

Business Results for the Fiscal Year Ended March 31, 2020

April. 28th, 2020

EIKEN CHEMICAL CO., LTD.

(Code : 4549)



EIKEN CHEMICAL CO., LTD.

■ Topics

■ Early development and sale of reagent for detection of SARS-CoV-2*

- ◇ Detection of SARS-CoV-2 in 35 minutes using RNA extracted from specimen.
RNA extraction can be done in 10 minutes using the Company's existing reagent.
- ◇ Approx. 80,000 tests were shipped to hospitals, quarantine stations, local health institutes, public health center, private inspection companies, etc., throughout Japan. (until the end of April 2020)

Background from development to sale of IVD medical supplies.

Feb. 14 News release regarding the development of reagent for detection of SARS-CoV-2.

Mar. 18 Release of research reagent for detection of SARS-CoV-2; insurance coverage received on same day.

Mar. 19 Application for manufacturing and sales approval.

Mar. 31 Acquisition of manufacturing and sales approval; insurance coverage received on same day.

Apr. 10 Release of the IVD “Loopamp® SARS-CoV-2 Detection Kit”.

The development of this product was conducted as part of the “Research on development of diagnostic tests for the novel coronavirus disease (COVID-19)” by the Japan Agency for Medical Research and Development (AMED), in which the Company participates.



“Loopamp® SARS-CoV-2 Detection Kit”

* SARS-CoV-2 is the causative virus of COVID19.

■ Topics

- Finished development of the compact fully automated genetic testing system “Simprova”; released in April 2020
- ◇ Notification for manufacturing and sale of medical equipment: fully automated nucleic acid diagnostic system “Simprova” . (September 2019)
- ◇ Acquisition of manufacturing and sales approval: Simprova respiratory infection disease panel. (February 2020), Simprova mycobacterial panel. (March 2020)
- ◇ Release of fully automated nucleic acid diagnostic system “Simprova”, in vitro diagnostic medical supplies “Simprova respiratory infection disease panel BP, LP, MP”, and release of the nucleic acid extraction reagent “Simprova Extraction Kit/S1”. (April 2020)



Fully automated nucleic acid diagnostic system “Simprova”



“Simprova respiratory infection disease panel BP, LP, MP,”



Simprova Extraction Kit/S1

■ Topics

- Decision to continue use in national colorectal cancer screening tests in France. (January 2020)
- Initiatives for adoption of the LAMP tuberculosis detection at The Seventh Tokyo International Conference on African Development (TICAD7). (August 2019)
 - Announced the Company's activity policies at the side event GGG+ Forum.
 - Agreed to promote the spread of TB-LAMP at the MOU signing ceremony with Zambia and Cameroon.



GGG+forum



MOU Ceremony

■ Consolidated financial highlights

(Million of yen)

	FY ended Mar.31,2019		FY ended Mar.31,2020		YOY ratio	Achieving budget ratio*
	Results	Constituent ratio	Results	Constituent ratio		
Net sales	35,761	100.0%	36,585	100.0%	102.3%	99.4%
(Overseas sales)	6,070	17.0%	7,040	19.2%	116.0%	95.1%
Operating profit	4,611	12.9%	4,622	12.6%	100.2%	106.3%
Ordinary profit	4,681	13.1%	4,723	12.9%	100.9%	106.1%
Profit attributable to owners of parent	3,447	9.6%	3,538	9.7%	102.6%	104.1%

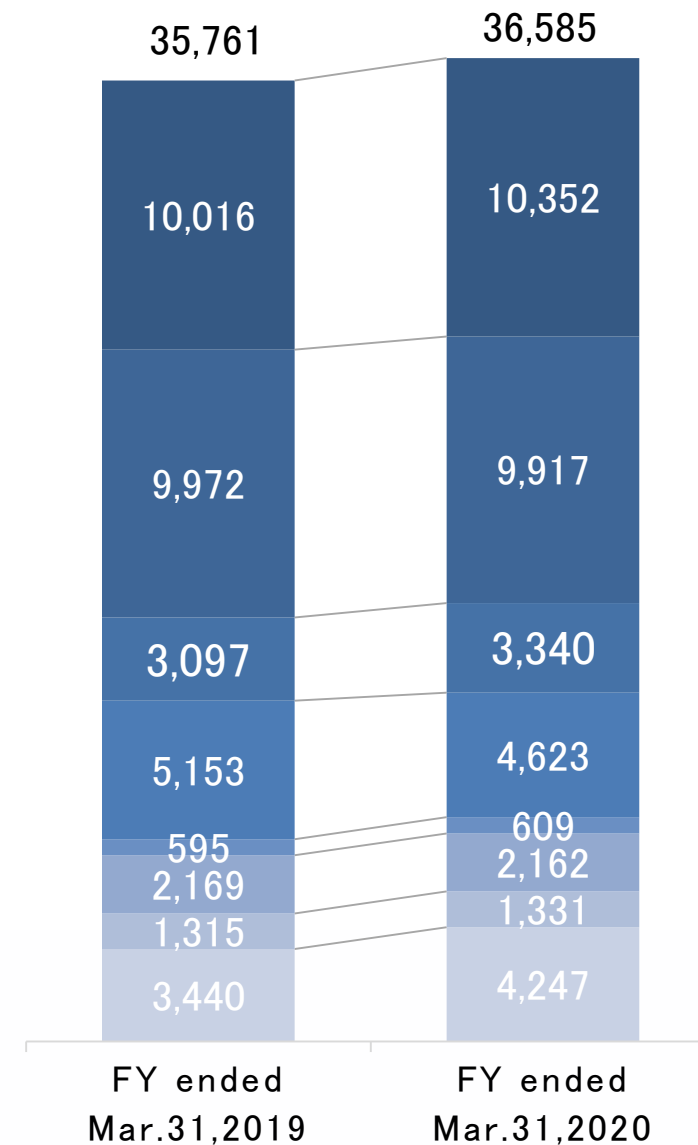
- Sales increased mainly in overseas urinalysis test strips/analyzers and fecal immunochemical test reagent.
- In terms of income, although selling, general and administrative expenses increased mainly due to research and development costs, operating income increased slightly year-on-year due to an increase in income associated with increased revenue.

* Revised budget (The forecast of results was revised on January 28, 2020)

■ Sales by Segment –Consolidated–

Sales are favorable for fecal immunochemical test reagents and urinalysis test strips. Sales of medical equipment increased significantly, mainly in analyzers for urine tests for overseas.

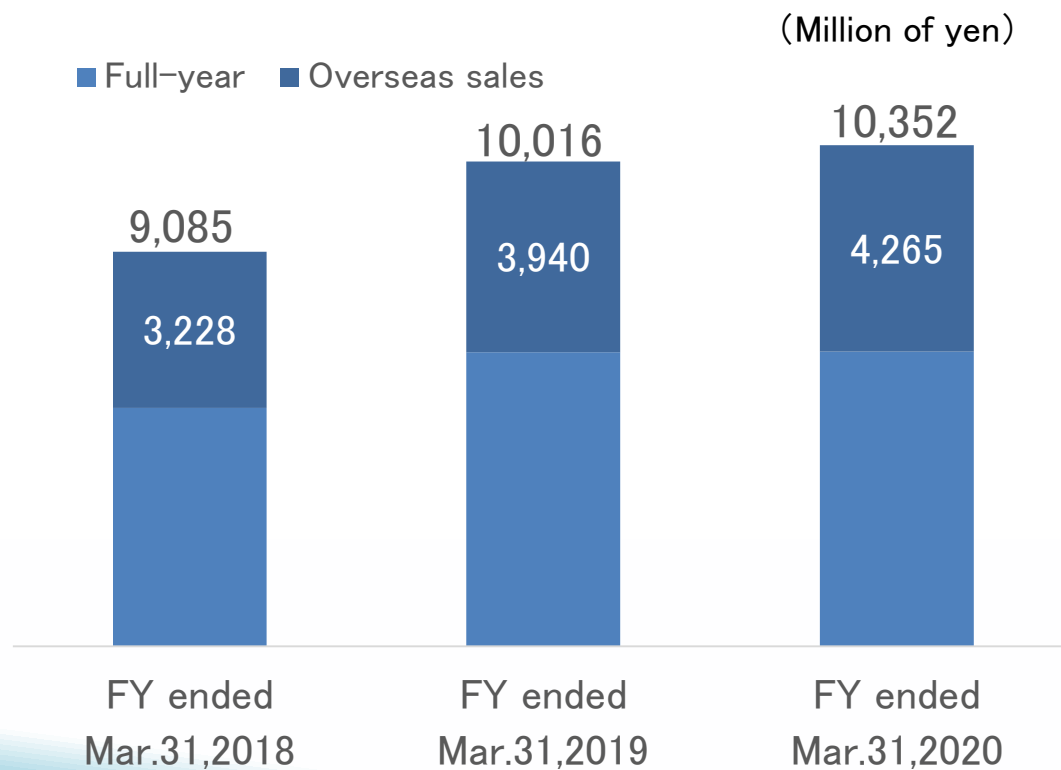
	(Million of yen)		
	FY ended Mar.31,2019	FY ended Mar.31,2020	YoY ratio
FIT reagents (OC)	10,016	10,352	103.4%
Immunological and serological reagents	9,972	9,917	99.4%
Urinalysis test strips	3,097	3,340	107.8%
Microbiological reagents	5,153	4,623	89.7%
Clinical chemistry reagents	595	609	102.4%
Food and environment category, equipments	2,169	2,162	99.7%
Molecular genetics(LAMP)	1,315	1,331	101.3%
Medical devices/Others	3,440	4,247	123.4%
Total	35,761	36,585	102.3%



■ Sales by Segment — FIT reagents (OC)

Sales increased both domestically and overseas

- Domestic: Promote switching from competitor's products to the Company's products and hold enlightenment activities to increase the rate of screenings for colorectal cancer.
- Overseas: Sales are favorable mainly in North America, Asia, and Oceania.



The mainstay of our revenue.
Domestic share is over 60% ※



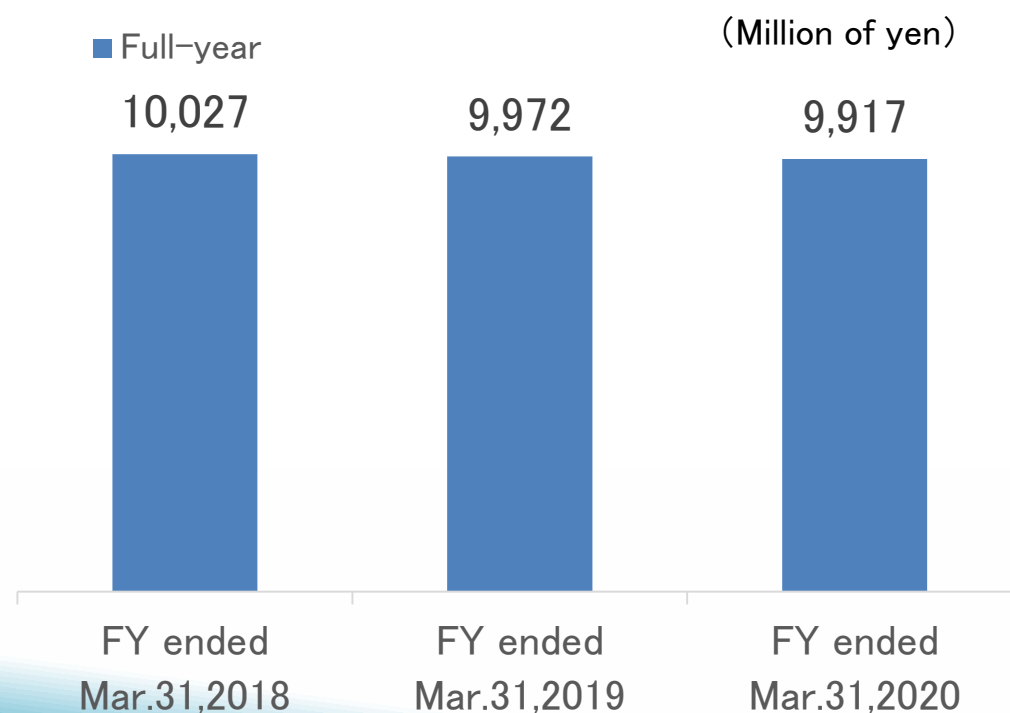
Test reagent (OC) used for colorectal cancer screening. Contributes to early detection of colorectal cancer by it.

※by Fuji-keizai

■ Sales by Segment — Immunological and serological reagents

Sales of latex products increased, but overall sales decreased slightly due to intensifying competition

- AIA-related reagent: Maintained sales of all AIA-related reagents due to new introduction of hemoglobin A1c. Promoted comprehensive proposals with a focus on biochemistry, immunity, and hemoglobin A1c.
- Latex products: Sales increased for LZ reagents (FER, MMP3, etc.) .
- EIA-related reagent: Sales decreased due to intensifying competition.



AIA products (product by Tosoh Co.) and In-house products such as LZ reagent.



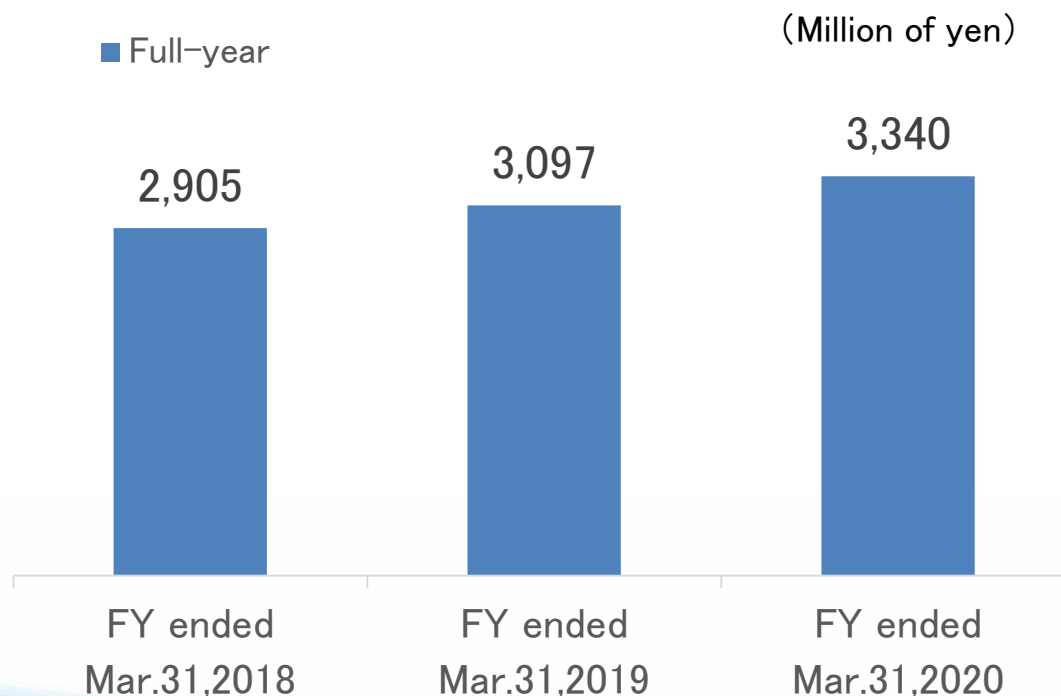
LZ reagent 'EIKEN'

Reagents for various tests used for testing for infectious diseases and rheumatism, hormone measurement, stomach health assessment (ABC classification), etc.

■ Sales by Segment — Urinalysis test strips

Increased sales of urinalysis test strips domestically and overseas

- Domestic: Expanded new adoption by proposing a combination of US-3500 and urinary sediment equipment to medical facilities.
- Overseas: Sales to Sysmex Corporation remained steady.



Overseas sales collaborated with Sysmex Corporation from 2017.



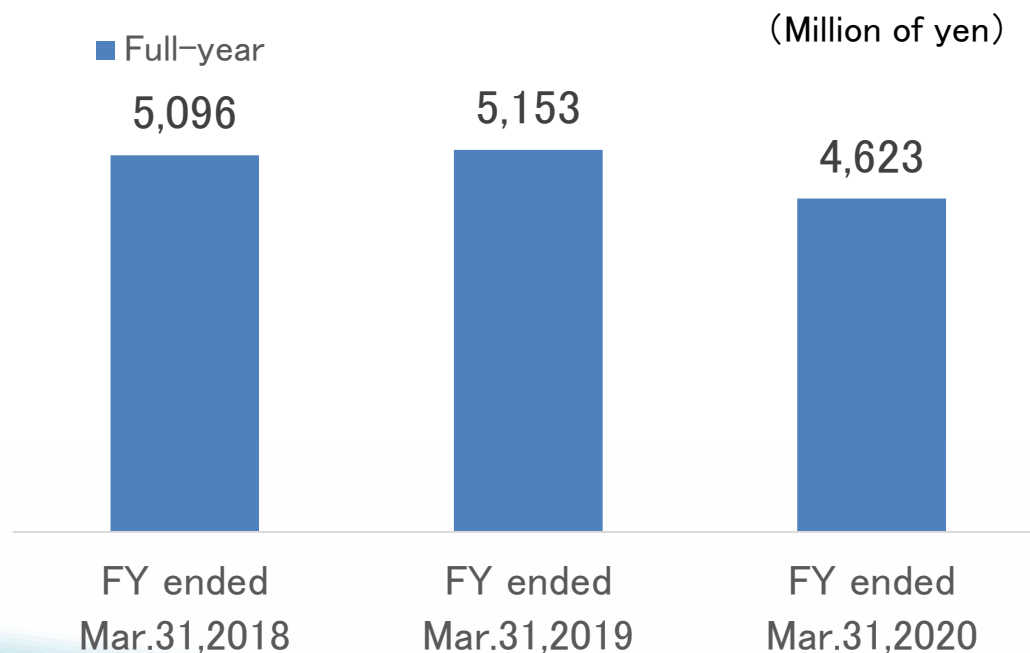
Uro paper αIII 'EIKEN'

Urinalysis test strip "Uropaper" that can test up to 12 items such as urinary occult blood, protein and glucose and various other reagents.

■ Sales by Segment — Microbiological reagents

Sales of culture medium decreased despite growth in bacterial drug sensitivity testing reagents

- Culture medium: Sales decreased due to factors including the termination of sales contracts for blood-culture testing products (introduction and sales).
- Rapid testing: Sales increased of the Immunocatch Series *Streptococcus pneumoniae*/*Legionella pneumophila*.
- Drug sensitivity testing: Sales increased for drug sensitivity testing reagents.
Continue to propose combination with MALDI biotyper.



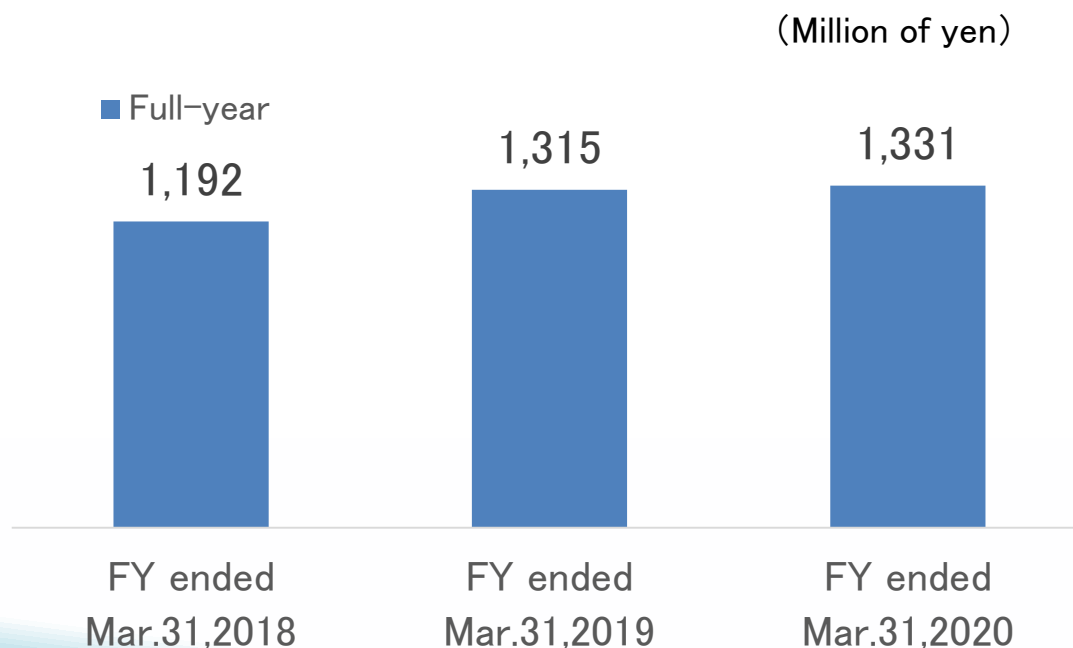
Immunocatch-Pneumococcal / Legionella 'EIKEN'

Reagents for various tests that are useful for diagnosis and treatment of microbial infections, such as culture media, rapid testing, and reagents for drug susceptibility testing.

■ Sales by Segment — Molecular genetics(LAMP)

Sales increased due to strong domestic sales

- Domestic: Sales of *Mycoplasma* and *B. pertussis* detection reagent kits remained strong.
- Overseas: Horizontal deployment of Cameroon and Philippines cases for the purpose of applying for global funds.
- License/patent fee income: 556 million yen. (previous year: 521 million yen)



Loopmp Bordetella
pertussis Detection Kit D



Products in a wide range of fields such as medical care, food and environment using our original technology LAMP. TB-LAMP (Tuberculosis Test) received WHO recommendations in 2016 and is currently being sales for developing countries.

■ Consolidated overseas sales

(Million of yen)

Europe

Sales of fecal immunochemical test reagents increased in the U.K. and Spain, but sales decreased in France (temporarily suspended program) and Italy.

North America

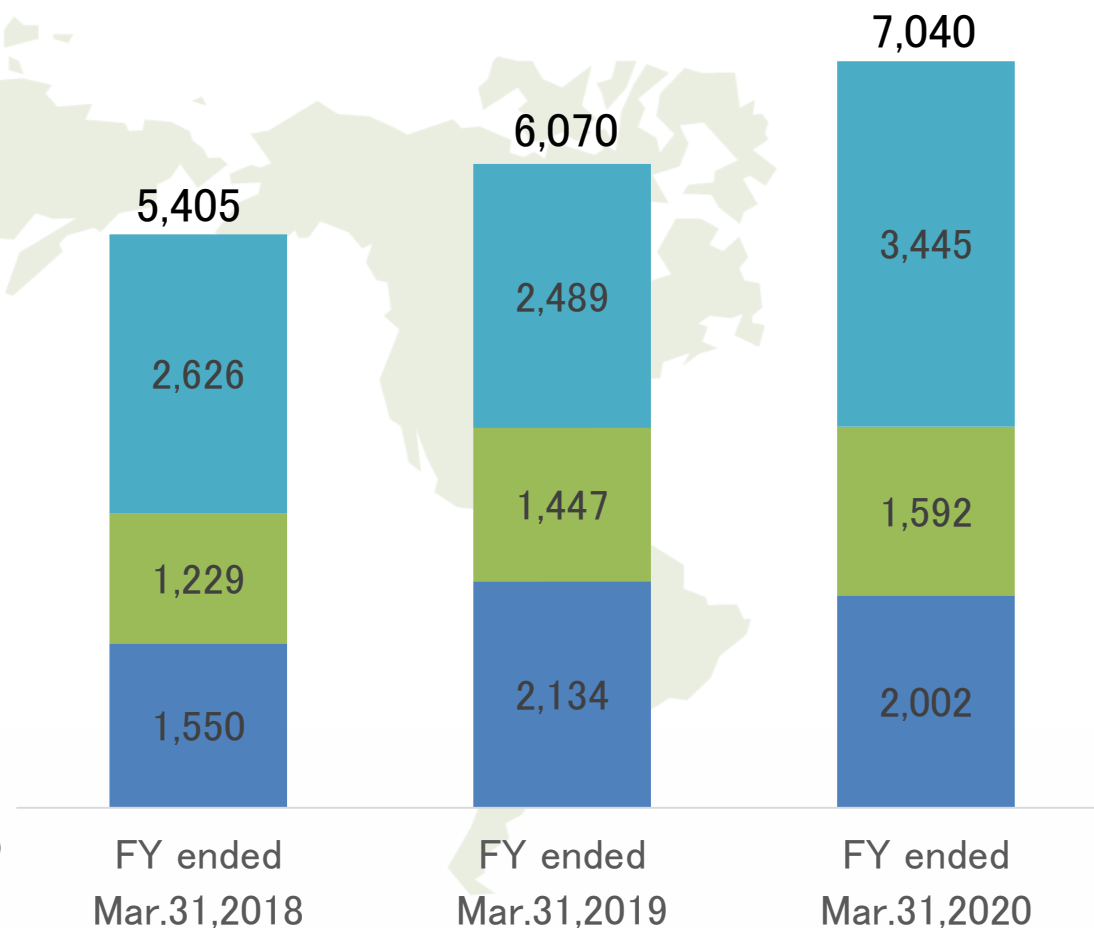
Sales increased to large customers such as LabCorp and Kaiser in the U.S., and sales of fecal immunochemical test reagents increased in Canada.

Asia, Oceania, Other

Sales of urinalysis test strips/analyzers for Sysmex Corporation increased significantly.

Increase in sales of fecal immunochemical test reagents in Oceania, South Korea, etc. .

■ Europa ■ North America ■ Asia,Oseania, etc.



※All sales of reagents and equipment for urinalysis overseas (to Sysmex Corporation) are included in this region.



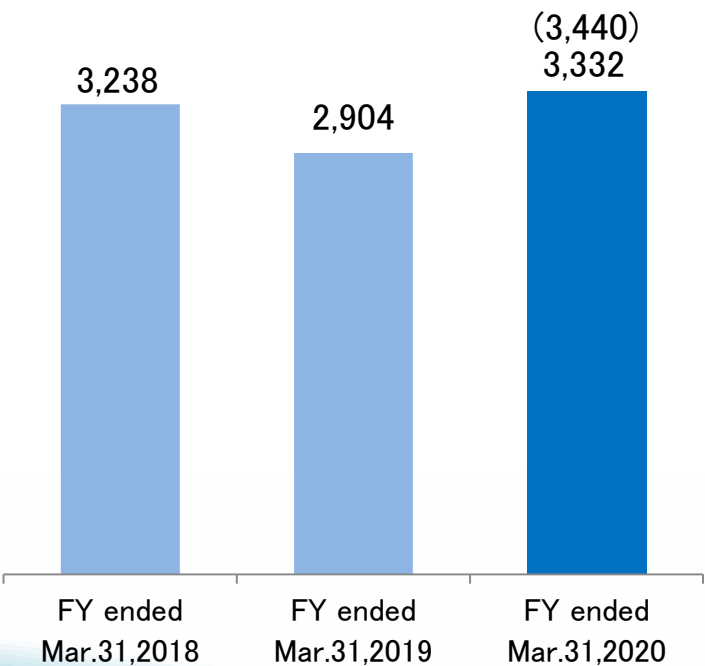
EIKEN CHEMICAL CO.,LTD.

Trends in R&D expenses and Capital investment

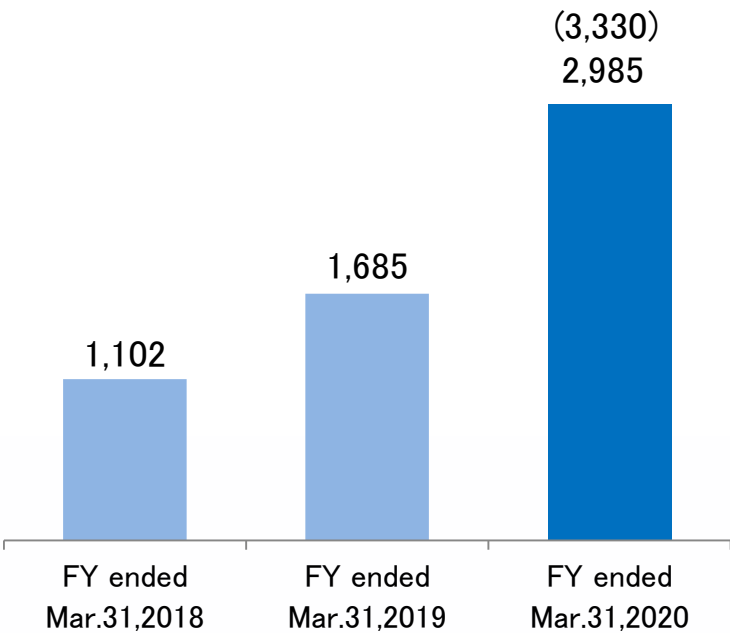
(): forecast of beginning of term

(Millions of yen)

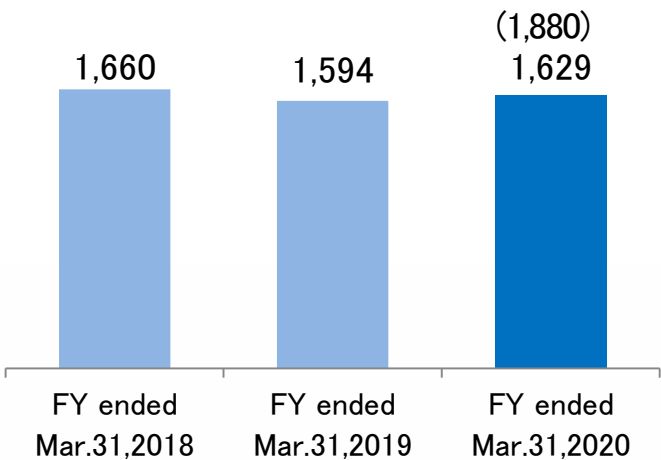
R&D expenses



Capital investment



Depreciation



■ Consolidated Balance Sheets –highlight–

	FY 2019	FY 2020	Changes
	As of March 31, 2019	As of March 31, 2020	
Current assets	25,852	28,903	3,051
Cash and deposits	7,554	10,098	2,543
Other	11,095	12,041	946
Non-current assets	744	1,019	275
Intangible assets	9,587	8,357	(1,230)
investment securities	555	3,487	2,932
long-term time deposits	5,900	1,900	(4,000)
Total assets	47,279	50,322	3,042

(Million of yen)

	FY 2019	FY 2020	Changes
	As of March 31, 2019	As of March 31, 2020	
Current liabilities	10,981	11,740	758
Non-current liabilities	1,284	1,278	(5)
Total net assets	35,014	37,303	2,289
Total liabilities and net assets	47,279	50,322	3,042
Equity ratio	73.5%	73.5%	

Main reasons for increases/decreases

Increase in property, plant and equipment: Purchase of land adjacent to Nogi Division.

Increase in investment securities and decrease in long-term time deposits: Acquisition of investment securities for efficient fund management.



■ Consolidated Statements of Cash Flows

(Million of yen)

	FY ended Mar.31,2019	FY ended Mar.31,2020
Cash and cash equivalents at beginning of the period	6,651	4,448
Net cash provided by (used in) operating activities	3,318	5,460
Net cash provided by (used in) investing activities	(4,435)	(3,711)
Net cash provided by (used in) financing activities	(1,083)	(1,220)
Effect of exchange rate changes on cash and cash equivalents	(2,202)	532
Cash and cash equivalents at end of the period	4,448	4,981

Main items in operating cash flows	Changes
Income before income taxes and minority interests	4,724
Depreciation and amortization	1,627
Income taxes paid	(1,280)

Main items in investing cash flows	Changes
Purchase of property, plant and equipment	(2,307)
Purchase of investment securities	(3,021)
Net increase in time deposits	1,973

Main items in financing cash flows	Changes
Cash dividends paid	(1,106)

Return to shareholders policy

Positioning returning profits to shareholders as one of the most important tasks of management and continuing stable dividend policy taking into account profit distribution according to performance and enhancement of retained earnings. Specifically, based on the above-mentioned policy, the Company will endeavor to maintain dividends with a goal of 30% or higher for its consolidated dividend payout ratio.

annual dividend per share : 30 yen per share

(Interim 13yen, Term-end 17yen)

Consolidated total dividends: 1,106 Million of yen

Dividend payout ratio: 31.3%



Primary strategies and Forecasts for the FY ending Mar.31, 2021



■ Primary strategies for the FY ending Mar.31, 2021

1. Developing foundations to increase management efficiency

○ Integration of core systems

Production system introduction phase: Scheduled to be introduced in the year ending March 2022.

○ Reform of organization function/structure

Creation of personnel systems/organizational reform proposals to achieve ROAD MAP 2019 targets, promotion of health management.

○ Strengthening and consolidation of production and distribution bases

Creation of detailed plan for concept of new research building.

2. Promoting global expansion

○ Spread of colorectal cancer screening tests

- U.S.: Focus on acquiring new customers by introducing OC-io (UL) in the U.S. market.

Efforts to acquire new examinees who have been subject to changes in ACS guidelines (reduced target age).

- Europe: Continue efforts to improve consultation rates in countries which already use colorectal cancer screening test and obtain national screening.

- Acquisition of new markets: Middle East, Russia, Eastern Europe, South America.

○ Conducting field studies aimed at expanding the spread of stratified gastric cancer risk assessment (ABC classification)

○ Expand sales in the field of qualitative urinary testing (promote collaboration with Sysmex Corporation)

○ Accelerate development of tuberculosis and malaria tests

Realization of TB-LAMP: Achieve the WHO recommended price (\$6) and promote global fund application.



■ Primary strategies for the FY ending Mar.31, 2021

3. Maintaining domestic sales and increasing market share

- **Contribute to medical care by improving the supply system of reagent for detection of COVID-19**
⇒ Plan to supply about 200,000 tests per month from May to June 2020.
- **Expand lineup of in-house products**
 - Expand the market through activities to promote colorectal cancer screenings.
 - Construct a market for early screenings for kidney disease and for screening of school children.
 - Promote the spread of stratified gastric cancer risk assessments (ABC classification).
- **Develop market after launch of Simprova**
(promote sales of respiratory infection disease panel, launch of mycobacterial panels, etc.)

4. Improving research and development ability

- **Promote development of Simprova successor panels** (respiratory virus panel, imported infectious disease panel)
- **Develop new biomarkers through open innovation**
 - Search for new biomarkers (cancer, cardiovascular disease, etc.) and new technologies.
- **Develop a new POCT platform targeting primary care fields**



■ Forecasts of consolidated performance for the FY ending Mar.31, 2021

Regarding future economic prospects in Japan and overseas in the next fiscal year, even tougher conditions are forecasted due to the impact of COVID-19 and it is necessary to exercise caution toward the risk of an even more severe economic downturn. Within this business environment, there is the possibility of significant impact on the clinical diagnostics business of the Group. However, at the current time, it is difficult to forecast when COVID-19 will end; consequently, we have decided that the impact on business cannot be rationally calculated. Therefore, we will refrain from announcing a business forecast for the next fiscal year at the current time. We will immediately disclose a forecast once rational calculation has become possible.

We will continually strive to contribute to countermeasures against COVID-19 by developing systems for the stable supply of reagent for detection of SARS-CoV-2.



Saving Your Health

Continuing to protect people's health as a global clinical diagnostics company

Forward-Looking Statements

This material contains forward-looking statements about EIKEN CHEMICAL CO., LTD. (EIKEN). These forward-looking statements are based on the current judgments and assumptions of EIKEN in light of the information currently available to it.

Uncertainties inherent in such judgments and assumptions, the future course of our business operations and changes in operating environments both in Japan and overseas may cause our actual results, performance, achievements, or financial position to be materially different from any future results, performance, achievements or financial position either expressed or implied within these forward-looking statements.



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