

## Our Management Philosophy

### Protect the health of the public through health care services.

Based on this management philosophy, we contribute to society through the provision of products and services that protect the health and lives of people around the world.

## Our 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.**

## Our Motto

**We EIKEN provide trustworthy quality, and develop with technology.**



## EIKEN WAY



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### Editorial Policy

The Eiken Group has prepared the Integrated Report as a tool for communicating with stakeholders.

During the course of editing this Report, the editors referred to documents such as the IIRC's "International Integrated Reporting Framework" and the Ministry of Economy, Trade and Industry's "Guidance for Collaborative Value Creation." It is hoped that it will facilitate understanding of what kind of value Eiken Chemical has provided in the past, and what kind of value it seeks to provide in the future.

### Disclaimer Regarding Forward-Looking Statements

Forward-looking statements, etc. contained in this Report represent the judgments of the Company based on information available at the time it was published, and actual performance going forward may differ from forecasts for a variety of reasons.

### Period of the Report

FY2023 (April 1, 2023-March 31, 2024)

\*Includes reports on some events occurring on or after April 1, 2024

### Scope of the Report

EIKEN CHEMICAL CO., LTD. and its Group companies

# At a Glance

The Eiken Group in FY ended Mar. 31, 2024



Net sales

**40,052** million yen

R&D expenses

**3,939** million yen



Net profit

**2,634** million yen

ROE

**5.6%**



Number of employees  
(full-time employees + temporary employees)

**1,101**

Number of  
R&D personnel

**192**



Overseas sales  
as share of total

**25.3%**

Number of countries  
in which products deployed

**53**



CO<sub>2</sub> emissions  
(Scope 1 + 2)

**2,742** t-CO<sub>2</sub>

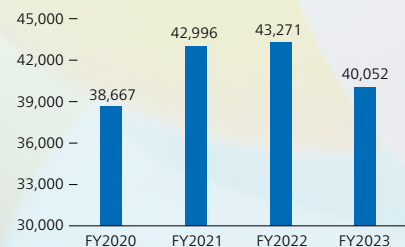
Water volume consumed  
(all production sites)

**68,700** m<sup>3</sup>

## Change in major financial indicators over time

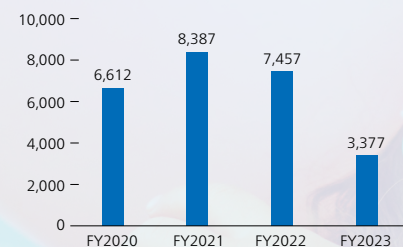
### Net sales

(million yen)



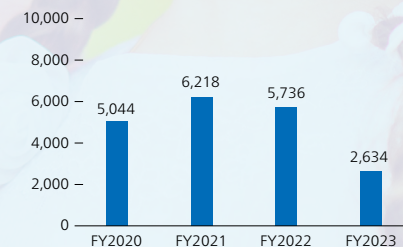
### Operating profit

(million yen)



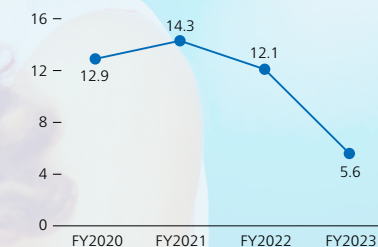
### Net profit

(million yen)



### ROE

(%)





## Message from CEO



**Tsugunori  
Notomi,**  
President & CEO

**As a medical testing pioneer  
we contribute to the health of  
people worldwide, working  
to resolve social issues and  
enhance corporate value**

- 1** Long-term growth curve unchanged despite COVID-19 pandemic
- 2** Encouragement for employees with abundant challenging spirit
- 3** Clarifying the roadmap for growth
- 4** Doing everything we can for our diverse stakeholders

## Message from CEO

### Focus on our roadmap for the future as we complete the building of our foundation

#### 1 Long-term growth curve unchanged despite COVID-19 pandemic

Eiken Chemical is moving steadily forward with initiatives focused on the management framework EIKEN ROAD MAP 2030, which was conceived from a long-term perspective. With the COVID-19 pandemic coming to an end, FY2023 had some challenging aspects in terms of profitability. On the other hand, the Medium-Term Management Plan (MTMP) that Eiken Chemical is currently executing has been designated a period for building the foundation to implement the roadmap, and in this we are moving steadily forward despite significant changes in the business environment.

In Japan, our traditional main products for fecal immunochemical testing and immunological and serological testing have already returned to pre-COVID-19 levels, and the business environment is becoming one in which we can continue to expect steady expansion. In the overseas business there are also products for which we anticipate growth going forward, such as fecal immunochemical testing and urinalysis, and tuberculosis reagents for genetic testing. Our profits were temporarily depressed by such one-off

factors as market trends during the COVID-19 pandemic, but our main businesses remain strong and I do not believe any major changes in policy are required.

The impact on society of the COVID-19 pandemic has also driven some changes in the clinical diagnostics market from which there can be no going back. One example of this is the positioning of the field of genetic testing. Numerous manufacturers entered this testing field during the COVID-19 pandemic. The competition was severe, but right from the development stage we had planned for our genetic testing platform to also be applicable to testing for cancer. At Eiken Chemical, we have hitherto focused our development resources on multi-target testing methods that enable multiple items to be tested at once, and it is likely that techniques to combine multiple test items to obtain accurate diagnoses will become even more widely used going forward. In that sense it gives us confidence that the direction we have taken as a company is the correct one. Elsewhere, we have submitted an application with regulatory authorities for our companion diagnostic system for lung cancer, named MINTs, and we expect approval to be granted in the first half of FY2024. It is important that

the initiatives that we have not yet completed, including MINTs, are brought to fruition as we build the foundations of the future during

FY2024, which is the final year of the current MTMP.

#### Fully-automated fecal occult blood analyzer OC-SENSOR Ceres



#### Fecal immunochemical test reagents



#### Urinalysis test strips for overseas



#### Tuberculosis reagents for genetic testing



## Message from CEO

### Changing workplace environments that discourage challenges By providing employees with a workplace in which it is easy to take on challenges we encourage them to do so

#### 2 Encouragement for employees with abundant challenging spirit

Driven by the bursting of the bubble, the global financial crisis, and repeated disasters of natural and human origin, society has become afraid of emerging risks and is trending towards strengthening regulation. Of course, it is also necessary for corporate managements to seek safety, but I am apprehensive that this will lead to a dwindling of our capability to take on challenges. My perception is that, even among our own employees, we have seen an increase in the number of individuals who are oversensitive to risk and who dislike taking on challenges. Despite originally having this challenging spirit, they have become unable to demonstrate it.

I myself spent many years working as an engineer and researcher, and although I did of course engage with my work during that time with a strong sense of the mission of the organization, a good deal of it was left to my own judgment. Due in part to this experience, I am careful not to put too much pressure on engineers in particular. Sometimes engineers may experience difficulties but it is important that they overcome these through strength

of will.

I believe that among younger people we are increasingly seeing individuals who have the ability to think and to give coherent explanations of what they want to do, as well as possessing the willpower to make it happen. With the external environment becoming increasingly difficult, I see it as my job to give such talented employees a gentle push in the back to ensure that they do not become demotivated by an organization that concerns itself only with responding to regulation and addressing risks, and so disappear from view. Failure is an unavoidable part of taking on challenges. However, it is important that we assess them properly so that they take on challenges without being afraid of failure, take the approach of using any such failures to open the way to success, and take the necessary steps to achieve this.

#### 3 Clarifying the roadmap for growth

Under the roadmap I mentioned earlier, we stated that while focusing on the current business areas as the core operations we will address the three key business fields of contribution to cancer prevention and



treatment, contribution to eradication and control of infectious diseases, and provision of products and services useful for health care. In the field of cancer, we have declared our intention to expand into products and services that are more directly related to treatment, while in the field of infectious diseases we are seeking to establish simpler test technology, and in the field of healthcare we plan to expand products and services that address remote treatment and testing at home. We are proceeding with the MTMP in accordance with this roadmap, and we will be sure to complete the building of the foundations by the end of the three-year period of which FY2024 is the final year.

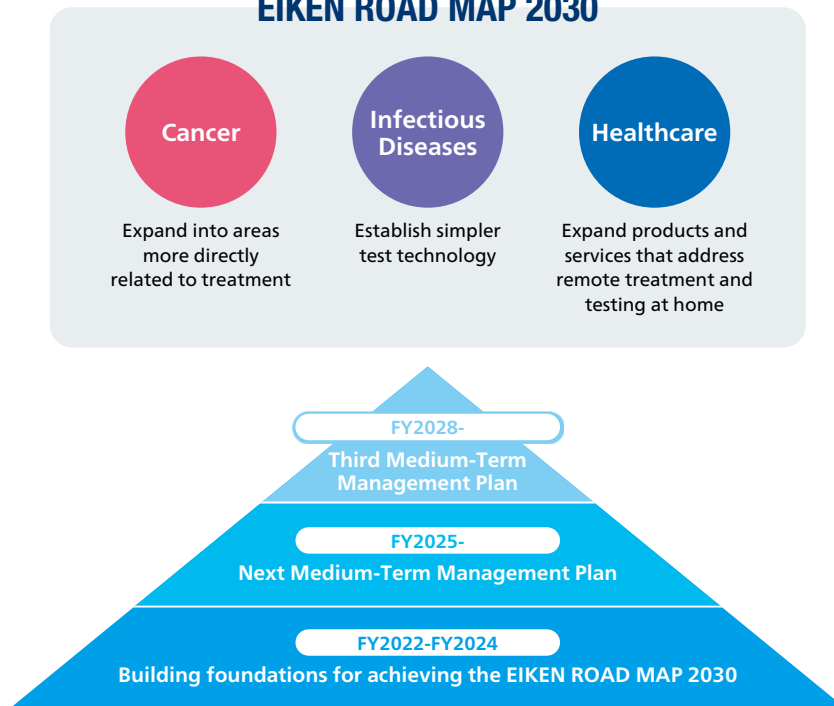
Having engaged in dialogue repeatedly with investors and other stakeholders, I have become aware that we should make this roadmap a little easier to understand. I believe it is important to provide concrete information to address such issues as the approximate scale of the markets in our main business areas, what specifically we are going to promote, which of Eiken Chemical's technologies will result in what kind of products, how they will be commercialized, and how this will lead to profit. By outlining these points in ways that are easier to visualize, we will make the reasonableness of these investments easier for investors to grasp. If we can raise expectations for the

## Message from CEO

future growth of Eiken Chemical by clarifying our use of funds, it will become easier to obtain an appropriate assessment from

the capital markets. In addition to actively returning profits to shareholders, we intend to clarify the Eiken Chemical growth story.

### EIKEN ROAD MAP 2030



## Discussions on the next MTMP have already begun We have started to move forward to the next stage in order to continue to provide value to stakeholders

### 4 Doing everything we can for our diverse stakeholders

With regard to the evolution of the roadmap, we are already engaging in frequent discussions on the Board of Directors and elsewhere within the Company, on the next MTMP, including its preparation. In the next MTMP, one major theme will be using the foundation that we built during the current MTMP as a springboard for action. What is important is whether we are a positive force that creates value for various stakeholders, from a long-term perspective. Based on our philosophy of protecting the health of the public through health care services, and as a medical testing pioneer, we try to be aware at all times, and discuss, what we can do for patients and in what form this benefits stakeholders.

Eiken Chemical's diagnostics can now be delivered even to low- and middle-income countries where medical services have not yet been adequately provided. However, delivery alone will not lead to resolution of the issues. What is most important is that these diagnostics actually reach patients, are used

in volume, and result in people becoming healthy. This applies not only to products for low- and middle-income countries but also to the Company's products and services in general. In order to continue to make such contributions we must be sure to generate profit from our business activities, and we ourselves must continue to grow and develop. With regard to the part of the sustainability management perspective that relates to mitigating environmental impacts in the course of business activities, we have addressed and continue to address this seriously. For example, we have achieved the 2030 target for decarbonization that is one of our KPIs. It is nonetheless distressing to look around the world and note that conflicts in Ukraine, the Middle East, and other regions have resulted in further destruction of the environment.

Eiken Chemical's desire is to continue to be a company that provides value to a diverse range of stakeholders including patients. I invite you to look forward with expectation to the future of Eiken Chemical now that we have completed the building of our management foundations and are moving on to the next stage of our development.



# Eiken Chemical's Value Creation Process

As a medical testing pioneer, since the foundation we have provided products and services that are trusted by our customers. While valuing those things that are possible only because we are a comprehensive manufacturer, we will continue to protect people's health as we prepare for 2030 and the future that lies beyond.

- Contribution to cancer prevention and treatment
- Contribution to eradication and control of infectious diseases
- Provision of products and services useful for health care

Human Capital Strategy

Structural Reform

IT Strategy

Financial Strategy

Governance

## Medium-Term Management Plan

▶ P19

## EIKEN Vision 2030

- Contribution to cancer prevention and treatment
- Contribution to eradication and control of infectious diseases
- Provision of products and services useful for health care
- Business activities in harmony with the global environment
- A vibrant corporation making use of employee's talent

▶ P18

## Materialities

▶ P20

EIKEN WAY

Output

▶ P16

Business Model

Sales Marketing

Comprehensive manufacturer of clinical diagnostics

Research &amp; Development

Manufacturing

Procurement

Inputs

(types of capital)

▶ P16

### Our goals for the future

Build the future of testing for the health of people worldwide and a sustainable society

Redress global disparities in health care

Establish simpler test technology for infectious diseases

Enhanced personal care, such as remote clinical system and at-home self-testing

Improve quality of life by enhancing personal care

Reduce workloads on the medical front line and control medical expenses through enhanced testing

Achieve carbon neutrality

Contributing to health and quality of life for people around the world

Business activities in harmony with the global environment

A vibrant corporation making use of employee's talent

An organizational base that supports sustainable growth



## Value Provided to Stakeholders

# Stakeholder Message

### Graeme P Young AM

Matthew Flinders  
Distinguished Emeritus Professor,  
Flinders University

FTSE FAHMS FGESA AGAF,  
MD FRACP

#### Profile

Graeme Young graduated MB, BS in 1969 from the University of Melbourne. He studied at Washington University, St Louis in 1978-1980 after which he obtained his MD by research thesis in 1981. Following academic appointments at University of Melbourne, in 1997 he was appointed as the foundation Professor of Gastroenterology at Flinders University of South Australia. In 2011 he was appointed Professor of Global Gastrointestinal Health at Flinders University and was honoured with the title Matthew Flinders Distinguished Professor. He is a Fellow of two academies and three professional bodies. He was a founding member of the World Endoscopy Organization's (WEO) Colorectal Cancer Screening Committee in 1998. He chaired this committee in 2005-2013 and remains an active member, leader of major international publications and health policy in the field. During the first 20 years of the committee, the number of countries implementing population-based organised colorectal cancer screening rose from just 2 to more than 40, most of which screen using faecal immunochemical tests for haemoglobin (FIT). He is an internationally recognised expert on colorectal cancer (CRC) screening and biomarkers, screening policy and its implementation. His early work with international colleagues established the key role that FIT would play in establishing CRC screening in many countries. Graeme has published nearly 500 scientific and medical papers, with over 400 colleagues – several hundred of these are international colleagues.

Key awards include: 2017: Winner of the Australian Museum Eureka Prize for Innovation in Medical Research. 2014: Membership of the Order of Australia (AM). 2013: South Australian Scientist of the Year. 2009: Distinguished Research Prize of the Gastroenterological Society of Australia.



## Expectations for Manufacturers of Clinical Laboratory Reagents and Equipment for Detection of Fecal occult Blood

### ■ Global status of colorectal cancer

CRC is a significant cause of cancer-related deaths and thus a major health problem. It is ranked in the top ten diseases for health burden by the World Bank. [\*1]. There is wide geographic variation in CRC incidence[\*2], being higher in developed than developing countries. Incidence is increasing in those with growing affluence [\*3]. It is predicted that by 2040, the number of cases will have risen from 1.850 million now to 3.093 million in 2040 [\*4].

### ■ The effectiveness of FIT

Studies have shown that FIT reduces CRC mortality as well as incidence through detection and removal of early stage cancers or pre-cancerous adenomas [\*5]. The quantitative FIT is now the predominant FOBT screening technology used worldwide [\*6].

FIT have proved superior to guaiac-FOBT in various ways: increased participation rates (single stool sample and simpler collection technique), automated analyzer for objective and



consistent measurement, increased sensitivity for cancer and adenomas, no significant drug or dietary interference and an objective adjustable endpoint that can be tailored to available colonoscopy capacity and expectations of test performance [\*7]. Quantitation of stool hemoglobin (Hb) concentration has provided flexibility for those managing screening programs to choose the criterion value (the threshold or “cut-off” Hb concentration at which a test is reported as positive) that triggers diagnostic verification by colonoscopy [\*5]. This in turn facilitates planning of the health services capacity to manage the resultant colonoscopy workload [\*5].

### ■ What is required of a FIT when screening for colorectal cancer.

It is important that a FIT meets the analytical performance characteristics required for its use. Manufacturers and laboratories must comply with regulatory bodies to ensure that they provide accurate, reliable and reproducible results under a range of conditions applicable to sampling, handling, transport, measurement and reporting of results [\*5].

While post-analytic considerations are the responsibility of those responsible for conducting the screening program, manufacturers can facilitate selection of a test in several ways.

The first is to provide information on how to convert the sample buffer fecal hemoglobin concentration (f-Hb) to a concentration in the stool by correcting for the amount of stool usually collected into the sample device buffer and the dilution effect of the buffer. This would facilitate comparing measurement results between different FIT assay systems [\*8]. Unfortunately, there are no international reference preparations that provide a standard for direct comparison of different FIT tests but this is the first step for harmonization of different assay systems.

Such preparations would also facilitate external quality control programs for laboratories. Manufacturers are therefore encouraged to indicate quantitative results as mcg Hb/g faeces.

The second is that reporting quantified results allows the end-user to choose the f-Hb concentration that serves as the positivity threshold and so determines if the result is positive or negative and requires follow-up colonoscopy. There is now emerging evidence that there is advantage in being able to adjust the positivity threshold according to age and gender as these are determinants of f-Hb in these demographic subpopulations and mean that test utility at a single f-Hb threshold might not be equitable across all subpopulations.

### ■ Conclusions

Manufacturers provide the crucial means for achieving program goals in FIT-based screening. Their tests are relevant, not just for the analytical laboratory aspects but also for key pre-analytic and post-analytic elements of a screening program.

- \*1 Begg SJ et al., Burden of disease and injury in Australia in the new millennium: measuring health loss from diseases, injuries and risk factors. *Med J Aust* 2008;188:36-40.
- \*2 Ferlay J et al., Global Cancer Observatory: Cancer Today. . Lyon, France: International Agency for Research on Cancer, 2018. <https://gco.iarc.fr/today>
- \*3 Ferlay J, Colombet M, F B. Cancer Incidence in Five Continents, CI5plus: IARC Cancer Base No. 9 [Internet]. Lyon, France: International Agency for Research on Cancer, 2018. <http://ci5.iarc.fr/CI5plus/Pages/references.aspx>
- \*4 <http://gco.iarc.fr/tomorrow/home>
- \*5 Bresalier RS et al. Members of the World Endoscopy Colorectal Cancer Screening New Test Evaluation Expert Working Group., An efficient strategy for evaluating new non-invasive screening tests for colorectal cancer: the guiding principles. *Gut*, 2023; 72:1904-1918. Epub ahead of print doi:10.1136/gutjnl-2023-329701
- \*6 Young GP et al., The Global Paradigm Shift in Screening for Colorectal Cancer. *Gastroenterology*. 2019;156: 843-851 e842.
- \*7 Young GP et al., Which fecal occult blood test is best to screen for colorectal cancer? *Nat Clin Pract Gastroenterol Hepatol* 2009;6:140-141.
- \*8 Benton SC et al. Faecal immunochemical tests for haemoglobin: Analytical challenges and potential solutions. *Clin Chim Acta* 2021;517:60



To read the full text of “Expectations for Manufacturers of Clinical Laboratory Reagents and Equipment for Detection of Fecal occult Blood,” please refer to the following.

<https://www.eiken.co.jp/en/ourfields/message.html>

## What is FIT?

✓ Recommended Grade  
A for colorectal cancer  
screening in Japan<sup>\*1</sup>

✓ Low cost

✓ Specificity **96%**

✓ Simplicity

✓ Number of countries  
in which deployed **47** countries

✓ Domestic share **67%**<sup>\*2</sup>

✓ International references for our products **100** or more



## The socioeconomic significance of FIT

Nearly all cases of colorectal cancer are discovered at stage III or stage IV<sup>\*3</sup>. Colorectal cancer is a disease that progresses relatively slowly and, if detected early, a complete recovery can be realistically hoped for. It has been argued that by raising the proportion of sufferers diagnosed at stage I<sup>\*3</sup> from 13% to 50% in Europe, at least 130,000 lives could be saved each year, with a reduction in medical expenses of more than 3.0 billion euro annually<sup>\*4</sup>.

The **fecal immunochemical test (FIT)** provided by Eiken Chemical is simple and inexpensive approach that only requires the surface of the stool to be scratched for a sample to be taken, and results in the discovery of around 30% of colorectal cancer, of which 70% are early stage cancers. Research<sup>\*5</sup> reports that repeated testing reduces the risk of colorectal cancer mortality by 60%, which provides scientific evidence of its effectiveness. For this reason it is rated highly for cost effectiveness, and FIT appears in guidelines for colorectal cancer screening published by various countries<sup>\*6</sup>, and our own products have been adopted for colorectal cancer screening programs in 47 countries around the world.

	2023	2030	Calculation method
Positive value	USD 4.1 billion	USD 5.1 billion	Economic impact of early detection of colorectal cancer using FIT 2023: Number of persons undergoing tests, calculated by the number of stool sampling bottle sold in FY2023 × cancer detection rate × early detection rate × 5-year survival rate × GDP (USD per capita) Reference: OECD data 2030: Estimated market × estimated market share × cancer detection rate × early detection rate × 5-year survival rate × forecast GDP (USD per capita) eference: OECD data
Negative value	USD 600 million	USD 1 billion	Expenses incurred by endoscopies of persons with false positives 2023: Number of persons undergoing tests, calculated by the number of stool sampling bottles sold × positive rate × false positive rate × secondary testing ratio × cost of endoscopy 2030: Estimated market × estimated market share × positive rate × false positive rate × secondary testing ratio × cost of endoscopy *Endoscopy costs are calculated for Japan, the United States, and the EU in yen, dollars, and euro respectively and converted at the exchange rate as of March 31, 2024
Social value	USD 3.5 billion	USD 4.1 billion	Positive value - Negative value

\*1 National Cancer Center Institute for Cancer Control

\*2 FUJII KEIZAI

\*3 There are five stages of colorectal cancer: 0, I, II, III, IV, and V

\*4 COLORECTAL SCREENING IN EUROPE

\*5 Colorectal Cancer Guidelines Based on Effectiveness Assessments (FY2004 Ministry of Health, Labour and Welfare Cancer Grant, "Research on Establishing Appropriate Methods for Cancer Screening and Evaluating Their Effectiveness")

\*6 Guidelines, etc. of various countries <https://www.eiken.co.jp/en/publication/fit/>

## Differences in techniques for colorectal cancer testing

Various tests for colorectal cancer other than FIT exist, such as chemical fecal occult blood tests, DNA stool tests, and endoscopies, but only FIT is recommended for colorectal cancer screening in Japan. Compared to chemical fecal occult blood tests, the immunological method requires no restrictions on food or other requirements before the test, and is reported to be the most-cost effective of all tests when implemented<sup>\*3</sup>. Simplicity and low cost are other features of the test. The weakness of FIT compared to other methods is low sensitivity, but by implementing the two-day method (testing specimens from two days at once) every year, the required level of sensitivity can be achieved.

	Fecal immunochemical test (FIT)	Stool DNA test	Chemical fecal occult blood test
Principle	Detects human hemoglobin in stool	Detects DNA markers and human hemoglobin in stool	Detects peroxidase-like action of heme in red blood cells
Sensitivity <sup>*Refer to P.15</sup>	74% <sup>*1</sup>	93% <sup>*1</sup>	75% <sup>*1</sup>
Specificity <sup>*Refer to P.15</sup>	93-96% <sup>*1</sup> Number of publications: 14, n=34,352	84-86% <sup>*1</sup> Number of publications: 4, n=12,424	96-98% <sup>*1</sup> Number of publications: 2, n=3,503
Test frequency	Every year/every other year	1-3 years	Every year/every other year
Cost	Low cost (USD 18.05) <sup>*2</sup>	High cost (USD 509) <sup>*2</sup>	Low cost (USD 4.38) <sup>*2</sup>
Frequency of unsuitable stool samples	0.6% <sup>*3</sup>	6% <sup>*3</sup>	0.9% <sup>*4</sup>
Guidelines	Coverage in guidelines for various countries around the world Japan: Recommended Grade A	Covered only in the guidelines for the United States	Covered in the guidelines for some countries
Food restrictions before test	No	No	Yes
Number of colorectal cancer deaths averted per 1,000 individuals screened	26 <sup>*1</sup>	25-28 <sup>*1</sup>	24 <sup>*1</sup>
Life-years gained (LYG) per 1,000 individuals screened <sup>*5</sup>	318 <sup>*1</sup>	303-333 <sup>*1</sup>	298 <sup>*1</sup>

## Trend in guidelines

Health projects based on  
Health and Medical  
Service Act for the Aged

**1992**

Incorporated colorectal cancer screening using FIT as a method

European colorectal cancer screening guidelines

**2010**

"Immunological methods (automated) are the best."

USPS-TF  
**2016**

"The OC [name of Eiken Chemical's FIT products] have the best test performance characteristics."

NICE guidelines  
**2017**

Recommended with use of product name

ACS guidelines  
**2018**

Immunological methods for colorectal cancer screening recommended

NCCRT  
**2020**

Improved screening rates through FIT implemented by mail

USPS-TF Final Recommendation  
**2021**

Lowering of age for screening eligibility (50→45)

<sup>\*1</sup> USPSTF (<https://www.uspreventiveservicestaskforce.org/uspstf/document/RecommendationStatementFinal/colorectal-cancer-screening>)

<sup>\*2</sup> CMS.gov <https://bmcgastroenterol.biomedcentral.com/articles/10.1186/s12876-019-1121-y>

<sup>\*3</sup> Current and future colorectal cancer screening strategies Aasma Shaikat et al. Nat Rev Gastroenterol Hepatol. 2022; 19(8): 521–531.

<sup>\*4</sup> Santare et al. Eur J Gastroenterol Hepatol 2015; 27(5):536-43

<sup>\*5</sup> In the case of screening 1,000 people at the age of 45, the remaining life years obtained for those 1,000 people in total



## Value Provided to Stakeholders

# Stakeholder Message

**Dr. Shigeru Omi**

Chairman,  
Japan Anti-Tuberculosis Association

### Profile

Graduated from Jichi Medical University in 1978. For the first nine years after graduation, was engaged in regional healthcare on the seven islands of Izu. Served at the World Health Organization for 20 years, beginning in 1990. In 1999 he was appointed Regional Director of the WHO's Western Pacific Region Office, where he contributed to the eradication of polio and the control of SARS (Severe Acute Respiratory Syndrome) in the region. In 2016, he was appointed to the Global Health Crises Task Force at the request of the United Nations Secretary-General. Following the emergence of COVID-19 in 2019, he was appointed vice-chairman of a specialist committee on infectious disease countermeasures in Japan in 2020, and served as chairman of its infectious disease countermeasures subcommittee from 2020 to 2023. In 2022 he was appointed Chairman of the Japan Anti-Tuberculosis Association. He has devoted himself to working on countermeasures for infectious diseases both in Japan and overseas.



### ■ Tuberculosis: environment and issues

Excluding the three-year period during which the COVID-19 virus ran rampant, tuberculosis has for many years been the single largest cause of death by infectious disease globally. It used to be known as the national disease of Japan, but in recent years the incidence rate has declined and we have become a low-prevalence country. However, it remains an important health problem, even among OECD member countries, where elderly people are at the highest risk of tuberculosis and the proportion of young patients born overseas is on the constant rise. Among elderly people diagnosis is often delayed due to the lack of typical symptoms, resulting in examples of severe cases and transmission to younger generations.

Tuberculosis is still prevalent in developing countries. As was the case in Japan, people in the prime of their working lives die from tuberculosis, which is a serious socioeconomic problem. The issues faced by many developing countries are that they lack medical infrastructure and that there are few engineers specializing in testing, which means that tuberculosis is often discovered late

or overlooked. For as long as tuberculosis is not eradicated in the rest of the world, it will not be eradicated in Japan. Tuberculosis is a permanent pandemic.

### ■ Significance of the LAMP method and the role it fulfills

A target of eradicating tuberculosis globally by 2035\* has been set, but technological innovation will be indispensable for achieving this. The various tests for tuberculosis include culture tests, smear tests, and PCR, but LAMP is a test born of Japanese technology. It gives quick results, and because it does not require complex machinery it can be used anywhere. Because it is easy to perform the test procedure and interpret the results, it can be used by anybody. Technical support provided to the countries of Asia and Africa is also making a major contribution to the detection of tuberculosis patients who have been overlooked. It is a test that could help eradicate tuberculosis globally.

### ■ Expectations for the LAMP method going forward

Naturally it is expected to contribute to the eradication of tuberculosis, but there are also hopes that it will help to control infectious diseases other than tuberculosis, such as malaria and neglected tropical diseases (NTDs). Controlling infectious diseases globally will require the strengthening of healthcare systems and cooperation between industry, academia, government, and the private sector. Those of us alive today have a grave responsibility to determine what sort of world we will leave to the next generation of children. Implementing steadfast countermeasures in all countries against tuberculosis, which is the most widespread infectious disease globally, is an important duty that we as adults must fulfill on behalf of children. I expect LAMP to play a role in achieving this goal.

\*End TB Strategy: An initiative that targets a reduction in annual tuberculosis incidence rates of 90% by 2035 compared to 2015, a reduction in deaths by 95% compared to 2015, and a reduction in catastrophic impacts on household finances caused by tuberculosis to zero, and sets out measures to achieve them. It was adopted by the Global Health Council in 2014.

# LAMP

## What is TB-LAMP?

✓ Recommended as a tuberculosis genetic test by the WHO

✓ Rapid

✓ Number of countries in which deployed **8** countries

✓ Cases detected using LAMP reagents as a percentage of annual new tuberculosis patients **20%**

## Socioeconomic significance of TB-LAMP

With the exception of COVID-19, tuberculosis is the single largest cause of deaths by infectious disease. It is estimated that in 2022 an additional 10.6 million people contracted the disease, and that it led to the deaths of 1.3 million people<sup>\*1</sup>. Many of these were people from developing countries. Preventive care for tuberculosis is highly cost effective, with a benefit-cost ratio (BCR) of 46 (meaning that USD 1 of investment generates a return of USD 46)<sup>\*2</sup>. On the other hand, it is reported that diagnosis and treatment of tuberculosis and drug-resistant tuberculosis through Active Case Finding (ACF)<sup>\*3</sup> generates BCRs of 32 (6-47) and 2 (0-23) respectively<sup>\*4</sup>, which means that it is a disease for which early intervention is significant.

The LAMP method developed by Eiken Chemical has sensitivity and specificity equal to that of the PCR method, which is the global standard for genetic testing, but permits faster diagnosis than PCR. In research that assessed diagnostic algorithms that can cut time and costs associated with the detection of tuberculosis and drug-resistant bacteria, it was reported that it was more cost effective to perform PCR tests on a LAMP positive specimen than to use PCR testing alone<sup>\*5</sup>, indicating that it makes a significant socioeconomic contribution.

Countries in which tuberculosis is prevalent have average life expectancies of little more than 60 years, with malnutrition being the leading cause of death, and with poverty and starvation remaining major social issues. The future social value generated directly by our TB-LAMP reagents up to the elimination of tuberculosis in 2030 is approximately USD 2.4 billion, in addition to which the eradication of tuberculosis will doubtless increase average life expectancy, which we believe will generate incalculable social value for the global economy as a whole.

	2023	2024-2030	Calculation method
<b>Social value</b>	<b>USD 700 million</b>	<b>USD 2.4 billion</b>	Economic effect of detecting tuberculosis using TB-LAMP 2023: Number of people tested inferred from TB-LAMP sales × detection rate × GDP (USD per capita) 2024-2030: Number of persons affected by tuberculosis calculated using international targets × estimated share × detection rate × GDP (USD per capita)

\*1 WHO Global Tuberculosis Report 2023

\*2 One Million Lives Saved Per Year: A Cost-Benefit Analysis of the Global Plan to End Tuberculosis, 2023–2030 and Beyond Carel Pretorius et al. Journal of Benefit-Cost Analysis (2023), 14: S1, 337–354

\*3 An approach in which medical professionals focus on people at high risk of being affected by tuberculosis, and identify those affected by actively testing for tuberculosis

\*4 Economic evaluation of a community health worker model for tuberculosis care in Ho Chi Minh City, Viet Nam: a mixed-methods Social Return on Investment Analysis Luan Nguyen Quang Vo et al. BMC Public Health. 2023; 23: 945.

\*5 A cost-benefit algorithm for rapid diagnosis of tuberculosis and rifampicin resistance detection during mass screening campaigns Valerie Flore Donkeng-Donfack et al. BMC Infectious Diseases volume 22, Article number: 219 (2022)

## Tuberculosis genetic testing: differences in technique

Tuberculosis testing is traditionally performed using a culture of tuberculosis bacteria. When using the culture method, diagnosis has to wait until the tuberculosis bacteria have grown, so it takes 2-6 weeks for the result to be generated. Moreover, because it is the original bacteria that are reproduced, there is a risk of infection for medical professionals. In the case of genetic testing it is the genes of the bacteria or virus that are amplified, so the risk of infection for medical professionals is low. The LAMP method development by Eiken Chemical improves on the weak points of the traditional genetic test, which are ease of use (complexity and length of time required) and economics (high cost of measuring equipment and reagent). It has been reported that for groups of people for which there is a risk of tuberculosis, such as refugee camps, the quickest and most effective approach to provide tuberculosis care is to use LAMP for screening, then use PCR testing on LAMP-positive individuals\*<sup>1</sup>.

	LAMP	PCR
Principle	Detects presence of genes	Detects presence of genes
Sensitivity	84% *2	84% *2
Specificity	100% *2	100% *2
Test time	1 hour	2-3 hours
Test process	Isothermal	Repeated heating and cooling
Guidelines	Appears in WHO guidelines	Appears in WHO guidelines
Can detect drug-resistant bacteria	No	Yes
Test environment	No restrictions	Restrictions apply
Maximum tests per day	70 tests per day	16 specimens per day

Sensitivity: ability to accurately judge that a person with the disease has the disease

Specificity: ability to accurately judge that a person who does not have the disease does not have the disease

## Trends in overseas guidelines/international cooperation



\*1 A cost-benefit algorithm for rapid diagnosis of tuberculosis and rifampicin resistance detection during mass screening campaigns Valerie Flore Donkeng-Donfack et al. BMC Infectious Diseases volume 22, Article number: 219 (2022)

\*2 Masahiro Kobayashi et al. The Journal of the Japanese Society for Clinical Microbiology Vol. 25 No. 2 2015. 29

# Management Resources (Capital)

The six types of capital are the driving force behind value creation, and are the indicators we use for EIKEN Vision 2030 and creating the future beyond that.

FY2023



## Financial Capital

An organizational base that supports sustainable growth

### Input

- Total assets:  
**¥61,651 million**
- Net assets:  
**¥45,971 million**

### Output

- ROE:  
**5.6%**
- Operating cash flow:  
**¥3,806 million**

### Issues and responses

- Improving ROE/operating profit margin
- Improving the balance sheet
- Making effective use of internal reserves



## Human Capital

Growth driver for the Group as a whole

- Number of employees (full-time employees + temporary employees):  
**1,101**
- Systematic HR development program
- Personnel evaluation program aimed at talent acquisition

- Total actual work hours per full-time employee per year:  
**1,864**
- Employee satisfaction score:  
**48.1**
- Percentage of managerial positions held by women:  
**15.4%**

- Continuing to acquire and develop employees
- Establishing an environment in which employees can take on challenges



## Intellectual Capital

Research and development that builds the future of testing

- Proportion of R&D employees:  
**17.4%**
- R&D expenses:  
**¥3,939 million**
- Consolidated R&D network

- Number of patents held:  
**847**

- Strengthening R&D investment
- Innovation that leads to business creation



## Social Capital

Partnerships rooted in the management philosophy

- EIKEN WAY
- Number of surveys implemented:  
**7**
- Number of inquiries received:  
**1,405**
- Number of IR events held:  
**107**
- Cooperation on information with WHO and other international organizations
- Conduct of due diligence in value chain
- Partnerships with a variety of external research institutions

- Number of countries in which products deployed:  
**53**
- Networks with hospitals and clinics
- Appropriate relationships with shareholders and investors
- Market share in fecal occult blood reagents:  
**67% (Japan)**

- Investigating direct sales network overseas
- Strengthening IR activities



## Manufacturing Capital

Stable supply of high-quality products

- Manufacturing locations:  
**3**
- Capital expenditures:  
**¥1,812 million**

- Products tailored to user needs

- Reviewing factory system
- Improving CCC through the use of digital technology
- Ongoing response to quality and supply risks



## Nature Capital

Mitigating environmental impacts as “the last generation”

- Energy consumed:  
**126,895 GJ\***
- Water volume consumed:  
**68,700 m³**
- Use of Tochigi Furusato Electricity:  
**11,655 MWh (90.5% of total)**

- CO<sub>2</sub> emissions per employee:  
**2.49 t**
- Water volume consumed per employee:  
**62 m³**
- Solar power generated:  
**108,828 kWh (0.8% of total)**

- Developing and manufacturing eco-friendly products
- Introducing renewable electric power

\*Amount reported in accordance with Revised Energy Conservation Act