

About IVD

IVD, which involves studying blood, urine, and other samples taken from the body, is used in a variety of ways. It is used during medical checkups to help prevent disease. IVD is also used in diagnosing diseases, determining treatment methods, measuring treatment results, preventing illness from increasingly in severity, and for post-treatment monitoring. Healthcare without accurate test results is like walking through mist; the path is uncertain. IVD is essential because it allows medical professionals to assess a patient's state of health accurately and swiftly, and to determine optimal treatment methods.

In Sysmex's main businesses of hematology, urinalysis, and immunochemistry, fundamental testing is conducted to check a patient's physical condition during medical checkups for disease prevention and early-stage detection. They are also used for a wide range of other purposes, such as treating disease or managing prognoses. On the other hand, in such fields as hemostasis and gene testing, tests are performed to

measure a person's physical condition in greater detail and are mainly used in the process of diagnosing and treating illnesses.

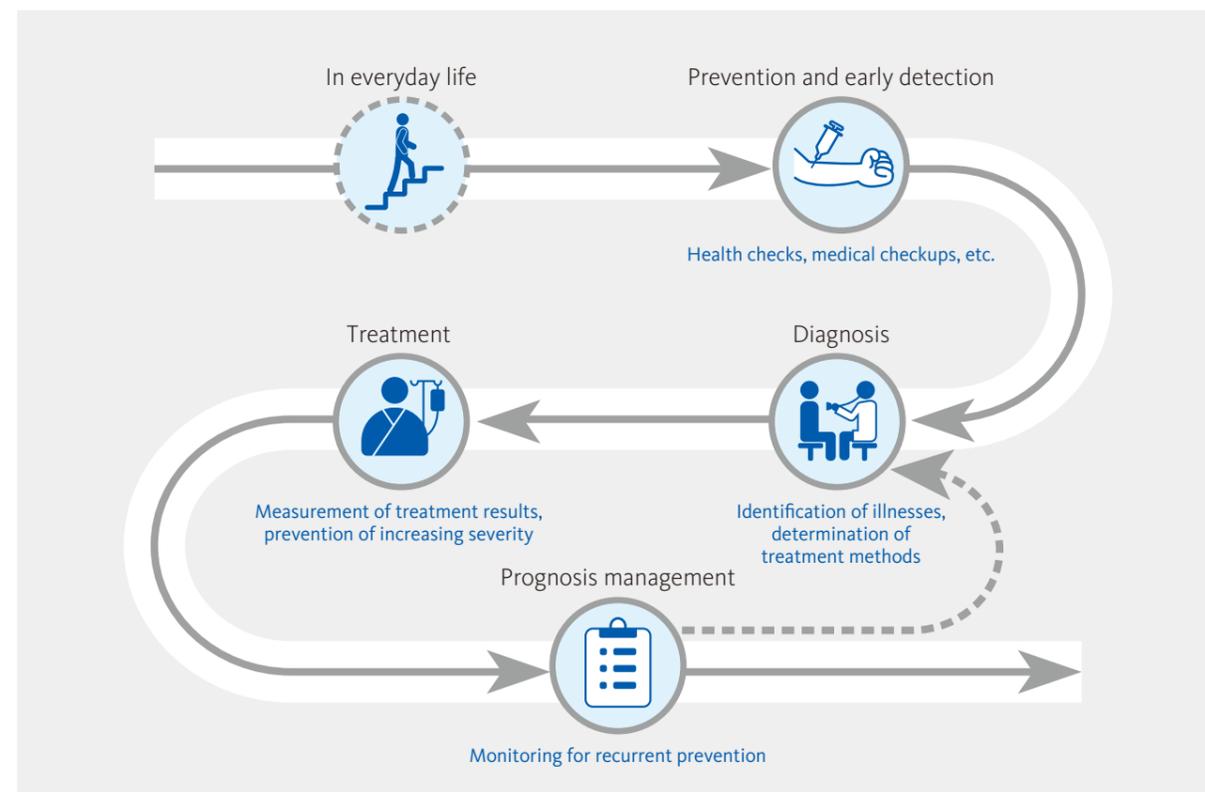
The Growing Importance of IVD in Healthcare

In recent years, technological innovation and its application to the field of healthcare have been leading to the practical realization of new treatment methods. For example, cancer genomic medicine—a type of personalized medicine that enables treatment tailored to an individual patient's constitution and disease—is coming to the fore. Realizing this type of medicine will require analysis based on the gene testing of cancer cells.

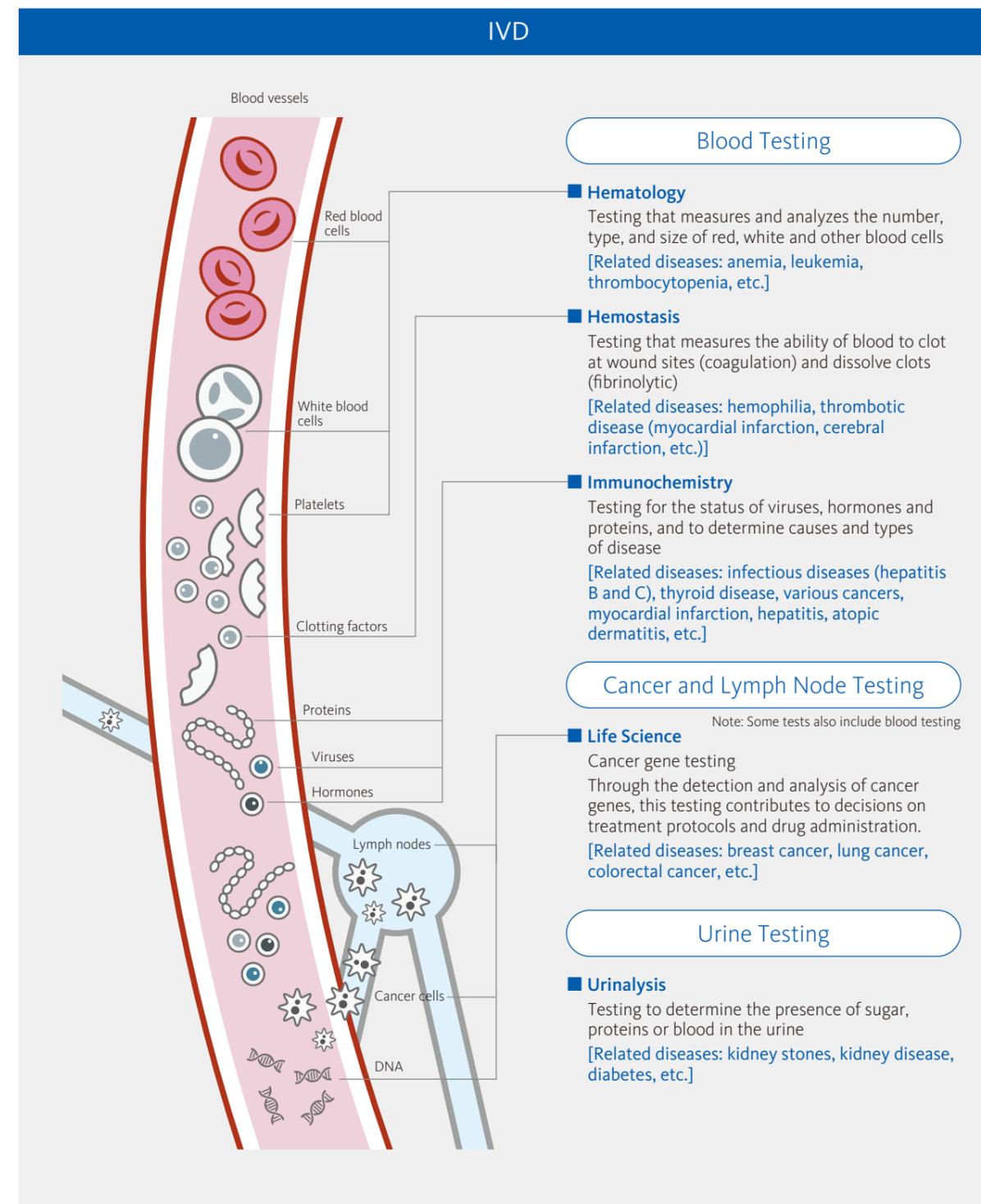
Sysmex is working to achieve this type of cancer genomic medicine and to make liquid biopsy a reality. Liquid biopsy involves testing a patient's blood and body fluids, which places less of a burden on the patient than a physical biopsy. As a result, we aim to help improve patients' quality of life and hold down healthcare expenses.

>>Realizing Personalized Medicine through Liquid Biopsy P87

Where IVD is used



What can be determined from samples (such as blood, urine, and cancer tissue)

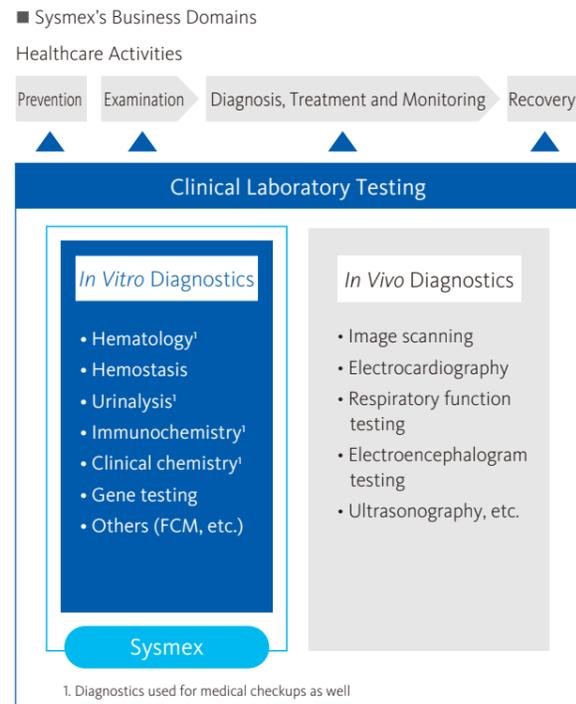


Main Business Domains

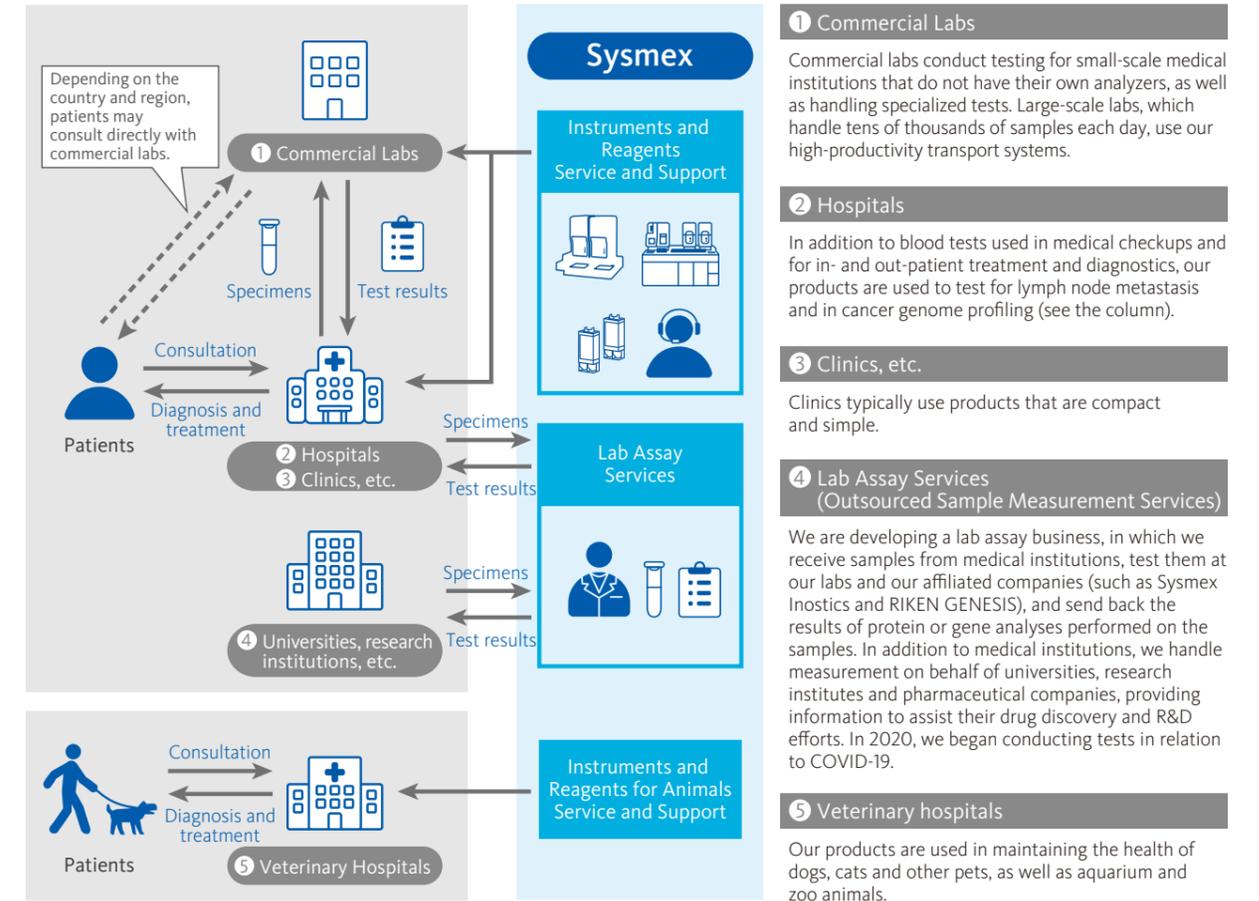
Clinical testing is essential to healthcare, where it is used in diagnosing and treating illness, measuring the results of drug administration and diagnosing health to aid prevention, among other applications. Clinical testing can be broadly divided into two categories: *in vitro* diagnostics (IVD) that involve the examination of blood, urine and other samples taken from the body, and *in vivo* diagnostics that involve direct examination using X-rays or electrocardiograms. Sysmex's primary business is in the IVD domain, where we provide medical institutions and other customers with instruments, reagents, and software on a global basis.

In response to technological innovation and its application to healthcare, personalized medicine has begun to gain traction in recent years. This type of medicine is aimed at conducting risk diagnosis and monitoring treatment results tailored to individual patients. In such areas, IVD is taking on an increasingly important role in healthcare.

>>Supporting Healthcare with *In Vitro* Diagnostics (IVD) P85



Sysmex's Products in Use

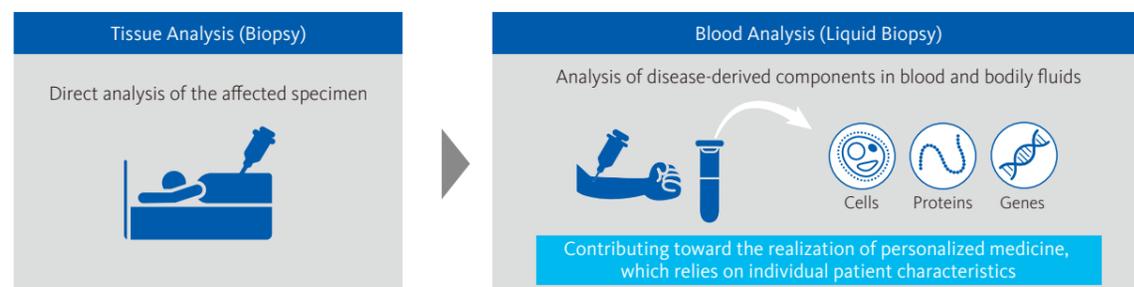


Realizing Personalized Medicine through Liquid Biopsy

Liquid biopsy is a testing method that involves highly sensitive analysis to detect disease-affected areas present in minute quantities in blood and bodily fluids. Compared with conventional physical biopsy, which is carried out on samples taken from tumors or other tissue, liquid biopsy is in the spotlight for its potential for imposing less of a physical, emotional, and economic burden on patients. It also increases opportunities for testing and helps to determine drug administration and other treatment methods at an early stage.

Examples of Initiatives

In 2016, Sysmex forged an operational alliance with Eisai Co., Ltd. aimed at realizing a diagnosis for Alzheimer's disease. By using blood tests to detect structural abnormalities in minute proteins, which are thought to impact disease state, we are conducting joint research aimed at early diagnosis and treatment.



Contributing to Cancer Genomic Medicine through a System for Use in Cancer Gene Profiling

This system, which targets patients for whom standard treatment has been concluded, provides a comprehensive analysis of genes that frequently mutate due to cancer. The information received from this system facilitates the determination of treatment methods based on gene mutations, the selection of anti-cancer drugs, and drug administration, allowing healthcare to be optimized for individual patients. In addition to introducing this system to medical institutions and providing support through lab assay services handled by RIKEN GENESIS, the Company is creating a flow of testing that can be conducted entirely in Japan, including the provision of detailed support. Furthermore, in 2020 we began providing an expert panel support system as part of our efforts to help implement a structure for the efficient realization of cancer genomic medicine.



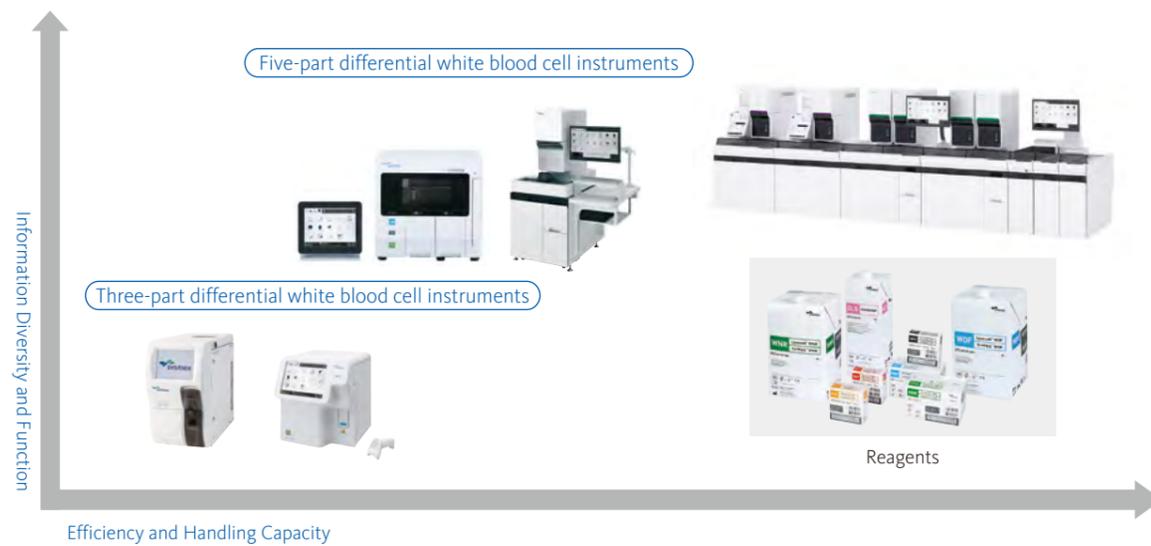
Hematology

For small and medium-sized institutions, Sysmex offers three-part white blood cell differential models, used for determining basic parameters, as well as five-part white blood cell differential models. Numerous reagents are used with these models to deliver a high degree of clinical significance. In addition, we offer a wide-ranging lineup, including transport systems that can be used for rapid, high-volume testing in large-scale labs. In 2021, in Japan we launched a new five-part white blood cell

differential flagship model, as well as a compact model providing three-part white blood cell differentiation. Going forward, we plan to roll out these models globally.

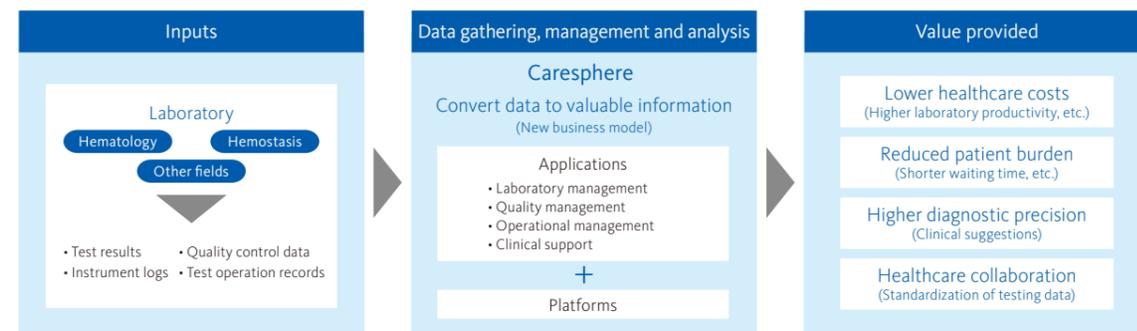
In 2018, we launched the first products to have received CLIA-waiver certification to clinics and other small-scale facilities in the United States. We are also rolling out products to help realize the early-stage detection and treatment of malaria. For example, in Europe in 2019, and in Japan in 2020, we launched an analyzer that supports standardization and improved efficiency in malaria testing.

■ Multiparameter Automated Hematology Analyzers



Caresphere, a New Network Solution

Caresphere, which we began providing in 2018, manages centrally the various information obtained from diagnostic instruments and healthcare information systems, using IoT and the cloud to link and analyze data in real time on a platform that is safe and globally standard. The various applications and services of this platform provide information that augments operational efficiency and quality control at hospital laboratories and commercial labs, all with the aim of resolving customer issues and enhancing patient satisfaction. Currently, we provide applications that support more sophisticated operations at clinical laboratories, reduce the burden of operations related to ISO 15189, and support human resource development.



Flow Cytometry (FCM)

We are developing products that utilize the flow cytometry method. Areas of business include clinical FCM (clinical testing to perform detailed analysis in diagnosing leukemia, malignant lymphoma and HIV/AIDS), industry FCM (used in the quality control of food) and research FCM (analyzing the function of cultured cells and other research applications). In 2020, we launched a product (for research) in North America, the world's largest market for FCM testing.



Flow cytometer

Urinalysis

We developed the world's first urine formed sediment analysis system using the flow cytometry method. We are also adding to our portfolio of urinalysis products by making use of alliances as we work to expand our lineup in response to diverse urinalysis needs. In 2020, we signed a distributorship agreement with Siemens Healthineers for the North American market, and we plan to further expand our market scale.



Fully automated system for the analysis of formed elements in urine
Fully automated urine chemistry analyzer
Fully automated imaging unit for formed elements in urine



Reagents

Hemostasis

Sysmex handles products offering a wide range of processing capacity to meet the needs of different-sized facilities. Demand for hemostasis testing has increased and grown more diverse due to a rise in thrombotic diseases stemming from lifestyle diseases, as well as to the development of new blood preparations. In 2018, we launched a new product offering enhanced productivity, reliability and operability, and we are working toward a global roll-out. In addition to an alliance with Siemens Healthineers in the area of reagents, we work with Group company HYPHEN BioMed, SAS to develop products offering high clinical value.



Automated hemostasis analyzer



Reagents



Automated immunochemistry system



Reagents

Cancer Gene Profiling

We developed a system for use in cancer gene profiling in collaboration with the National Cancer Center. In 2019, this became the first such system to be covered under Japanese health insurance.

>>System for Use in Cancer Gene Profiling P88

Testing of Cancer Lymph Node Metastasis

We apply the OSNA method, which we developed, in products we provide to automatically and easily detect information to help in diagnosing lymph node metastasis, among other items. We launched products in this category in China in 2020.



Cancer Lymph Node Metastasis Testing System

Cytogenic Testing

Oxford Gene Technology (OGT), which became a Sysmex subsidiary in 2017, conducts business in the area of cytogenic testing, which involves testing cells for chromosomal and genetic abnormalities. We have launched a Flow FISH testing system (for research) that utilizes imaging FCM technology to automate FISH testing.

Other Lab Assays

We also offer assay services for research use to determine expression levels of breast cancer-related gene types, making use of BEAMing technology to detect to a high degree of sensitivity genes that are present in minute samples of blood. In Kobe, where our headquarters and major bases are located, Sysmex took the lead in working with the City of Kobe through an industry-government alliance to build a system for PCR testing amid the COVID-19 pandemic, with our employees also providing a lab assay service.

>>Initiatives Targeting COVID-19 P27
>>Lab Assay Services P88

Profit Model

A Business Model for Achieving Steady Profitability

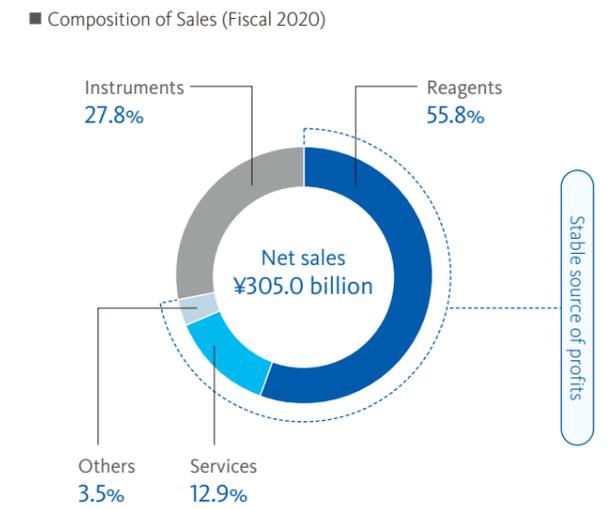
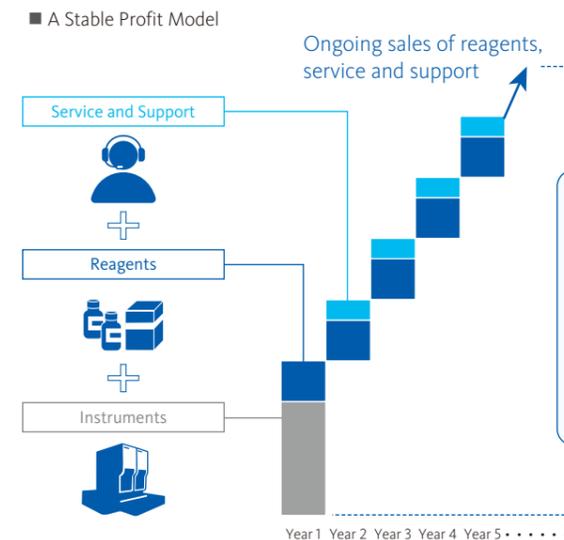
Demand for healthcare and testing is relatively unaffected by global circumstances and economic trends, so the IVD business delivers stable profitability.

Our main businesses—hematology and hemostasis—represent a recurring-revenue business model. Even after customers buy our instruments, we continue to provide reagents and service and support. Reagents are needed each time an analyzer is used to measure a patient's blood or other samples. Service and support are essential to ensuring customers can continue to use our instruments with confidence. The level of customer satisfaction for our products and services is high, so

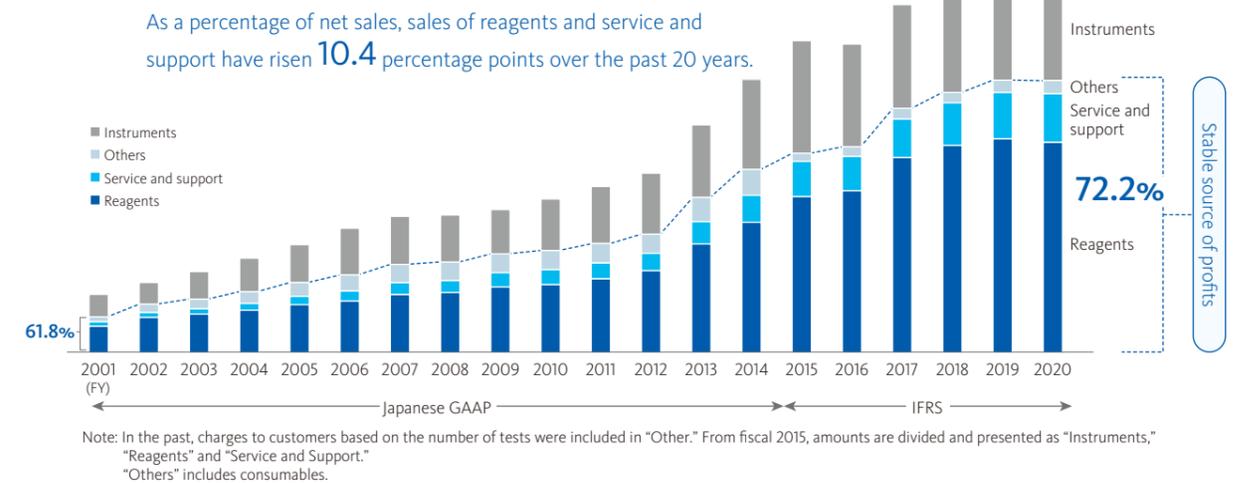
in addition to sales to new customers we frequently receive ongoing business from existing ones. This high repeatability is one reason we maintain high profitability.

>>Customer Assessment in the United States P22

In fiscal 2020, reagents and service and support accounted for 72.2% of net sales. Reasons for this high figure include the fact that our business comprises a rising share of large-scale institutions that use large quantities of reagents. Also, we are expanding our portfolio of reagent products with high clinical significance. Furthermore, we are leveraging the capital acquired through our highly profitable business model to invest proactively with a view to medium- to long-term growth.



Sales of Reagents, Service and Support



Robotic Assisted Surgery System

In recent years, it has become common to perform minimally invasive laparoscopic surgery to reduce the physical burden on patients. The global market for surgical robots is expected to grow from ¥550 billion yen in 2020 to approximately ¥1,150 billion by 2025.*

In August 2020, Medcaroid Corporation (a joint venture between Sysmex and Kawasaki Heavy Industries, Ltd.) received Japanese regulatory approval for the first made-in-Japan robotic assisted surgery system, followed by insurance coverage in September. As the global general distributor for this product, in December Sysmex began its launch, targeting the urology departments of medical institutions in Japan. Compact enough to fit in standard Japanese operating rooms, the system is equipped with user-friendly robot arms and a high-definition 3D videoscope. Furthermore, the system has been designed to be network compatible, to support more accurate treatment of medical workers.

In fiscal 2020, Sysmex focused on increasing the number of cases where the system is used in Japan, to heighten brand recognition and market penetration before its full-fledged introduction in fiscal 2021. Sysmex plans for a gradual rollout in overseas markets from fiscal 2023.

*Source: TechSci research Global Surgical Robots Market, Forecast and Opportunities, 2025

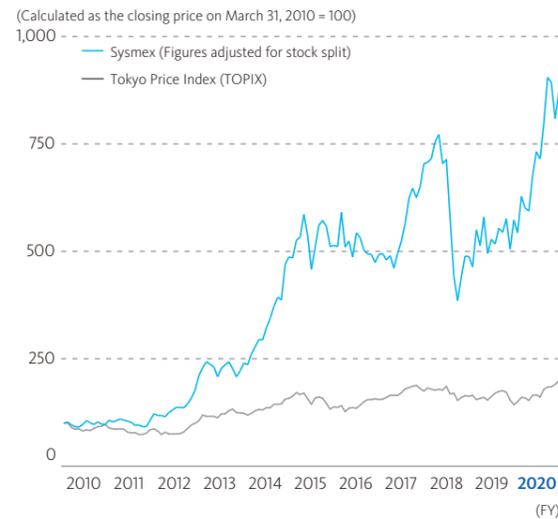


Robotic assisted surgery system

Antibody test	A test to measure for the presence of a protein (antibody) generated by the body's immune function, which endeavors to repel foreign exogenous matter that has entered the body. This test allows the checking of disease history, as well as current infection.
Antigen test	A test to measure for the presence of an antigen, virus, or other pathogen that has entered the body. By detecting virus-specific proteins, these tests confirm whether a virus is present in the body at the time of testing.
Antimicrobial resistance	This phenomenon occurs when living organisms develop a resistance to a drug, whose efficacy is decreased or neutralized as a result. Bacteria that have developed microbial resistance are known as antimicrobial-resistant bacteria.
Application	Corresponds to a test parameter in Sysmex's various technology platforms.
BEAMing technology	An acronym for "Bead, Emulsion, Amplification, and Magnetics," this gene analysis method combines digital PCR (ultrahigh-sensitivity PCR) and flow cytometry technologies for highly sensitive analysis of genetic mutations.
Cancer genome profiling	Analysis of information about genes significant to cancer diagnostics by looking at mutations, amplifications, and fusion of multiple genes in cancer tissue.
Caresphere	Caresphere utilizes IoT and the cloud to establish a platform for the real-time linking and analysis of a variety of information managed using testing instruments and clinical laboratory information systems. It is a new network solution that provides support for increasing the operational efficiency of professionals involved in testing and healthcare, enhancing quality and raising patient satisfaction.
CE Mark	A mark signifying compliance with certain regulations and standards, such as the <i>In Vitro</i> Diagnostic Regulation (IVDR), required of products intended for sale in the European Economic Area.
Clinical FCM	Refers to FCM used in a clinical testing setting for analysis in such areas as hemophilia, lymphoma, HIV, and hematopoietic stem cells.
Commercial lab	A company that specializes in testing operations, performing IVD on behalf of medical institutions, research institutes, and other facilities.
Cytogenic testing	Cytogenetics refers to the study of chromosomes, particularly research related to illnesses arising due to chromosomal abnormalities. Research and testing typically involve the use of white blood cells, amniotic fluid, or tissues samples and karyotype testing using G-banding or the FISH method.
Cytokine	A general term for physiologically active substances that contribute to intercellular interaction, which can be determined by measuring proteins secreted by cells. As infection spreads, the inflammatory response increases. When inflammatory cytokines are discharged in large quantities, immune cells can trigger acute multiple organ failure. Results include respiratory failure, sepsis, coagulation disorders and other severe illnesses, such as interferon-λ3.
Drug susceptibility test	A test to determine the efficacy of various antimicrobial drugs against pathogenic bacteria detected in a sample.
EMA	Europe, the Middle East, and Africa
Expert panel	A multidisciplinary investigative commission that meets to medically interpret gene panel testing results. Convened at core hospitals for cancer genomic medicine, expert panels recommend treatment methods optimized for individual patients on the basis of abnormal gene information. Members of such panels include oncologists, genome researchers, counselors, etc.
Flow cytometry (FCM)	Method involving the flow dispersion of minute particles and the use of laser light to optically analyze minute flows.
Flow FISH testing	Whereas FISH testing requires evaluation of slides under a microscope, flow FISH testing uses an imaging flow cytometer to capture images, enabling automated analysis.
Fluorescence <i>in situ</i> hybridization (FISH) testing	Testing method using fluorescent material binding only specific genes to detect abnormalities within a chromosome.
Genomic medicine	Medicine that allows the prevention of disease or the effective treatment of individual patients by analyzing their genetic information.
Hematology	The field of <i>in vitro</i> diagnostics that determines whether precise testing is necessary by analyzing the number, type, and size of red, white, and other blood cells.

Imaging FCM	A proprietary Merck technology that combines FCM for processing large quantities of cells with the rapid capture of images of cell morphology, fluorescent imaging and automated digital image analysis.
<i>In vitro</i> diagnostics (IVD)	In general, IVD refers to the testing of blood, urine and other samples to determine physical condition. IVD may also refer to the domain of laboratory testing in which IVD is performed.
Knockdown production method	A production method in which the principal parts are exported from Japan for local assembly into finished products.
Liquid biopsy	This is a general name for technology using blood or body fluid samples for diagnosis and the prediction of treatment impacts, rather than through the conventional practice of tissue biopsy, in which diagnosis is performed on diseased tissue that has been collected. Liquid biopsy is less invasive than tissue biopsy, but more highly sensitive detection technologies are required.
Manufacturing and marketing approval (regulatory approval)	In Japan, the manufacturing and marketing of medical devices and reagents requires approval from the Ministry of Health, Labour and Welfare. Such approval necessitates confirmation of a product's function and safety. Other countries have their own regulatory procedures: approval from the Food and Drug Administration in the United States, obtaining the CE Mark in Europe, and in China, approval from the National Medical Products Administration (NMPA).
OSNA method	Abbreviation of One-Step Nucleic Acid Amplification method, developed by Sysmex, which enables detection of lymph node metastasis.
Panel testing	A test that allows multiple markers to be measured at once. Particularly in genomic medicine, cancer panels are used to analyze the mutation, proliferation, and fusion of multiple genes having diagnostic significance.
Personalized medicine	Different from the conventional practice of providing selected predetermined or uniform treatment for a given disease, personalized medicine aims to select treatment methods optimized to individual patient characteristics, based on gene and other data.
Polymerase chain reaction (PCR)	A gene amplification technology for copying small quantities of DNA to produce larger quantities.
Precision management	A management method used to guarantee the values measured by customers' testing equipment and to confirm that a customer's equipment is functioning correctly. External quality control is a method under which the same specimens (such as artificially produced blood) are distributed to multiple clinical laboratories, and the measurement results obtained are analyzed using statistical methods, thereby allowing the precision of individual laboratories' measurement results to be evaluated. The results are provided as feedback to these laboratories, helping to increase their quality of testing.
Primary care	The initial care provided at clinics or other locations when a patient first falls ill.
Quality of life (QOL)	Refers to the maintenance of human dignity and improved wellbeing.
RAS genes	One of the genes that is known to cause cancer when it mutates. As the likelihood is high that patients with RAS gene mutations will not benefit (prolongation of life, tumor reduction) from the administration of anti-EGFR drugs, companion diagnostics may be performed to treat the gene mutation first.
Reagent	A pharmaceutical product for medical use in laboratory testing, also called an <i>in vitro</i> diagnostic product. It is not used directly on the human body, but on samples of blood or other bodily fluids.
Specimen	Material necessary for testing. May include blood, cerebrospinal fluid, pus, punctured fluid, urine and feces.
Sysmex Network Communication Systems (SNCS)	An online support service that connects the Sysmex Customer Support Center and customers' instruments via an Internet connection to provide real-time external quality control and scientific information, and to monitor instrument conditions.
Technology platforms	Sysmex's three technology areas (cell measurement, protein measurement, and gene measurement) and the measurement platforms that use them.
Transport system	A system that links multiple analyzers, allowing testing to be automated. In addition to making testing operations more efficient, automation helps reduce the risk of infection when samples are handled manually, and prevents mishandling.
Urine sediment testing	Testing performed to analyze formed elements in the urine, including blood and other cells. Urine chemistry testing, on the other hand, is conducted by using a test paper to analyze for the presence of sugar, protein, or blood cells in urine.

■ Stock Price Range



■ Stock Price Movements

Fiscal years	High (Yen)	Low (Yen)	Closing price (Yen)	Volatility (%)
2010	6,010	2,789	2,942	27.8
2011	3,340	2,387	3,340	23.6
2012	5,800	2,900	5,790	25.7
2013	7,180	3,130	3,290	37.5
2014	6,880	3,070	6,670	27.6
2015	8,640	5,430	7,040	39.2
2016	8,170	6,010	6,750	29.9
2017	9,730	6,080	9,640	24.7
2018	11,110	4,810	6,690	38.7
2019	8,420	5,814	7,846	38.4
2020	13,310	7,024	11,925	27.8

Note: Volatility refers to the annualized standard deviation based on the daily closing price.

■ Total Shareholder Return (TSR)¹⁾ (Annualized Rate)

Investment period	Past 1 year		Past 3 years		Past 5 years		Past 10 years	
	Cumulative/Annual rate	Cumulative	Annual rate	Cumulative	Annual rate	Cumulative	Annual rate	
Systemex	52.1	24.1	7.5	70.3	11.2	722.1	23.4	
TOPIX	42.1	22.1	6.9	62.3	10.2	179.4	10.8	
TOPIX (Electrical equipment)	68.6	48.4	14.1	134.3	18.6	226.4	12.6	

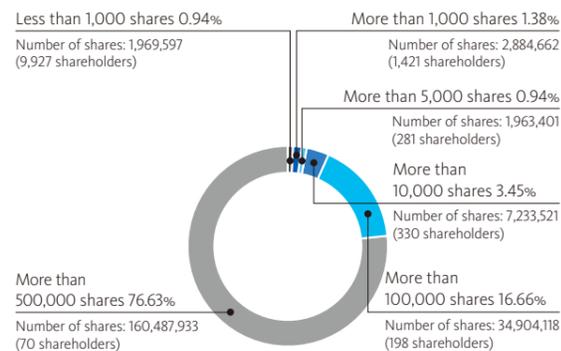
1. TSR: Total shareholder return, including capital gains and dividends
 • Prepared by Sysmex based on data from Nikkei NEEDS-Financial QUEST
 • Base date of March 31, 2021
 • TSR calculated on the assumption that dividends are reinvested in shares

■ Principal Shareholders (Top 10)

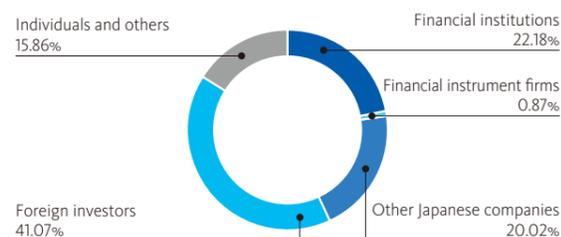
Shareholders	Number of shares held (Thousands)	Percentage of shareholding (%)
Custody Bank of Japan, Ltd. (Trust Account)	23,564	11.3
The Master Trust Bank of Japan, Ltd. (Trust Account)	13,723	6.6
The Kobe Yamabuki Foundation	12,000	5.7
Nakatani Foundation for Advancement of Measuring Technologies in Biomedical Engineering	11,830	5.7
Nakatani Kosan, Ltd.	10,457	5.0
Kazuko Ietsugu	6,124	2.9
Taeko Wada	6,124	2.9
Rusoru, Ltd.	4,750	2.3
Tadako Nakatani	4,012	1.9
NORTHERN TRUST CO. (AVFC) SUB A/C AMERICAN CLIENTS	3,219	1.5

Note: Percentage of shareholding excludes treasury stock (446,876 shares).

■ Distribution of Shares by Number of Shares Held



■ Composition of Shareholders



Systemex Corporation

Established	February 20, 1968
Head Office	1-5-1, Wakino-hama-Kaigandori, Chuo-ku, Kobe 651-0073, Japan
Inquiries	IR & Corporate Communication Department, TEL: +81-78-265-0500
Website	https://www.sysmex.co.jp/en/
Number of Employees	9,510 (consolidated basis) (including part-time employees and others)
Fiscal Year	April 1–March 31
Shareholders' Meeting	June
Number of Shares Authorized	598,688,000 shares
Number of Shares Issued	209,443,232 shares
Paid-in Capital	¥13,229.9 million
Stock Listings	Tokyo Stock Exchange, First Section
Ticker Code	6869
Transfer Agent	Mitsubishi UFJ Trust and Banking Corporation
Independent Auditor	Deloitte Touche Tohmatsu LLC
Rating	AA- (Rating and Investment Information, Inc. (R&I))
Major Indexes	Dow Jones Sustainability World Index Dow Jones Sustainability Asia Pacific Index FTSE4Good Index FTSE Blossom Japan Index MSCI ESG Leaders Indexes MSCI SRI Indexes MSCI Japan ESG Select Leaders Index MSCI Japan Empowering Women Index (WIN) S&P/JPX Carbon Efficient Index Ethibel Excellence Ethibel Pioneer Ethibel Sustainability Index (ESI) Euronext Vigeo Eiris World 120 Index Sompo Sustainability Index



»Sustainability Data Book > Evaluations and Results Related to Sustainability P62