BRIDGE REPORT Bridge Salon

President
Morifumi Wada

EIKEN CHEMICAL (4549)

EIKEN CHEMICAL CO.,LTD.

Company Information

Exchange	TSE 1st Section
Industry	Pharmaceuticals (manufacturing and sales)
President	Morifumi Wada
HQ Address	7 Yamaguchi building, 4-19-9 Taito, Taito-ku, Tokyo 110-8408, Japan
Year-end	End of March
Homepage	https://www.eiken.co.jp/en/

Stock Information

Share Price	Share Outstanding		Market Cap.	ROE (Act.)	Trading Unit
1,721 yen	43,541,438 Shares		74,934 Million yen	9.9%	100 Shares
DPS (Est.)	Dividend Yield (Est.)	EPS (Est.)	PER (Est.)	BPS (Act.)	PBR (Act.)
Undecided	-	Undecided	-	1,002.86 yen	1.7 times

*Share price is as of the end of May 25. The number of shares issued and ROE, BPS are from the FY March 2020 financial settlement report. The forecast for the current fiscal year has not been made as it is difficult to reasonably estimate the impact of the new coronavirus at this stage.

Business Performance Trends

Fiscal Year	Net Sales	Operating Income	Ordinary Income	Net Income	EPS	DPS
March 2017 Actual	33,274	3,976	4,112	2,918	79.69	25.00
March 2018 Actual	34,991	3,478	3,549	2,608	71.21	25.00
March 2019 Actual	35,761	4,611	4,681	3,447	93.63	30.00
March 2019 Actual	36,585	4,622	4,723	3,538	95.95	30.00
March 2021 Est.	-	-	-	-	-	-

*Unit: Million yen, Yen. The definition for net income means net income attributable to owners of parent. On April 1st, 2018, a two-for-one split of the stock was performed. EPS and DPS adjusted retroactively. The forecast for the current fiscal year has not been made as it is difficult to reasonably estimate the impact of the new coronavirus at this stage.

This Bridge Report presents EIKEN CHEMICAL's earnings results for the fiscal year March 2020.

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Key Points

- **The sales for the fiscal year (FY) 2020 were 36.5 billion yen, up 2.3% year on year. In Japan, the sales of fecal immunochemical test reagents and urinalysis test strips grew, but overall sales declined slightly. Outside Japan, the sales of fecal immunochemical test reagents increased mainly in North America and Europe. Operating income improved 0.2% year on year to 4.6 billion yen. While SG&A augmented, increased sales resulted in a slight rise in profit. The forecast for the full fiscal year was revised upward in January 2020 mainly due to strong overseas sales. The dividend estimate was also increased from 27 yen/share to 30 yen/share. Sales exceeded the forecast made at the beginning of the termbut slightly fell below the revised forecast.**

- **The business environment in FY 2021 is expected to be severe considering the impact of the COVID19. While the clinical diagnostics business could also be greatly affected, the company has not yet determined the earnings estimate since it is difficult to predict when the pandemic will subside at the moment and reasonably estimate the impact on the company's performance.**

- **The impact of the COVID19 has been both positive and negative, with an increase in the supply of test kits and a significant decline in the number of tests, mainly fecal immunochemical test, in Japan and overseas. It is difficult to predict the extent of the decline in the number of tests and the timing of the recovery at this point in time, which is the main reason why the earnings forecast for the current term has not been made.**

- **On the other hand, "Simprova," which has been developed completely, is expected to create an unprecedented "testing platform" centered on infectious disease and trigger a post-pandemic paradigm shift in the world "after coronavirus," which may provide an opportunity to further accelerate the company's global expansion. We would like to pay close attention to it.**

1.Company Overview

EIKEN CHEMICAL is a general manufacturer of clinical diagnostics, including immunological and serological, microbiological, clinical chemistry, urine analysis and genetic screening test. It also develops and sells medical devices.
It offers many products that occupy high market share including fecal immunochemical test that occupy about 60% of the domestic share, Urinalysis test, Microbiological test and so on. Its unique gene amplification technology, "LAMP", is recognized in the world. With the fecal immunochemical test reagents, urinalysis test strips and LAMP, EIKEN is aiming to become a global corporation.

1-1 History

1939	Established Koa Kagakukogyo Co., Ltd. and began manufacturing and sales of nourishing food articles and pharmaceuticals using livestock internal organs as raw materials.
1949	First in Japan to successfully commercialize a powder medium (SS agar) for bacteriological examination.
1961	Established Clinical Laboratory Division and began R&D on clinical diagnostics.

1969	Company name changed to EIKEN CHEMICAL CO., LTD. in recognition of its 30th anniversary.
1972	Commencement of the sales of "Uropaper EIKEN," a urine analysis test strip.
1987	Commencement of the sales of "OC-hemodia" (visual determination method), the fecal immunochemical test reagent.
1989	Commencement of the sales of "OC Sensor," the automated fecal immunochemical test analyzer.
1990	Listed stock in the second section of the Tokyo Stock Exchange.
1992	Commencement of the sales of "US-2100," an automated urine analyzer.
1998	Developed LAMP, the new innovative gene amplification technology, and filed patent applications.
Apr. 2001	Began sales of in-house clinical reagents and devices.
Mar. 2002	Listed stock in the first section of the Tokyo Stock Exchange.
Mar. 2002	Obtained patent for LAMP method in the U.S.A.
Mar. 2002	Commencement of the sales of "Loopamp Bovine Embryo Sexing Kit," the first product to use the LAMP method, and of specialized equipment.
May 2002	Obtained patent for LAMP method in Japan.
Dec. 2003	Commencement of the sales of "Loopamp SARS Coronavirus Detection Test Kit" utilized with LAMP method.
Nov. 2004	Acquired FDA approval for fecal immunochemical test reagents and analyzer and began sales in U.S.
Jul. 2005	Entered into an agreement with the Foundation for Innovative New Diagnostics (FIND) for joint development of a LAMP-based rapid genetic diagnostic test for tuberculosis.
Oct. 2008	Entered into a new agreement with FIND for joint development of drugs and therapies against malaria, African sleeping sickness, and HIV.
Jun. 2011	Established a European office (now the European branch) in Amsterdam, the Netherlands.
Dec. 2011	Entered into an agreement with FIND for joint development to treat and prevent leishmaniasis.
Nov. 2012	Commencement of the sales of "Immuno Catch Noro" which uses the immunochromatographic analysis method.
Jan. 2014	Entered into an agreement with FIND for joint development to treat and prevent Chagas disease.
Nov. 2014	Commencement of the sales of "OC Sensor-PLEDIA," the automated fecal immunochemical test analyzer.
Jan. 2015	Developed next generation compact fully automatic genetic testing device and multi-item testing chip, using the LAMP method.
Feb, 2015	Commencement of the sales of "US-3500", a full-automated urine analyzer.
Jan. 2016	Formed a tie-up with SYSMEX CORPORATION for the urine chemistry testing business in overseas markets.
Aug. 2016	Acquired WHO (World Health Organization) recommendation for TB-LAMP. Formed a global sales alliance with HUMAN mbH for TB-LAMP, and malaria testing.
April 2019	Established the new management scheme "EIKEN ROAD MAP 2019."
March 2020	Released the SARS-CoV-2 detection reagents utilizing the LAMP method.
April 2020	Released the "fully-automated genetic testing device Simprova."

*For further information about the LAMP method and FIND, please refer to "2. Characteristics and Strengths (4) Competitive Advantages of the LAMP Method."

1-2 Management Philosophy

"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 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.

EIKEN group formulates "EIKEN WAY" as its attitude toward each stakeholder, centering these philosophy vision, and motto.

(Source: EIKEN CHEMICAL)

1-3 Market Environment

Domestic Market

The market scale of clinical reagents is about 366.8 billion yen and 600.0 billion yen (including research reagents and diagnostic devices) as of 2018 (survey by the Japan Association of Clinical Reagents Industries, or JACRI. Eiken Chemical Data.).

To control rising medical costs, the Japanese government is focusing on preventive medicine such as special health check-ups (metabolic check-ups) and cancer screenings. It is expected that this, along with the aging population, will lead to an increase in the number of samples (number of specimens).

Some negative factors include the impact of population decline because 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 insurance (medical laboratory test fees) show that, even though they were cut by some 40% from 1997 to 2006, the fees have been stable or only slightly reduced after 2007. (Laboratory test fee in fiscal 2018: -0.4%)

This is a result of the activities for emphasizing the importance of prevention and checkups in the industry, including the company. In the medium term, the domestic market is expected to grow with an annual rate of around 2%.

Out of 131 member companies (as of April 2020) of JACRI mentioned above, about 80 are manufacturers, and there are about 15 companies with over 10 billion yen in sales. Most of them are small to medium sized companies. Because the test

items of diagnostic tests range widely, each company has its own field of strength, and business segregation is already established in the industry. As a result, collaboration, such as supplying raw materials and products from other companies and manufacturing and selling them, is often observed. Against such a backdrop, the market is modestly growing. Therefore, there is currently no apparent trend of weeding out uncompetitive corporations.

Overseas Market

The global clinical laboratory test reagent/device market is estimated to be US$ 67.2 billion and, by region, the market is occupied by the USA at 36%, followed by Europe at 28% and Asia at 24% (As of 2018) (Fuji Keizai "2019 World Wide Clinical Testing Market" Eiken Chemical Co., Ltd.).

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 over 5%, 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, however, Roche being the most dominant with the sales of $61.4 billion in 2019, large global companies such as Abbott, SIEMENS, and Beckman are the main players, and in order to survive the competition, Japanese companies must strengthen their competitiveness by, for example, developing unique products or systems.

1-4 Business Description

1. What are Clinical Tests?

One type of clinical tests is the “Biological test” that directly examines the body using medical equipment such as X-ray, CT, MRI, electrocardiogram, and ultrasound. Another type of clinical tests is the “Laboratory test” that examines biological samples (specimens) 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 amounts of blood contained in stool. They are made to support diagnosis. Most of these reagents are called in vitro diagnostics (IVD) and are regulated by the Pharmaceutical and Medical Device Act so reagent manufacturers file applications with PMDA (Pharmaceuticals and Medical Devices Agency) and obtain its approval. Users include hospitals, clinics, medical offices, medical test centers that carry out tests commissioned by medical institutions, health screening centers, public health centers, and institutions for health research, and others.

2. Major Products

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

As they deal with a wide range of reagents, they not only sell their in-house products but also purchase and sell products from other companies.

Major in-house products include fecal immunochemical test reagents, microbiological reagents, immunological and serological reagents, urinalysis test strips, genetic testing reagents, etc. The sales ratio of in-house products to other companies’ products is approximately 60:40. The gross profit margin is approximately 55% for in-house products and approximately 35% for other companies’ products.

Product Name	Sales	Sales Proportion
Fecal immunochemical test reagents (FIT)	10,352	28.3%
Immunological and serological reagents (excluding fecal immunochemical test reagents)	9,917	27.1%
Urinalysis test strips	3,340	9.1%
Microbiological test reagents	4,623	12.6%
Biochemical test reagents	609	1.7%
Equipment/Culture medium related to food and environmental	2,162	5.9%

Related molecular genetics (LAMP), (including its devices)	1,331	3.6%
Medical Devices (excluding molecular genetics related devices)	4,247	11.6%
Total sales	36,585	100.0%

*Results for the fiscal year ended March 2020. Unit: Million Yen

Fecal immunochemical test reagents

The major products for EIKEN CHEMICAL are reagents and sampling bottles for fecal immunochemical tests to specifically detect and measure human hemoglobin in feces as a colorectal cancer screening and diagnosis and are sold globally.

Immunological and serological reagents (excluding Fecal immunochemical test reagents)

EIKEN CHEMICAL develops, manufactures, and sells reagents for various tests, such as LZ Test EIKEN, a reagent for general-purpose automatic analyzers used for diagnosing rheumatism and inflammatory disorders and gastric cancer risk stratification test(the ABC method). The company also procures reagents for fully automated enzyme immunoassay devices and reagents for automatic glycohemoglobin analyzers from Tosoh Corporation, and sells them.

Urinalysis test strips

EIKEN CHEMICAL develops, manufactures, and sells "UROPAPER III 'EIKEN'," a urinalysis test strip for testing various items such as occult blood, protein and glucose, as well as the "UROPAPER α III 'EIKEN'," a specialized test strip for fully automated urine analyzers.
Outside Japan, the company formed a business tie-up with Sysmex Corporation in 2017 and started sales.

Microbiological test reagents

Since its establishment, EIKEN CHEMICAL has been developing biological specimens as well as reagents for microbiological tests for food and environment 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 mediums, powder mediums, antimicrobial susceptibility tests, and rapid test reagents.

Clinical chemistry test reagents

EIKEN CHEMICAL develops, manufactures and sells reagents for clinical chemistry tests including "EXDIA XL 'EIKEN'" series that assist to measure and analyze biological components in blood serum and urine, with a focus on the test items that are related to lifestyle related diseases.

Equipment/ Culture mediums related to food and environment

EIKEN CHEMICAL sells reagents for microbiological tests on food to detect food poisoning bacteria as well as reagents for environmental microbiological tests and equipment and devices to measure contamination of work environments.

Molecular genetics (LAMP)

In 1998, EIKEN CHEMICAL developed and patented an innovative gene amplification technology called "LAMP." The LAMP is "simple, rapid, accurate, and low price" and is a critical tool for Eiken's future global expansion of its business. (Details are described below)

Medical devices

EIKEN CHEMICAL sells various types of automated analyzers. They contract manufacturing specialized equipment that uses their in-house reagent. Since beginning sales of "OC Sensor" in 1989, they have worked continuously on technological innovation and quality improvement of this fecal immunochemical test analyzer. Also, they offer the "US," an automated urine analysis device that uses Eiken's proprietary image processing system, the "BLEIA-1200," a fully automated biochemistry photogenetic immunoassay device that was the world's first of its kind in the clinical testing field, and

"Loopamp EXIA," a LAMP-based real time turbidity measuring device.

3. Sales structure

EIKEN CHEMICAL has 10 sales divisions in Japan. Its academic department supports sales promotion.
Out of 724 employees (consolidated) during FY 2020, about 300 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 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 44 countries (FY 2020). The high proportion of overseas sales is occupied by the sales in the USA, Germany, Italy, Spain, England, France, Australia, South Korea, and Taiwan.
In addition to the Europe Branch in Amsterdam (the Netherlands), 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 2020 are 7,040 million yen, out of which 4,265 million yen, 60.6%, is from the sales of fecal immunochemical test reagents.

1-5 ROE Analysis

	FY3/12	FY3/13	FY3/14	FY3/15	FY3/16	FY3/17	FY3/18	FY3/19	FY3/20
ROE (%)	**7.0**	**10.9**	**8.3**	**8.3**	**8.9**	**10.0**	**8.3**	**10.3**	**9.9**
Net Profit Margin	5.27	8.56	6.61	6.77	7.55	8.77	7.45	9.64	9.67
Asset Turnover Ratio	0.84	0.84	0.84	0.83	0.83	0.80	0.78	0.77	0.75
Leverage	1.58	1.52	1.50	1.47	1.42	1.43	1.43	1.38	1.36

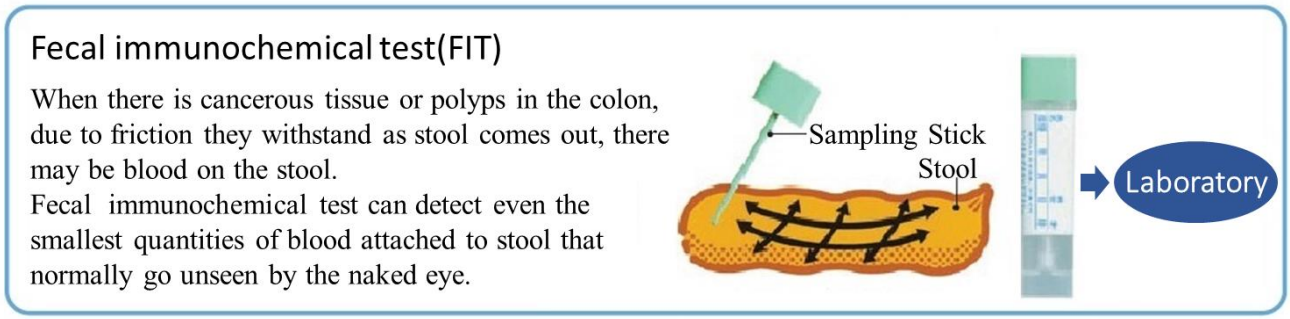
*Unit: %, times, x

The Company continues to fortify priority measures, including developing high value-added products, generating new businesses and new markets, improving further profitability and productivity through reducing COGs rate and SG&A rate.

1-6 Characteristics and Strengths

(1) Products that Occupy High Share in the Market

The share of Eiken's fecal immunochemical test reagents is ranked top (63%) in the domestic market. Furthermore, many of their in-house products occupy high market share in the market, for example, urinalysis test strips occupying approximately 27% (ranked second) of the market, and microbiological reagents occupying approximately 16% (ranked fourth) of the market.
The background to how Eiken's fecal immunochemical test reagents have come to hold such a high share of the market includes that in 1987, Eiken began sales of "OC-Hemodia," a visual determination method fecal immunochemical test reagents, a product that more closely conformed to user needs when compared to competitor's products, and that in 1989 they adopted the latex photometric immunoassay method and began sales of "OC-Sensor," the world's first fully automated analyzer.
Also, the Health and Medical Service Act for the Aged was revised in 1992, making it possible to have fecal immunochemical test reagents as a method in colon cancer screening and diagnosis using public funds (no cost to the patient) which led to an accelerated spread and increased competition. But in 2001, Eiken began sales of the "OC-Sensor neo," with completely remodeled functions, which increased its market share.



(Source: EIKEN CHRMICAL)

As for fecal immunochemical tests, Eiken will expand its business globally based on the above characteristics.
The immunochemical method used in Japan applies reagents that react only to human hemoglobin and can process a large volume simultaneously.
Meanwhile, in other countries, reagents for the chemical method (Guaiac method) based on old measuring principles are still used, which presents accuracy challenges. In 2011, the test guidelines in Europe have finally begun recommending automated analyzers that use the immunochemical method. As a result, the market is beginning to undergo a dramatic change.
Furthermore, although the chemical method is also still common in the United States, which has the largest potential market, trends show a gradual shift toward the immunochemical method. Additionally, new guidelines on colorectal cancer screening by USPSTF (US Preventive Medicine Special Committee) was published in June 2016. These guidelines pointed that the immunization method is superior to the conventional chemical method and pursuantly, and assessed Eiken's fecal immunochemical test product, "the OC FIT-CHEK family of FITs" has the utmost inspection performance with high sensitivity and specificity. Besides, the large markets which are underdeveloping exist on the leading and emerging countries in Asia and South America.
Because the fecal immunochemical test market is a niche market, Japanese companies, the forerunners of the immunochemical method, own the most advanced technique, and hence Eiken's reagents and equipment are the global standard.

(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 110.
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 in 1939, 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 biochemiluminescent immunoassay analyzer " BLEIA " 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 a 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 Advantages of the "LAMP"

Thus far the mainstream technology for amplifying genes as a process of gene tests has been what is called "PCR" Under such circumstances, in 1998, EIKEN CHEMICAL developed a unique technology called the "LAMP."

Compared to the PCR, the "LAMP" offers the following superior characteristics and allows users to carry out simple, rapid, and accurate gene tests.

Simple	Amplification response occurs at a constant temperature (with the PCR, the temperature needs to be changed for amplification).
Rapid	High amplification efficiency, with genes being detected within 30 to 60 minutes (with the PCR, it takes 2 to 3 hours).
Accurate	Extremely high specificity.

Currently in the medical field, the LAMP is used to diagnose infectious diseases such as tuberculosis, mycoplasma (a genus of bacteria, it can also cause pneumonia), legionella, pertussis, etc.
EIKEN CHEMICAL is making focused efforts on infectious disease diagnostic test in order to establish the status of the LAMP. At the same time, it is promoting the use of the LAMP in other fields such as food production and processing, environment, agriculture/veterinary to spread and enhance recognition of the LAMP. In fact, the LAMP-based products have been commercialized one after another since 2002.
Furthermore, for the same purposes, EIKEN CHEMICAL is actively giving licenses to external companies to build the LAMP camp.
One of the major actions to spread the LAMP in the world is an alliance with "FIND."
"FIND" stands for "Foundation for Innovative New Diagnostics" and is a non-profit organization recognized by the Swiss government, launched at a meeting of the United Nations World Health Assembly in May 2003. In its initial five years of existence, it received a grant from the Bill & Melinda Gates Foundation to start up their activities.
Their goal is to develop and introduce affordable, simple, and advanced diagnostic tests to eradicate infectious diseases in developing countries.

FIND's scope of activities includes tuberculosis, malaria, and African sleeping disease. With tuberculosis, collaborative research between EIKEN CHEMICAL and FIND for a tuberculosis test using the LAMP began in July 2005. The purpose of this research is to improve the accuracy of tests by replacing the microscopy test (sputum smear test), which is the current practice in developing countries.
As a result of this collaboration, improvements which are not possible with the conventional PCR such as simplified pretreatment (PURE), improved reagents storage (store at room temperature) and simplified devices have been made to enable the developing countries to carry out the procedure (TB-LAMP).
This LAMP-based product was already launched in Japan in 2011.
After that, in order to obtain endorsement from the WHO (World Health Organization), FIND has completed its clinical evaluation in 14 developing countries and submitted this information to the WHO.
In consequence, the company has acquired the recommendation by WHO as an evaluation replaces with microscopic examination or as an inspection reinforcing microscopic examination in August 2016.

According to a report on global tuberculosis announced by WHO in November 2017, the number of patients suffering from tuberculosis in 202 countries all over the world in 2016 was 10.4 million, an increase of 0.8 million from 9.6 million in 2014. Additionally, the number of deceases was 1.7 million, an increase of 0.2 million from 1.5 million in 2014.
Most of them are inferred as matters of undiagnosed or untreated, and WHO indicates "the enforcement of countermeasures for the countries where access to diagnosis and treatment is not yet maintained is demanded".
Following these situations, the company expects that dissemination and penetration of TB - LAMP contribute greatly to

solve these problems.
In addition to tuberculosis and other diseases listed above, EIKEN CHEMICAL and FIND also conduct collaborative research of reagents for leishmaniasis and Chagas disease.

Also, EIKEN CHEMICAL completed the development of a testing system "Simprova" that uses a next-generation compact fully automated genetic testing device and multi-item testing chip using the LAMP and started selling it in April 2020.
This equipment fully automates the process from specimen preprocessing (nucleic acid extraction and purification) to amplification and detection. By developing the unique protocol that exploits the LAMP's characteristics, the operation time that used to take over 2 hours with a conventional high purity nucleic acid extraction and purification device and an amplification and detection device combined, is now shortened to less than an hour.
At first, the company plans to release the respiratory organ infections panel and then the acid-fast bacterium disease panel, and will gradually increase the number of test items.
It is anticipated that "Simprova" will accelerate the spread of the LAMP and establish its position as the global standard in a newly created market.

＊Gene amplification technology
Since the number of genes found in a genetic test sample is extremely small, to detect genes, the targeted gene must be amplified first. Gene amplification technology, therefore, is crucially important for genetic testing.

＊African trypanosomiasis
An endemic found in tropical Africa; African trypanosomiasis is a serious tropical disease transmitted to HUMAN mbH by a protozoa called Trypanosoma brucei. The disease is transmitted by a tsetse fly. Trypanosoma in HUMAN mbH blood sucked by a tsetse fly develops and propagates inside the HUMAN mbH body in 2 to 5 weeks, before turning itself into a terminal Trypanosoma-type, which becomes a source of next round of infection. The disease causes fever, headache, and vomiting, and the patient falls into constant sleep. Since the patient cannot take meals, he or she becomes thin and complain of generalized weakness and, in many cases, leads to a complication and dies.

＊Leishmaniasis
Leishmaniasis is a disease transmitted by a protozoon called leishmania, and has various types such as visceral leishmaniasis (also known as black fever), Brazilian leishmaniasis that affects skin and mucous membranes, and tropical leishmaniasis which affects skin. All these types are transmitted by blood-sucking insects, especially sandflies. Visceral leishmaniasis, after about three months incubation period, causes fever, sweating, diarrhea, etc. and, in about one month, causes a swollen liver and spleen, the patient develops an anemia and becomes weak if untreated, and may die in half a year to two years.

＊Chagas disease
Found in southern U.S. as well as Central and South America, Chagas disease is an infectious disease transmitted by Reduviidae, a kind of blood-sucking Triatominae. The disease does not develop symptoms immediately after infection; it usually has a latency period of about 30 years. It causes symptoms such as inflammation of sinews, liver and spleen, myalgia, myocarditis, cardiomegalia encephalomyelitis, cardiac disturbance.

2.Fiscal Year March 2020 Earnings Results

(1) Overview of consolidated results

	FY 3/19	Share	FY 3/20	Share	YOY	Divergence from Initial Estimate	Divergence from Revised Estimate
Sales	35,761	100.0%	36,585	100.0%	+2.3%	+1.9%	-0.6%
Domestic	29,691	83.0%	29,545	80.8%	-0.5%	+1.9%	-
Overseas	6,070	17.0%	7,040	19.2%	+16.0%	+1.7%	-
Gross margin	15,692	43.9%	16,230	44.4%	+3.4%	-	-
SG&A	11,080	31.0%	11,608	31.7%	+4.8%	-	-
Operating income	4,611	12.9%	4,622	12.6%	+0.2%	+28.4%	+6.3%
Ordinary income	4,681	13.1%	4,723	12.9%	+0.9%	+29.4%	+6.1%
Net income	3,447	9.6%	3,538	9.7%	+2.6%	+36.1%	+4.1%

(unit: million yen)

Sales grew and profits increased slightly. Results exceeded the forecast made at the beginning of the term.

The sales were 36.5 billion yen, up 2.3% year on year. In Japan, the sales of fecal immunochemical test reagents and urinalysis test strips grew, but overall sales declined slightly. Outside Japan, the sales of fecal immunochemical test reagents increased mainly in North America and Europe. Operating income improved 0.2% year on year to 4.6 billion yen. While SG&A augmented, increased sales resulted in a slight rise in profit.

The forecast for the full fiscal year was revised upward in January 2020 mainly due to strong overseas sales. The dividend estimate was also increased from 27 yen/share to 30 yen/share. Sales exceeded the forecast made at the beginning of the termbut slightly fell below the revised forecast.

(2) Sales by product

Products	FY 3/19	FY 3/20	YoY
Fecal immunochemical test reagents (FIT)	10,016	10,352	+3.4%
Immunological and serological reagents (excluding fecal immunochemical test reagents)	9,972	9,917	-0.6%
Urinalysis test strips	3,097	3,340	+7.8%
Microbiological test reagents	5,153	4,623	-10.3%
Biochemical test reagents	595	609	+2.4%
Equipment/Culture medium related to food and environmental	2,169	2,162	-0.3%
Related molecular genetics (LAMP), (including its devices)	1,315	1,331	+1.3%
Medical Devices (excluding molecular genetics related devices)	3,440	4,247	+23.4%
Total sales	35,761	36,585	+2.3%

(unit: million yen)

○Fecal immunochemical test reagents (FIT)

Sales grew by 0.2% year on year in Japan. While focusing on the switch from competitors' products, the company continued to promote awareness-raising activities to increase the colorectal cancer screening rate. On the other hand, sales rose 8.2% year on year overseas. Sales were particularly strong in North America, Asia, and Oceania. In the U.S., the age for fecal immunochemical tests in Kentucky was lowered in response to the revision to the American Cancer Society (ACS)

guidelines, which lowered the age for tests from 50 to 45 years old. The market is expected to expand in the future.
A new screening program commenced in Canada and the U.K.
Furthermore, it is decided that reagents will continue to be used in France's government screening test for colorectal cancer for five years.
However, there have been delays in testing due to the impact of the COVID19.

	FY 3/19	FY 3/20	YoY
Domestic	6,076	6,087	+0.2%
Overseas	3,940	4,265	+8.2%
Total	10,016	10,352	+3.4%

(unit: million yen)

○Immunological and serological reagents (excluding fecal immunochemical test reagents)

The sales of AIA-related reagents (adopted by Tosoh) were maintained through the new introduction of hemoglobin A1c.
As for latex products, sales increased for LZ reagents (such as FER and MMP3) while the sales of EIA-related reagents declined as the competition intensified.

○Urinalysis test strips

In Japan, the strips were adopted by more centers, thanks to the proposals for the combination of urine sediment apparatus and US-3500 to medical facilities.
Outside Japan, the sales of urinary test strips for Sysmex contributed. The application to FDA in the U.S. is ongoing.

○Microbiological test reagents

In rapid test reagents, sales of the combo kits of pneumococcus/legionella of Immunocatch Series increased as the demand for negative tests for the new coronavirus surged.
The sales of reagents for testing drug sensitivity increased through proposals for combination with MALDI Biotyper.
The sales of culture media dropped due to the termination of a sales contract of products for blood culture test (procurement and sale).

○Related molecular genetics (LAMP)

Inside Japan, sales of reagent kits for detecting the mycoplasma and the pertussis bacteria remained firm.
Outside Japan, the horizontal application of the Cameroon and Philippines cases was conducted for the global fund application.
The revenue from patents grew 35million yen year on year to 556 million yen.

(3) Overseas trends

	FY 3/19	FY 3/20	YoY
Overseas sales	6,070	7,040	+16.0%
North America	1,447	1,592	+10.0%
Europe	2,134	2,002	-6.2%
Asia, others	2,489	3,445	+38.4%
For OC	3,940	4,265	+8.2%
Others	2,130	2,775	+30.3%

(unit: million yen)

North America: The sales of fecal immunochemical test reagents augmented for major customers, such as LabCorp and Kaiser, in the U.S. and in Canada.
Europe: The sales of fecal immunochemical test reagents grew in Germany, Spain, the U.K., etc., whereas the program was suspended in France, and sales declined in Italy.

Asia, Oceania, and other countries: The sales of urinalysis test strips and devices for Sysmex rose significantly. The sales of fecal immunochemical test reagents also grew in Oceania, South Korea, and other countries.

(4) Capital investment, R&D, Depreciation

	FY 3/18	FY 3/19	FY 3/20	FY 3/20 (Initial Est.)
R&D	3,238	2,904	3,332	3,440
Capital investment	1,102	1,685	2,985	3,330
Depreciation	1,660	1,594	1,629	1,880

(unit: million yen)

R&D cost was almost in line with the estimate. Capital investment for Nogi Factory was slightly pushed back into the next term.

(5) Financial status and cash flow

Major BS

	End of March, 2019	End of March, 2020		End of March, 2019	End of March, 2020
Current assets	25,852	28,903	**Current liabilities**	10,981	11,740
Cash and deposits	7,554	10,098	**Notes and accounts payable trade**	6,580	7,324
Notes and accounts receivable-trade	11,959	11,017	**Income tax payable**	770	702
Inventory	5,825	7,173	**Noncurrent liabilities**	1,284	1,278
Noncurrent assets	21,427	21,418	**Total liabilities**	12,265	13,018
Property, plant and equipment	11,095	12,041	**Net assets**	35,014	37,303
Intangible assets	744	1,019	**Shareholder equity**	34,537	36,969
Investment and other assets	9,587	8,357	**Total liabilities and net assets**	47,279	50,322
Total assets	47,279	50,322	**Equity ratio**	73.5%	73.5%

(unit: million yen)

*Accounts payable includes Electronically recorded monetary claims

Total assets increased 3,043 million yen from the end of the previous term to 50,322 million yen due to the increase in current assets.
Total liabilities increased 753 million yen from the end of the previous term to 13,018 million yen, due to the rise in accounts payable, etc.
Net assets increased 2,289 million yen from the end of the previous term to 37,303 million yen, due to the rise in retained earnings, etc.
As a result, equity ratio is the same with the end of the previous term, 73.5%.

◎Cash flow

	FY3/19	FY3/20	Changes
Operating CF	3,318	5,460	+2,142
Investing CF	-4,435	-3,711	+724
Free CF	-1,117	1,749	+2,866
Financing CF	-1,083	-1,220	-137
Cash and cash equivalents	4,448	4,981	+533

(unit: million yen)

The surplus of operating CF expanded due to the increase in net income before taxes and other adjustments, and free CF turned positive.
The cash position increased.

(6) Topics

◎Early development and release of a new coronavirus detection reagent

The company developed a new coronavirus detection reagent that can detect the virus in 35 minutes from the RNA extracted from specimens and released it on March 18. Furthermore, the company obtained a manufacturing and marketing approval from the Ministry of Health, Labor and Welfare and launched the "Loopamp 2019-nCoV Testing Reagent Kit," an in vitro diagnostic, on April 10. With existing reagents, it is possible to extract RNA in 10 minutes. By the end of April, about 80,000 tests had been shipped to hospitals, quarantine stations, local health laboratories, health centers, and private testing companies nationwide.
The company will expand the supply to 200,000 tests from May onward.

3.Fiscal Year March 2021 Earnings Estimates

(1) Consolidated Earnings Forecast

The company expects a severe business environment due to the impact of the COVID19.
While the clinical reagent business could also be greatly affected, the company has not yet determined the earnings estimate for the FY 2021 for now since it is difficult to predict when the pandemic will subside at the moment and reasonably estimate the impact on the company's performance.

(2) Intensive Measures

This company continue to work on the 4 intensive measures set in the new "Medium-Term Management Plan" (FY 3/2020 – FY 3/2022)

Intensive Measure	Outline
(1) Establishment of a foundation for increasing management efficiency	○Integrating mission-critical systems The company has moved into the production system installation phase and planned to install it in FY 2022. ○Reform of organizational function and structure The company will prepare a plan for organizational and personnel system reforms and promote a healthy company for the achievement of ROADMAP2019. ○Strengthening and consolidation of production and distribution bases The company will make a detailed plan for the new research building.
(2) Promoting global business development	○Spread of colon cancer screening In the United States, we will work to acquire new patients who have received changes to the ACS guidelines and lowered the age of the target. In Europe, the company will make continuous efforts to win government screening transactions in

	addition to improving the consultation rate in the existing adopting countries. The company aims to acquire new markets in the Middle East, Russia, Eastern Europe, and South America. ○The company will carry out a field study for the spread of gastric cancer risk stratification test (ABC classification). ○Expansion of sales in the field of urine qualitative testing Promote collaboration with Sysmex. ○Accelerated development of tuberculosis and malaria testing, etc. The company will realize the price ($6) recommended by the WHO in TB-LAMP and promote global fund application.
(3) Maintenance of domestic sales and increase of market shares	○Contribution to medicine through the establishment of a supply system for the new coronavirus detection reagents. The company plans to supply around 200,000 tests/month from May to June 2020. ○Expansion of product line-up The company aims to expand the market through activities to promote colon cancer screening. Also aims to build a market for early screening of kidney disease and screening for school children. Spread of fecal immunochemical test reagents, especially gastric cancer risk stratification test(ABC classification) ○Market development after the launch of Simprova (sales promotion of respiratory organ infections panel, the launch of acid-fast bacterium disease panel, etc.)
(4) Strengthening of research and development	○Development of a new panel for Simprova Increasing the number of items is recognized as an essential issue (respiratory organ virus panel and imported infectious disease panel) ○Development of a new biomarker through open innovation The company focuses on the search for new biomarkers (cancer, cardiovascular disease, etc.) and new technologies. ○Development of a new POCT platform for the primary care area, etc.

4. Conclusions

The impact of the COVID19 has been both positive and negative, with an increase in the supply of test kits and a significant decline in the number of tests, mainly fecal immunochemical test, in Japan and overseas. It is difficult to predict the extent of the decline in the number of tests and the timing of the recovery at this point in time, which is the main reason why the earnings forecast for the current term has not been made.
On the other hand, “Simprova,” which has been developed completely, is expected to create an unprecedented “testing platform” centered on infectious disease and trigger a post-pandemic paradigm shift in the world “after coronavirus,” which may provide an opportunity to further accelerate the company’s global expansion. We would like to pay close attention to it.

<Reference1 : EIKEN ROAD MAP 2019 and the New Medium-Term Management Plan>

(1) EIKEN ROAD MAP 2019

The company is projecting a target in 10-year intervals and constructing and promoting a basic strategy to achieve that target. For that, the company newly formulated "EIKEN ROAD MAP 2019" that will start this term in order to continue growing and speed up and expand business.
The grand vision of "EIKEN ROAD MAP 2019" is the "Saving Your Health: Continuing to protect your health as a global clinical test agent manufacturer" in FY 3/2029, which is the 90th anniversary of foundation.

Aiming to achieve the vision, the company formulated the following 3 basic strategies.

Basic Strategy	Outline
(1) Basic Strategy 1: To enhance growth and profits	① Promoting global operation ② Maintenance of domestic sales and increase of market shares ③ Increasing profits
(2) Basic strategy 2: Creation of a new Business	① Strategic partnership through open innovation ②Creation and advancement of new businesses and new markets
(3) Basic strategy 3: Development of a Foundation	① Increase in productivity through IoT and AI ② Nurturing and procurement of personnel and structural reform ③ Development of sales networks and strengthening of marketing

Under "EIKEN ROAD MAP 2019," the company will divide a 10-year period into 3 stages and set a theme in each stage.

Period	Theme
FY 3/2020 – FY 3/2022	Structural Reform Period: Firmly forging a foundation
FY 3/2023 – FY 3/2025	Brand Value Improvement Period: Nurturing brand value that can circulate globally through a strong system
FY 3/2026 – FY 3/2029	Sustainable Growth Period: Firm growth based on the newly created value

(2) The New "Medium-Term Management Plan" (FY 3/2020 – FY 3/2022)

The company formulated a medium-term management plan that would become the first stage of the "EIKEN ROAD MAP 2019."
Recognizing it as the Structural Reform Period, the company develops the corporate structure to become a global enterprise "EIKEN", contribute to the world through healthcare, and aims for continuous growth and an increase in profitability.

① Intensive Measures

The company set the following 4 intensive measures under "Structural Reform Period: Firmly Forging a Foundation"

Intensive Measure	Outline
(1) Establishment of a foundation for increasing management efficiency	* Offering high value-added services by integrating mission-critical systems and applying IT to quality systems and the operation services department. Continuing IT application in the entire company. * A simple and flat reform of organizational function and structure in order to promote global business development * An increase in efficiency by strengthening and consolidation of production and distribution bases. Currently planning for an expansion of Nogi Office.

(2) Promoting global business development	* Promotion of colorectal cancer screening, the winning of government screening transactions, and cultivation of the markets of emerging nations * Spread of fecal immunochemical test reagents, especially gastric cancer risk stratification test(ABC classification) * Expanding sales in the urine qualitative examination field by forming a marketing tie-up with Sysmex Corporation * Speeding up the business of tests for tuberculosis complex and malaria using the LAMP method. Promoting the application of the Cameroon-Philippines model in mainly Africa and Asia
(3) Maintenance of domestic sales and increase of market shares	* Steady growth due to expansion of the company's product lineup. Focusing on construction of a market for screening of early stage kidney diseases and medical checkups of school children. * Promotion of reagents for colorectal cancer tests and the ABC classification (evaluating the health of the stomach), and establishment of a screening for cancer in digestive organs. * Marketing for a compact, fully automated genetic testing device (Simprova)
(4) Strengthening of research and development	* Development of a new panel for a small-sized automatic genetic test system (Simprova) * Development of a new biomarker through open innovation * Development of a new POCT platform for the primary care area, etc.

② R&D・Capitala Investment

It was disclosed at the time of formulating the medium-term management plan but is undecided at the moment under the current environment.

The basic policy is to make aggressive investments to build a solid foundation.

The main themes in research and development are "Brushing up of core technology and evolution to new technology," "Promoting development of new reagents and technology and antibody production technology," "Enrichment of the multiple item chip lineup under Simprova" and "Development of a later model of the fecal occult blood analysis measuring device."

As for capital investment, the company will be focusing on "Integration of mission-critical systems: application of IT in quality systems and the operation services department," "New manufacturing system," "Reconstruction of Nogi Office including adjoining areas" and "Manufacturing system of Simprova."

③ Performance Targets

It was disclosed at the time of formulating the medium-term management plan but is undecided now under the current environment.

④Shareholder Returns

The company will continue to aim for a stable dividend with a payout ratio of more than 30%.

<Reference 2: Regarding Corporate Governance>

◎ Organization type, and the composition of directors and auditors

Organization Type	Company with a nominating committee and others
Directors	9, including 6 outside ones
Nominating Committee	3, including 2 outside ones
Compensation Committee	3, including 2 outside ones
Audit Committee	3, including 3 outside ones

◎ Corporate Governance Report
Last updated: submitted on June 26, 2019

<Basic Policy>
Our policy for corporate governance is based on our management philosophy, management vision, and motto.

*Management philosophy
We protect the health of people through healthcare services.

*Management vision
In order to protect the health of people, EIKEN Group offers reliable products and services as a pioneer in checkups, to improve its corporate value.

*Motto
"EIKEN" winning trust with quality and growing with technology

To improve our corporate value by enhancing the soundness, speed, and transparency of our business administration, we are enriching our corporate governance while emphasizing the viewpoint of shareholders and recognizing it as an important managerial mission.
Our company has adopted a corporate structure that has a nominating committee, separating the business execution function and the supervisory function of the management. Important items regarding the basic policy for business administration are determined through the deliberation of the board of directors, and business execution is conducted swiftly and smoothly under the appropriate chain of command, in accordance with our in-company regulations and rules.

<Reasons for Non-compliance with the Principles of the Corporate Governance Code (Excerpts)>
The company has implemented every principle detailed in the Corporate Governance Code.

<Disclosure Based on the Principles of the Corporate Governance Code (Excerpts)>

Principles	Disclosure content
[Principle 1-3 Objective of Capital Policy]	Our company has designated improving capital efficiency and continuous and stable returns to shareholders as the objective for our capital policy in order to maintain and boost shareholder value. As a concrete index, we will aim to achieve ROE of 10% in FY March 2020, which is the final fiscal year in the Medium-Term Management Plan. In addition, in terms of returns to shareholders, we have set a goal of continuing to have a consolidated payout ratio of 30% or more after taking into the account the extension of the necessary internal reserves for improving the financial structure and actively expanding business. When we implement a capital policy that brings about changes in authority and large-scale dilution (including increase in capital and MBO), we will adequately consider the necessity and rationality of it at the board of directors meeting and ensure that the proper procedures take place. Moreover, we will strive to thoroughly brief shareholders and investors.
[Principle 1-4 So-called Strategically Held Shares]	1. Objective Regarding Policy to Strategically Held Listing Shares Our company has set up the basic policy of holding shares of business partners so long as it is within the scope of rationality for ensuring smooth operations, maintaining relationships in transactions, and upholding business and capital alliances and of continuing to hold it so

	long as these strategically held shares are deemed to contribute towards the development of our company's business. To verify the significance of the holding, the board of directors holds a discussion every year on whether the return (comprehensive judgments are made on strategical importance, business relationships, etc., in addition to quantitative factors such as dividends and trading conditions) and risks are commensurate with the company's cost of capital. The company sells shares that are considered to be of little significance to hold, by considering share price trends, etc. Concerning the listed shares, the board of directors decided on a policy to sell one stock and continue holding ten stocks during the FY 2018 after conducting a review at its meeting on April 27, 2018. 2. Standard on Exercising Voting Right of Strategically Held Shares Our company exercise voting rights of strategically held shares by comprehensively considering the circumstances of maintaining the Corporate Governance of the firm, whether a bill will contribute to improve the shareholders' value, and how it will affect our company.
[Supplementary Principle 4-11-3 Evaluation of Effectiveness of the Board of Directors and Disclosure of Results]	Our company analyzed and evaluated the effectiveness of the board of directors in 2018, and will disclose an outline of the results. 1. Goal of the analyzation and evaluation To objectively check whether the board of directors is functioning adequately and operating effectively as well as to make improvements to issues presented, as necessary. 2. Target and Method A free description questionnaire with their name applied to all directors was used. 3. Questionnaire Items (1) Formation of Board of Directors; (2) Administration of Board of Directors (3) State of Observation and Supervision of Board of Directors 4. Summary of Results of Analysis and Evaluation We have taken into consideration the following points and have ensured that the board of directors is functioning adequately and is sufficiently effective. (1) The current number of directors comprises a suitable ratio of internal and external members, and possesses a perfect balance of experience, knowledge and diversity. (2) Active and smooth discussions take place with all the directors, including outside directors, actively stating their opinions from their respective viewpoints. Meanwhile, we have resolved the following actions regarding issues that were brought up. (1) In response to the previous year's questionnaire results, we are working to enhance the functions of the board of directors by adding one person with experience of corporate management and a female lawyer to the board of directors to ensure the diversity of knowledge and experience that cannot be gained by in-house directors alone. (2) Strive to further improve the administration of the board of directors by creating reference material and delivering briefings with more concise points and continuing to send updates on the progress of the important items regularly to increase the effectiveness of debates.

[Principle 5-1 Objective Regarding Constructive Dialogue with Shareholders]	Our company has formulated an IR policy approved by the board of directors and has released details about fundamental objectives, disclosed information, disclosure methods, and a quiet period, and has conversed with shareholders within a reasonable range to contribute to sustainable growth and increasing the mid- to long-term value of the company. Our company has designated the public affairs division to be responsible for IR and set up an IR framework which has the executive manager of general management in charge of the public affairs division as the executive officer of IR, and has established a place to engage in dialogue with shareholders and investors to gain their understanding and trust. The executive manager of general management also has control over posts that are relevant to the IR such as general affairs department, accounting department, and Dept. of Human Resources and General Affairs and links the departments together by closely sharing information between them. Regarding dialogue with shareholders, financial results briefing is conducted twice a year, namely the summary of financial results briefing for full-term and second quarter, for analysts and institutional investors, and involves a conference held in which the representative director and president will brief and interact with. The public affairs division engage in dialogue with shareholders and investors individually. Within the scope of rationality, management executives or directors will meet up with shareholders and investors themselves depending on their requests or the number of shares they hold. If deemed necessary, the executive responsible for IR will report the idea, understood from conversations with the shareholder or investor, to the board of directors. Our company has been interacting with shareholders and investors based on the IR policy and adequately operating based on internal corporate regulations formulated while taking into consideration the prescribed laws as well as sufficiently ensuring that no insider information has been included.