.
1972	Commencement of the sales of “Uropaper EIKEN”, a urinalysis test strip.
1987	Commencement of the sales of “OC-hemodia”, the immunochemical fecal occult blood test reagent.
1989	Commencement of the sales of “OC SENSOR”, the automated fecal occult blood analyzer.
1990	Stocks listed in the second section of the Tokyo Stock Exchange.
1998	Development of novel DNA amplification LAMP method and filing of its patent applications.
Mar. 2002	Stocks listed on the first section of the Tokyo Stock Exchange.



Mar. 2002	Commencement of the sales of novel “Loopamp Bovine Embryo Sexing Kit” and “Loopamp End Point Turbidimeter”, using LAMP.
2002	LAMP patent granted in March in the U.S.A. and in May in Japan.
Nov. 2004	Acquired FDA approval for fecal occult blood test reagent and analyzer and commencement of their sales in the U.S.A.
Jul. 2005	Conclusion of agreement with Foundation for Innovative New Diagnostics (FIND) for development of rapid diagnostic test for tuberculosis using LAMP.
Aug. 2006	Completion of construction of plant and company building of EIKEN SHANGHAI CO., LTD.
Oct. 2008	Expansion of collaborative development with FIND to include malaria and African trypanosomiasis.
Mar. 2009	Establishment of new management vision, ‘EIKEN WAY’ and ‘EIKEN ROAD MAP 2009’.
Jul. 2010	Commencement of the sales of various in vitro diagnostic products using LAMP including “Loopamp H1 pdm 2009”, “Loopamp Mycoplasma P Detection Kit”, “Loopamp Legionella Detection kit C”.
Jun. 2011	Commencement of the sales of “Loopamp MTBC Detection Kit”.
Dec. 2011	Conclusion of agreement with FIND for development of diagnostics for Leishmaniasis.
Aug. 2012	Commencement of the sales of highly sensitive Fully Automated Bioluminescent Immunoassay Analyzer, “BLEIA-1200” and “BL-NV EIKEN” to detect Norovirus.
Nov. 2012	Commencement of the sales of “Immuno Catch Noro” using the immunochromatographic analysis method.
2013	Commencement of the sales of BLEIA-1200 specific reagents, called “BLEIA EIKEN HCV antibody”, “BLEIA EIKEN HCV antigen”, and “BLEIA EIKEN HBs antibody”.

\* For LAMP and FIND, please refer to “2. Characteristics and Strengths (4) Competitive Advantage of LAMP”.

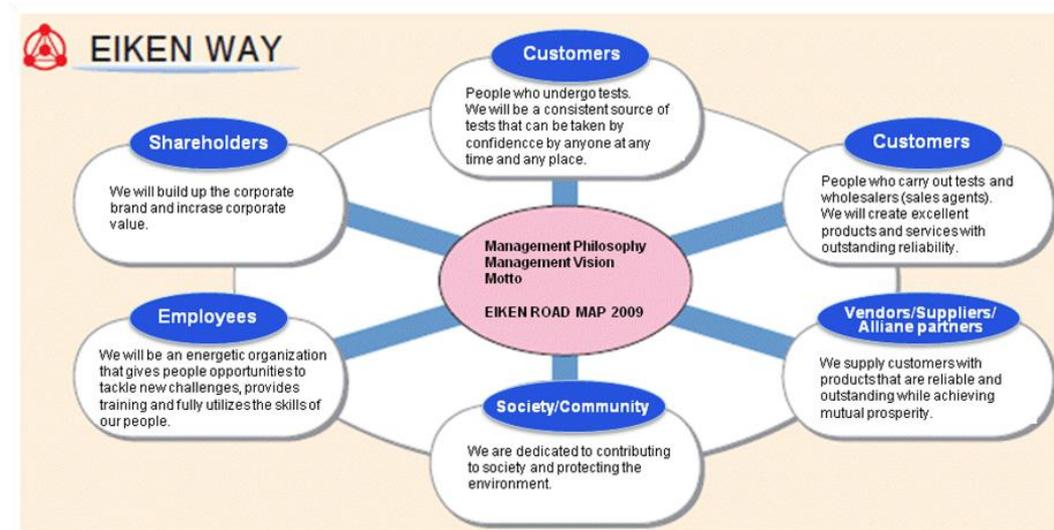
**【Management Philosophy】**

As a foundation of management, EIKEN CHEMICAL established the EIKEN WAY based on their “Management Philosophy”, “Management Vision”, and “Motto”.

“Management Philosophy”: Protect the health of the public through health care services.

“Management Vision”: EIKEN group is dedicated to leveraging expertise as a medical testing pioneer in order to increase corporate value by protecting the health of the public with products and services that customers can trust.

“Motto”: We EIKEN provide trustworthy quality, and develop with technology.



(From the Company’s information material)

## 【Market Environment】

### <Domestic Market>

The market scale of clinical reagents (including diagnostics devices) is about 512,000 million yen as of 2012 (study by Japan Association of Clinical Reagents Industries). In order to control medical cost, Japanese government is focusing on preventive medicine such as special health check-up (check of metabolic syndrome) and cancer screening. Thus, it is expected that the number of sample (number of specimen) for testing will increase as the population ages.

Some negative factors include impact of population decline as a result of decreasing birth rates and revision of medical treatment fees (reduction). However, the trends of laboratory test fees which had been subject to revision of medical treatment fees show that, even though they were cut by 40% from 1997 to 2006, the fees have been stable or only slightly reduced after 2007. This is a result of advocacy on the importance of prevention and test by the entire industry including EIKEN. Thus, in the medium to long term, the domestic market is expected to slightly grow by 3% per year.

According to the “Prospect of Clinical Laboratory Test Market, 2009” conducted by Yano Research Institute, EIKEN CHEMICAL ranked **the fifth** largest sales, occupying **5.8% market share**, after Sysmex (6869, first section of Tokyo Stock Exchange), Roche Diagnostics (Japanese corporation of the Roche Group in Germany), FUJIREBIO (Miraca Holdings, 4544, first section of Tokyo Stock Exchange), and Abbott Japan (Japanese corporation of the Abbott Group in the USA).

Out of 118 member companies (as of October 2013) of the Japan Association of Clinical Reagents Industries, about 80 are manufactures, and there are 8 companies with over 20,000 million yen sales. Most of them are small to medium sized companies. Because the test items of diagnostics tests range widely, each company has its own strong field, and business segregation is already established in the industry. As a result, collaboration, such as supplying the products from other companies and selling them, is often observed. In addition, the market is modestly growing. Therefore, there is currently no obvious trend of weeding out uncompetitive corporations.

### <Overseas Market>

According to the “Prospect of Global Clinical Laboratory Test Market, 2009” conducted by Yano Research Institute, the global clinical laboratory test reagent/device market is US\$ 44,500 million or 4,450 billion yen (1 USD=100 yen), and, by region, the market is occupied by the USA at 41.2%, followed by Europe at 36.9% and Asia/Pacific at 12.0%. Currently, the market is believed to be around US\$ 50,000 million.

The overseas market is over ten times larger than the domestic market. In developed countries, the number of tests is increasing as aging of population progresses. Furthermore, in emerging countries, the needs for medical services are expanding because of economic and income growth. As a result, the annual growth rate of overseas market is expected to be 7 to 8%, which is much higher than that of the domestic market. Therefore, the Japanese companies in the industry are vigorously undertaking globalization of their businesses.

In the global market, the global large companies such as Roche, Abbott, SIEMENS, and Beckman, whose sales are 200,000 to 900,000 million yen, are leading the market, and in order for Japanese companies to survive the competition, they must strengthen their competitiveness by, for example, developing unique products or systems.

## 【Business Description】

### 1. What are clinical tests?

One type of clinical tests is “biological tests” that directly examine body using medical equipment such as X-ray, CT, MRI, electrocardiogram, and ultrasound. Another type of clinical test is “**medical laboratory tests**” that examine biological sample (specimen) obtained from people such as blood, urine/feces, and cells.

The clinical test reagents made by EIKEN CHEMICAL are the ones used for medical laboratory tests. For example, they are used to test infectious diseases or to measure small amount of blood contained in stool. They are made to support diagnosis.

Most of these reagents are called in vitro diagnostics(IVD). Reagent manufactures usually file applications for the approval of the Ministry of Health, Labor and Welfare.

The users of these reagents include hospitals, clinics, medical test centers that carry out tests based on request from medical institutions, health check-up centers, public health departments, institutions for health research, etc.

## 2. Major products

EIKEN CHEMICAL mainly manufactures and sells the following reagents and medical devices.

As it deals with a wide range of reagents and medical devices, it not only sells their in-house products but also purchases and sells the products of other companies.

Their major in-house products include fecal occult blood test reagents, microbiological reagents, general test reagents (e.g. test strip for urinal test), and molecular genetics.

The sales composition ratio of their in-house products and other companies' products are 50%-50%. The gross profit margin rate is about 55% by the in-house products, about 35% by other companies' products, and about 15% by medical devices.

Name of product	Sales	Sales composition ratio
Fecal occult blood test reagents	6,390	22.3%
Immunological and serological reagents (excluding fecal occult blood tests)	9,262	32.4%
Microbiological reagents	4,624	16.1%
General test reagents (e.g. test strip for urinal test)	2,022	7.1%
Clinical chemistry reagents	695	2.4%
Equipments/ culture medium related to food and environment	2,353	8.2%
Medical devices (excluding devices related to molecular genetics)	2,372	8.3%
Molecular genetics (including devices)	923	3.2%
Total sales	28,645	100.0%

\* Results for fiscal year ending March 2013. Unit: Million yen

### Fecal occult blood test reagents

The reagents and feces sampling bottles for immunochemical fecal occult blood tests to specifically detect and measure human hemoglobin in feces as a screening test for colon cancer are the major products of EIKEN CHEMICAL. They are sold globally.

### Immunological and serological reagents (excluding fecal occult blood tests)

EIKEN CHEMICAL develops, manufactures and sells various reagents to diagnose and measure infectious disease, rheumatism, inflammation, atrophic gastritis, and prostate-specific antigen. Such reagents include reagents for automated analyzer called "LZ test EIKEN". EIKEN also purchases medical devices from TOSOH Corporation and sells them.

### Microbiological reagents

Since its establishment, EIKEN CHEMICAL has been developing reagents for microbiological tests in order to prevent infectious diseases and food poisoning. Currently, it develops, manufactures and sells various reagents that are effective for diagnosis and treatment of microorganism infection, such as medium, powder medium, drug sensitivity test reagents, and rapid test reagents.

### General test reagents (e.g. test strip for urinal analysis)

EIKEN CHEMICAL develops, manufactures and sells "UROPAPER EIKEN" series for testing various items such as occult blood, protein and glucose in urine as well as "UROPAPER  $\alpha$  III EIKEN", a dedicated test strip for fully automated urine analyzer.

### Clinical chemistry reagents

EIKEN CHEMICAL develops, manufactures and sells reagents for biochemical tests including "EXDIA XL EIKEN" series that assist to measure and analyze biological components in blood serum and urine, specifically for the test items that are related to life-style related diseases.

### **Equipments/ culture medium related to food and environment**

EIKEN CHEMICAL sells reagents for food microorganism tests to detect food-poisoning bacteria as well as reagents for environmental microorganism tests and equipments/devices to measure contamination of work environment.

### **Medical devices (excluding molecular genetics)**

EIKEN CHEMICAL sells various types of automated analyzers. Since its commencement of sales in 1989, it has been working on technical innovation and quality enhancement of its automated fecal occult blood analyzers, “OC CENSOR” series.

It also offers the “US Series”, automated urine analysis devices using EIKEN’s proprietary color CCD sensor, as well as fully automated biochemiluminescent immunoassay, “BLEIA-1200”, which is the first fully automated device in the clinical test field.

### **Molecular genetics (including devices)**

In 1998, EIKEN CHEMICAL developed an innovative gene amplification technology, called “LAMP” (Loop-mediated Isothermal Amplification), and applied for patent. LAMP is “simple, rapid, and accurate” and is a critical tool for EIKEN’s future global expansion of their business. (The details are described later.)

## **2. Sales structure**

EIKEN CHEMICAL has 11 sales offices and 2 sales divisions in Japan. Its academic department supports sales promotion.

Out of 641 employees (consolidated) during FY 2013, about 280 belong to the sales department.

As for the sales channels for medical institutions such as hospitals, the Company’s direct sales partners are medical wholesale companies, and it has businesses with almost all of the wholesale companies in the medical industry.

For overseas sales, EIKEN CHEMICAL has basically 1 agency per country, and the sales and maintenance are commissioned to the agencies.

EIKEN’s products are exported to 40 countries (FY 2013). The high proportion of overseas sales is occupied by the sales in the USA, Italy, South Korea, and Taiwan where fecal occult blood test is adopted as part of the national system.

In addition to the Europe Office in Amsterdam (the Netherland), the Company is strengthening its manufacturing and sales structure through its consolidated subsidiary, “EIKEN CHINA CO., LTD.”, as well as aiming to expand its businesses by setting a business office in China. In the future, it will explore the possibility of making the office as a local corporation, as the size expands.

The overseas sales for FY 2013 are 1,949 million yen, out of which 1,443 million yen, 74.0%, is from the sales of fecal occult blood test reagents.

## **2. Characteristics and Strengths**

### **(1) Products that occupy high share in the market**

The share of EIKEN’s fecal occult blood test reagents is top ranked (about 57%) in the domestic market. Furthermore, its in-house products occupy high share in the market, as its test strips for urinal analysis occupies about 23% (second rank) in the market and its microbiological reagents occupy about 18% (second rank) in the market.

The distribution of fecal occult blood test reagents rapidly expanded after 1992 when fecal occult blood test became available at public expense as a colon cancer screening method as a result of an amendment of the Health and Medical Service Act for the Aged.

The reasons why EIKEN could obtain a high share are that 1) it launched fecal occult blood test reagents called “OC-Hemodia” in 1987, 2) it kept improving sanitation aspect and handling of feces sampling bottle, 3) it developed automated analyzers using latex photometric immunoassay method for the first time in the world, and 4) the performance of its reagents is excellent.

Especially combination of sampling container and device was favorably accepted by the users, which became a big factor for the expansion of its distribution.

## Fecal occult blood test

When there is cancerous tissue or polyps in the colon, due to friction they withstand as stool comes out, there may be blood on the stool.

Fecal occult blood test can detect even the smallest quantities of blood attached to stool that normally go unseen by the naked eye.



(From the Company's information material)

As for fecal occult blood test, EIKEN will globally expand its business based on the above characteristics.

The immunochemical method in Japan applies reagents that react only to human hemoglobin, and also it is possible to process a large volume at the same time.

Meanwhile, in other countries, reagents for chemical method (Guaiac method) based on old measuring principles are still used, which presents accuracy challenges. In recent years, the test guidelines in Europe finally begin recommending automated analyzers using immunochemical method. As a result, the market is beginning to go through a dramatic change.

Furthermore, although the chemical method is still common in the USA that has the largest potential market, there is an increasing trend of shifting to the immunochemical method. This means that, in developed countries such as Europe, North America, Asia and Oceania, there is a large yet-to-be-developed market.

## (2) Focusing on research and development

EIKEN CHEMICAL is focusing on research and development of unique technologies as a research and development corporation, and the development of original products that respond to customers' needs, using the unique technologies. The number of staff assigned for research and development is about 100.

The demand from the customers is higher quality of medicine. Specifically, they demand for higher differential diagnosis accuracy with high sensitivity and high quality and improved detection rate. In addition, easier usage will lead to reduction in the work of medical staff. Responding to such needs is critical.

Since its establishment, EIKEN CHEMICAL has accumulated unique technologies for manufacturing reagents. Their unique technologies are applied to the measuring principles of their devices such as fecal occult blood test analyzer, automated urine analyzer, and bioluminescent immunoassay analyzer that are designed to optimize the performance of the reagents.

## (3) Development of various types of products in various fields through alliance strategy

Because clinical test reagents have wide range of subjects and items, it is not possible for one company to develop, manufacture and sell all types of reagents. The other companies in the industry are focusing on the technologies and products that they are specialized in. However, as an integrated manufacturer of clinical test reagents, EIKEN CHEMICAL aims at stabilizing profit structure, expanding their own strengths through alliance strategy, and pursuing synergy effects such as complementing functions and acquiring new technologies, while dealing with wide range of products and responding to the needs of customers and users such as medical institutions.

Another reason why they cover various types of products in various fields is that they believe that covering wide range of clinical tests is their social responsibility to protect the health of the public, as is stated in their management philosophy: "protect the health of the public through health care services".

## (4) Competitive advantage of "LAMP"

Currently, the mainstream technology for amplifying genes as a process of gene test is called "PCR method". Against this, EIKEN CHEMICAL developed a unique technology called "LAMP" in 1998.

As compared with the PCR method, LAMP offers the following excellent characteristics and allows the users to carry out simple, rapid and accurate gene tests.

Simple	Amplification response occurs at a fixed temperature. (With the PCR method, temperature needs to be changed for amplification.)
Rapid	Amplification efficiency is high, and gene can be detected within 30 to 60 minutes. (With the PCR method, it takes 2 to 3 hours.)
Accurate	Specificity is extremely high.

Currently, in the medical field, LAMP is used to diagnose infectious diseases such as tuberculosis, mycoplasma and influenza.

EIKEN CHEMICAL is making focused efforts on infectious disease diagnostic tests in order to establish the status of LAMP. At the same time, it is promoting the use of LAMP in the other fields such as food production and processing, environment, agriculture/veterinary in order to spread and enhance recognition of LAMP. In fact, the products based on LAMP have been commercialized one after another since 2002.

Furthermore, for the same purpose, EIKEN CHEMICAL is giving license to external companies in order to build the LAMP camp.

One of the major actions to spread LAMP in the world is the alliance with “**Foundation for Innovative New Diagnostics (FIND)**”.

FIND is a non-profit organization, recognized by the Swiss government. It was launched at a meeting of the World Health Assembly in May 2003. In the initial five years, it receives grant from the Bill & Melinda Gates Foundation for their activities.

The goal is to develop and introduce affordable, simple, and advanced diagnostic tests in order to mitigate infectious diseases in developing countries.

Their scope of activities includes tuberculosis, malaria and human African trypanosomiasis. For tuberculosis, collaborative research between EIKEN CHEMICAL and FIND for tuberculosis test using LAMP began in July 2005. The purpose of the research was to improve the accuracy of tests to make it better than the one by microscopy test (sputum smear test) that is currently common in developing countries.

As a result of the collaboration, improvements such as simplified pretreatment, improved reagents storage and simplified devices were made to enable the developing countries to operate the procedure. These improves were not possible with the conventional PCR method.

This product with LAMP was already launched in Japan in June 2011.

Currently, FIND is carrying out on-going clinical trials in various developing countries in order to obtain recommendation from World Health Organization (WHO) for the products.

Furthermore, in addition to tuberculosis and other diseases mentioned above, FIND and EIKEN CHEMICAL conduct collaborative research for reagents of Leishmaniasis.

EIKEN CHEMICAL expects that the results of these collaborative studies will accelerate the spread of LAMP as well as establish its status as a global standard, which will lead to their expansion in the gene test market.

### 3. First Half of Fiscal Year March 2014 Earnings Results

#### (1) Overview of Consolidated Performance

(Unit: Million yen)

	1H FY 2013	Composition ratio	1H FY 2014	Composition ratio	Year-on-year comparison	Estimate at the beginning of term
Net sales	14,638	100.0%	15,065	100.0%	+2.9%	+0.6%
Gross margin	5,963	40.7%	6,211	41.2%	+4.2%	+0.9%
SG&A	4,478	30.6%	4,573	30.4%	+2.1%	-4.1%
Operating income	1,484	10.1%	1,638	10.9%	+10.4%	+17.8%
Ordinary income	1,586	10.8%	1,692	11.2%	+6.6%	+20.9%
Quarterly net income	993	6.8%	1,085	7.2%	+9.3%	+21.9%

**Increase in income and profit as a result of good sales in Japan**

The sales were 15,000 million yen, up 2.9% (year-on-year basis). In Japan, EIKEN CHEMICAL has been promoting vigorous sales to increase the market share of their major products. As a result, fecal occult blood test reagents, immunological and serological reagents, and molecular genetics had excellent sales in Japanese domestic market.

In the overseas market, the sales showed steady growth in Europe and Asia as a result of focusing on global expansion. However, in North America, finding new customers was a challenge because the agency was busy dealing with inventory adjustment as well as responding to the instructions given by Food and Drug Administration (FDA) after their inspection.

Overall, EIKEN's efforts to reduce the manufacturing cost ratio of their in-house products and to better control use of SG&A expenses resulted in improvement of profit ratio. The operating income resulted in double-digit increase.

The sales and profit exceeded the upper half estimates, announced at the beginning of the fiscal year.

The depreciation was 509 million yen, which was slightly higher than that of the same term of previous year. The capital investment was 473 million yen, up 83% year-on-year.

EIKEN CHEMICAL provided the interim dividends of 15 yen per share, which was the same as previous term.

**(2) Sales by Products**

	1H FY 2013	1H 2014	Year-on-year Comparison
Fecal occult blood test reagents	3,573	3,635	+1.7%
Immunological and serological reagents (excluding fecal occult blood test reagents)	4,676	4,950	+5.8%
Microbiological reagents	2,320	2,375	+2.4%
General test reagents (e.g. test strip for urinal test)	1,021	1,051	+2.9%
Clinical chemistry reagents	368	357	-3.0%
Equipments/ culture medium related to food and environment	1,203	1,192	-0.9%
Medical devices (excluding devices related to molecular genetics)	1,098	1,088	-0.9%
Molecular genetics (including devices)	375	413	+10.1%
Overseas market	918	850	-7.5%

○ **Fecal occult blood test reagents**

Although the sales in Japan and Europe increased, the sales in North America decreased due to inventory adjustment, etc. As a result, the overall sales increased only slightly.

○ **Immunological and serological reagents (excluding fecal occult blood test reagents)**

The sales of the "E Plate EIKEN helicobacter pylori antibody II", which measures helicobacter pylori antibody in the blood, and the sales of the "LZ Test EIKEN Pepsinogen", which is used for a test to examine the condition of stomach (ABC classification) in combination with helicobacter pylori test, increased as a result of the expansion of insurance coverage from February 2013.

The sales of "AIA related reagents, HbA1c reagents" of TOSOH CORPORATION, which were introduced and sold by EIKEN CHEMICAL, have been steadily strong.

○ **Microbiological reagents**

The sales of the "Dry Plate EIKEN", a reagent for drug sensitivity tests, were good, and the sales of the "Immuno Catch Noro", a reagent for rapid testing launched in November 2012, contributed to the good sales of microbiological reagents.

○ **General test reagents**

The sales of the "URO PAPER  $\alpha$  III EIKEN", dedicated test strip for fully automated urine analyzer, increased.

○ **Clinical chemistry reagents**

The sales of clinical chemistry reagents decreased due to price competitions, etc.

○ **Equipments and food and environment related culture media**

The sales in this category also remained unchanged due to price competitions.

○ **Medical devices (excluding molecular genetics devices)**

Although the sales of fecal occult blood test devices and immunological and serological test devices increased, the fully automated urine analyzer and microbiological test devices decreased. As a result, the total sales decreased year-on-year basis.

○ **Molecular genetics (including devices)**

The sales of as well as the patent fee income from “Loopamp Mycoplasma P Detecting Reagent Kit” and “Loopamp tuberculosis complex Detecting Reagent Kit” based on LAMP went up.

○ **Overseas sales**

The sales of fecal occult blood test reagents decreased (decrease of 13.3% year-on-year basis). However, the molecular genetics gene (including devices) showed increase of 6.0% (year-on-year basis).

**\* North America**

The sales of fecal occult blood test reagents to North America in the first quarter decreased due to the effect of the agency’s inventory adjustments. Furthermore, expansion of customers did not grow much because the agency was busy responding due to instructions given by Food and Drug Administration (FDA) after their inspection.

**\* Europe**

The fecal occult blood tests are newly adopted in Norway (by the national government) and Belgium (by a district in Belgium). Furthermore, EIKEN CHEMICAL is making focused efforts to expand the sales in France, UK and Sweden. It predicts that the possibility of adoption is high during this year and next year.

In Italy, the sales of fully automated urine analyzer and test strips, are being promoted.

**\* Asia and others**

In Thailand, Hong Kong, and Australia, EIKEN CHEMICAL is making focused efforts to accelerate newly adoption and sales expansion of fecal occult blood tests.

In China, EIKEN CHINA CO., LTD. is promoting the sales expansion of LAMP reagents and LAMP devices.

**(3) Other activities**

◎ **Research and development**

- ✓ Among the already existing products, creatinine and albumin were newly added to the examination items of “URO PAPER III”. (Released in July 2013)
- ✓ As new immunological reagents using BLEIA, the Hepatitis C virus core protein kit, “BLEIA EIKEN HCV antibody” (in April 2013) and Hepatitis B virus surface antibody kit, “BLEIA EIKEN HBs antibody” (in April 2013) were released.
- ✓ As a line-up of the LAMP products, the DNA rapid detection kit “Loopamp SR DNA Extraction kit” was released in October 2013.
- ✓ The usability of Point-of-Care test (POCT) reagent, “Immuno Catch Noro”, was enhanced. (The renewed version was released in September 2013).
- ✓ The Research and Development cost was 900 million yen, almost the same level as the same term last year.

◎ **FIND Business**

The progress of the alliance business with FIND was as follows.

(1) Tuberculosis

Clinical assessments in developing countries to obtain WHO recommendation were continuously carried out in 14 countries in Africa, South East Asia, etc.

Private-public initiative project funded by the Ministry of Foreign Affairs was conducted in Republic of Haiti.

Application was filed to the China Food and Drug Administration.

Although the WHO recommendation has not been obtained yet, EIKEN CHEMICAL expects that it may be able to obtain the recommendation after submitting the clinical assessment results of 5,000 cases by spring in 2014.

# Bridge Report



(2) Malaria

EIKEN CHEMICAL sold reagents for screening to eradicate malaria.

(3) African trypanosomiasis (sleeping sickness)

Clinical tests were continuously conducted in Democratic Republic of the Congo and Uganda.

(4) Leishmaniasis

The assessment of samples by FIND was continuously carried out.

### (3) Financial Status & Cash Flow

◎Major BS

(Unit: Million yen)

	End of March 2013	End of Sep. 2013		End of March 2013	End of Sep. 2013
<b>Current assets</b>	25,293	25,413	<b>Current liabilities</b>	9,799	9,396
<b>Cash and deposits</b>	9,568	9,912	<b>Notes and accounts payable-trade</b>	5,988	5,893
<b>Notes and accounts receivable-trade</b>	9,208	9,410	<b>Short-term loans payable</b>	472	456
<b>Inventory</b>	5,179	4,768	<b>Noncurrent liabilities</b>	1,659	1,407
<b>Noncurrent assets</b>	9,845	9,749	<b>Long-term loans payable</b>	270	50
<b>Property, plant and equipment</b>	6,913	6,789	<b>Shareholders' equity</b>	23,209	23,942
<b>Intangible assets</b>	429	474	<b>Capital stock</b>	6,897	6,897
<b>Investment and other assets</b>	2,501	2,484	<b>Capital/surplus total</b>	19,724	20,443
<b>Total assets</b>	35,138	35,163	<b>Total liabilities and net assets</b>	35,138	35,163

Total assets were almost at the same level as of the end of March, 2013. On the other hand, current liability and noncurrent liabilities decreased by 400 million yen and 200 million yen, respectively, resulting in decrease of 600 million in total liabilities.

In addition, as a result of increasing retained earnings, the capital-to-asset ratio increased from 67.0% at the end of March 2013 to 68.8% at the end of September 2013.

## 4. Fiscal Year March 2014 Earnings Estimates

<Performance forecast>

(Unit: Million yen)

	FY 2013	Composition ratio	FY 2014 (estimates)	Composition ratio	Year-on-year comparison	Progress rate in upper half
<b>Sales</b>	28,645	100.0%	29,760	100.0%	+3.9%	50.6%
Overseas sales	1,949	6.8%	2,460	8.3%	+26.2%	34.6%
<b>Operating income</b>	2,548	8.9%	2,690	9.0%	+5.6%	60.9%
Ordinary income	2,812	9.8%	2,700	9.1%	-4.0%	62.7%
<b>Net income</b>	2,453	8.6%	1,720	5.8%	-29.9%	63.1%

\*The estimates were based on the announcement by the Company.

**There will be no change in the estimates. The domestic market will be continuously solid. Because of overseas sales recovery, profit will slightly increase. Operating income will also increase.**

There will be no change in the estimates.

In the domestic market, EIKEN CHEMICAL will consider fecal occult blood test reagents, test strips for urinal analysis tests, microbiological reagents, and immunological and serological reagents as the highest priority sales products and try to increase their share in the market.

In the overseas market, EIKEN CHEMICAL will establish OC branding of colon cancer screening and expand the sales in the area, promote the sales of the LAMP products, expand the sales of immunological and serological reagents in ASEAN, and accelerate the sales of fully automated urine analyzer and test strips.

Furthermore, in China, it will increase the sales of LAMP reagents and explore new business opportunities.

As for the businesses with FIND, EIKEN CHEMICAL will continue the clinical assessment of reagents for tuberculosis to obtain the WHO recommendation. It will also continue selling reagents, conducting clinical trials, etc. for malaria, African trypanosomiasis, and Leishmaniasis.

As for research and development, EIKEN CHEMICAL will work on the development of products for LAMP, BLEIA, POCT, and drug sensitivity test reagents. It will also improve their products by fine-tuning their existing technologies and study new diagnostic technologies.

Furthermore, because lowering cost is also a critical challenge, EIKEN CHEMICAL will continuously reduce its manufacturing costs as well as reduce SG&A expenses by improving productivity.

It also recognizes that development of core human resources based on the capacity development vision is a critical management challenge.

<Transition of costs for R&D, capital investment and depreciation> (Unit: Million yen)

	FY 2012	FY 2013	FY 2014 (forecast)
R&D	2,220	1,840	2,069
Capital investment	2,122	693	1,314
Depreciation	1,016	1,040	1,229

Dividends per year are expected to be 30 yen/share (15 yen/share at the end of the second quarter, and 15/yen at the end of FY). The dividend payout ratio is 31.7%.

## 5. New Management Framework, “EIKEN WAY・EIKEN ROAD MAP 2009”

EIKEN CHEMICAL set a goal for 2018, which will be the 80<sup>th</sup> anniversary, and established “EIKEN WAY・EIKEN ROAD MAP 2009” in March 2009, as a fundamental policy to promote “winning management”.

### 【Background】

In Japan, the trend of medical system reform to reduce medical costs will remain unchanged. The corporations in the clinical diagnostics industry are forced to enhance efficiency and streamline their business as a result of revision of medical fees and intensification of products and price competition.

Furthermore, securing safety and compliance with laws and ordinance are becoming increasingly important management challenges. As a result, the gap between corporations is expected to be larger.

Under these circumstances, in order to achieve steady growth and sustainable enhance of corporate values, EIKEN CHEMICAL recognizes that it is essential to clarify the goal of EIKEN group, optimize the efficiency of management resources, and implement the strategies to utilize environmental changes with new visions more quickly and boldly.

Based on this recognition, it established the “EIKEN WAY” as a plan to practice solid management and the “EIKEN ROADMAP 2009” as basic principles to promote “winning management” with long term goals.

### 【Overview】

#### 1. Business domain

EIKEN CHEMICAL set the “clinical diagnostics business” and “food and environment testing business” as their main business domains for which they can utilize the technologies and strengths owned by the EIKEN Group to achieve steady growth and increase in profitability. Furthermore, in these domains, they are aiming at creating new businesses for future growth.

# Bridge Report



## 2. EIKEN ROAD MAP 2009 Grand Vision

We will transform EIKEN into a global corporation by 2018 that can leverage expertise as a medical testing pioneer to protect the health of the public.

## 3. EIKEN ROAD MAP 2009 Principles of Action

- (1) To be proud of and responsible for protecting health of people in the world.
- (2) To enhance trust from stakeholders.
- (3) To pursue highly unique innovative technologies.
- (4) To create top share products that we can be proud of.
- (5) To challenge every possibility and try to achieve self-reform.
- (6) To always take action with global thinking.
- (7) To act for total optimization.

## 4. Fundamental policy

(1) Increase the market share of EIKEN products in Japan	Adopt the customers' perspective to improve products and services in every possible way. Achieve consistent growth by enlarging the lineup of core products and becoming more competitive.
(2) Expand global operations	To firmly establish the EIKEN brand outside Japan, rebuild the overseas sales infrastructure and network and steadily expand geographic coverage, extending from the U.S. and Europe to emerging markets.
(3) Further upgrade core technologies	Create and expand new sources of demand by leveraging innovative ideas, advanced technologies and other core EIKEN strengths. Accept the challenge of supplying products that exceed customers' expectations through the relentless pursuit of advances in performance and quality.
(4) Improve productivity	As a manufacturer, aim for constant improvements in productivity in all work processes, extending from R&D to manufacturing and sales.
(5) Establish superior competitive positions in markets	Channel resources to market sectors where EIKEN is most competitive and the development of strategic value-added products. The goals are to earn the highest possible returns on capital and achieve market superiority.
(6) Launch new businesses and create new markets	As a pioneer in medical testing, create new businesses and markets by drawing on new and highly specialized technologies. Seek business opportunities of all kinds in order to quickly launch new businesses that can drive the next phase of growth.
(7) Forge strategic alliances	Forge strategic alliances with partners that can produce synergies, such as by reinforcing existing strengths, providing complementary functions and acquiring new technologies.
(8) Make the corporate brand more powerful	Improve the quality of human resources and the company in order to build a base of operations for transforming EIKEN into a global organization.

## 5. Management goal

To become one of the global medical testing corporations in the future, we will strive to steadily enhance profitability while creating solid business foundation.

## 6. Message to Investors

With a focus on the “EIKEN WAY・EIKEN ROAD MAP 2009”, we interviewed President Teramoto concerning their future development.

### <Promotion of global development>

Although the domestic market is steadily growing, we are concerned about the increasing negative factors such as population decline and acceleration of price competition in the future in Japan. Therefore, we will strengthen our overseas businesses and strive to be a global corporation “EIKEN” as is stated in the grand vision of the “EIKEN ROAD MAP 2009”.

Specifically, we will expand the global market with “immunochemical fecal occult blood test” and “LAMP”, both of which were developed based on our unique technologies.

#### (1) Immunochemical fecal occult blood test

The competitive advantage of immunochemical test, which is a unique technology developed in Japan, include “high sensitivity and high specificity”, “react only to human hemoglobin (there is no need to control food and drug of patients before the test)”, and “full automated and quantifiable”. By highlighting such an advantage, we will strive to expand our market mainly in developed countries in Europe and North America.

In 2011, European guidelines for quality assurance in colorectal cancer screening and diagnosis was revised, and it is currently recognized that “immunochemical (automated) test is the best”. During the current fiscal year, Norway and Belgium newly adopted EIKEN’s products for the national screening test. Furthermore, France, UK and Sweden are considering the adoption.

In the USA, which has a large market, currently chemical method occupies 70% and immunochemical method occupies 30%.

In the future, by vigorously conducting sales activities to increase the number of tests with the existing customers and as well as to promote adoption our products in the new hospital market, EIKEN CHEMICAL will try to increase the share among the immunochemical test users and promote the shift from chemical to immunochemical method.

In Asia, our sales are expanding in South Korea, Taiwan, China, Singapore, New Zealand, and Australia. We are also planning to promote the new adoption in Thailand.

#### (2) Molecular genetics LAMP

As described above, EIKEN CHEMICAL is trying to globally distribute LAMP.

Especially, there will be a large market for the tuberculosis test with LAMP.

#### <Current status of tuberculosis>

- Around 1/3 of the world’s total population (7 billion) is infected with tuberculosis. Every year, 9.4 million people are newly infected and 1.8 million die from tuberculosis.

- Out of around 200 countries in the world, about 80% of reported tuberculosis cases occurred in 22 countries. 98% of the dead cases occurred in those countries.

Currently in the above 22 countries, approximately 40 million cases were tested by sputum smear tests (microscopy test). However, because the microscopy test has low detection rate, there is an increasing focus on the highly sensitive and highly specific tuberculosis diagnostic method, “LAMP”, which is simple, rapid to operate. If 40 million microscopy tests are replaced with LAMP tests, it will be an approximately 20 billion market.

#### (3) Development of super highly sensitive biochemiluminescent immunoassay method.

In addition to immunochemical fecal occult blood tests and LAMP, EIKEN will promote the biochemiluminescent immunoassay, “BLEIA” in the world. It was developed by EIKEN for the first time in the world and was released in August 2012.

This product offers super high sensitivity, equivalent of gene test, and rapid, simple and affordable running cost as immunochemical method to enable the users to simultaneously operate a large volume. EIKEN CHEMICAL first released reagent to detect Norovirus and then released reagent to detect hepatitis that require high sensitivity. As a large-scale product, EIKEN is planning to expand its sales in the mid to long term.

## <Increase share of in-house products in domestic market>

In order to enhance the rates for fecal occult blood tests from the current 30% to 40%, the Ministry of Health, Labor and Welfare is taking actions such as distribution of free coupons. EIKEN participates in awareness raising activities, while working on expansion of its share.

Furthermore, in order to expand the share of other products, EIKEN will refine and improve existing products.

## <Creation of new businesses/new market>

Although limited to “clinical diagnostics” and “food/environment test business” fields, EIKEN will handle groups of products that they have not dealt with yet, including expanding alliance with other companies.

## <Improve productivity>

EIKEN will continuously try to improve productivity, with a focus on reducing manufacturing cost.

It will also pursue “provision of added value to the customers” to win the price competition.

## <Human resource development>

It is a challenge to secure and develop excellent human resources in various fields for continuous growth in the future. Especially, it is an urgent task to secure global human resource in order to reestablish sales structure for the overseas market.

## <Regarding dividends>

The foundations of EIKEN’s value are ‘research and development’ and manufacturing. At the same time, EIKEN considers that returning the profit to the shareholders is also a very important management challenge. EIKEN seeks the balance of both and will maintain the minimum dividends of 30 yen/share, aiming at the “dividend payment ratio of 30%”.

## <Goal of EIKEN>

EIKEN had been focusing on research and development since its establishment. Continuously, it will keep on creating new market through its “own technology/unique technology” such as fecal occult blood tests and LAMP.

There are large corporations that are incomparable with EIKEN in the global market. However, EIKEN will take advantage of its strengths and will aim at becoming the “top in the field” with its unique technologies.

## 7. Conclusions

Overseas sales decreased due to poor sales in North America. However, as a whole, both sales and profit exceeded the upper half estimates announced at the beginning of fiscal year, and EIKEN is delivering strong results.

Meanwhile, new adoption and sales expansion of fecal occult blood test reagents are accelerated in Europe and Asia. The excellence of immunochemical method, as compared with the conventional chemical method (Guaiac method), is also gradually being recognized in Europe and Asia. The future expansion of the market share for the company in the field is highly expected. Including acquisition of WHO recommendation for the tuberculosis test with LAMP, their global expansion during this fiscal year should be closely monitored.

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