

MBL

COMPANY PROFILE



Our company was founded as Japan's first antibody manufacturing company in 1969 to continuously take on the innovative diagnostic technology for each life. We take great pride in consistently making straightforward strides with the belief that it is worth accepting the challenge of finding solutions for such diseases that no company has ever confronted.

In 1970s, we initiated the development of *in vitro* diagnostics for autoimmune diseases as a leader of the companies of such products in Japan. Furthermore, we launched the distribution of a companion diagnostic (CDx) for the first time in Japan, followed by business evolution that included the development of genetic diagnostic services. In January 2021, our company became a wholly owned subsidiary of JSR Corporation. By further enhancing cooperation with the group companies of JSR Life Sciences, we will



We contribute our
innovative diagnostic technology
to people's health
and medical development

CEO Hiroki Ito

provide innovative drug discovery support services in the pharmaceutical and biotechnology industries. Because future economic conditions and business environment are uncertain, we are willing to transform ourselves for future changes to create the future as intended with backcasting considerations. In particular, the coronavirus disease (COVID-19) that affected the world provided us with the opportunity to reconsider our company's significance of existence. We will continuously strive to supply our diagnostic reagents in consideration of our company's purpose for the health and happiness of individuals living every day and a secure society filled with laughter.

We will contribute to people's health and medical development using our innovative diagnostic technology to meet consistent challenges.

Clinical Diagnostics Business

We supply high-quality clinical diagnostics to the medical industry.

We are also working vigorously to develop clinical diagnostics for rare and intractable diseases that are difficult to diagnose, to ensure that patients with these diseases are diagnosed promptly and so can start treatment as soon as possible.



Immunology / serology diagnostics

Autoimmune disease diagnostics


Oncology diagnostics



Molecular diagnostics

Oncology diagnostics

Infectious disease diagnostics



OEM / Raw materials supply



CDx
development
contract
services



Raw materials
for regenerative
medicine
products



Antibody
development
contract
services



Our Businesses

Drug Discovery Support

In our efforts to promote the spread of personalized medical care, we are developing biomarkers and companion diagnostics (CDx) that provide information for therapeutic approaches or decisions on medication. We are also concentrating on our drug discovery support services, which contribute to the development of pharmaceuticals.

Research Reagents

We provide global support for basic research through our high-performance antibodies and kits of various types, with a focus on drug discovery in the fields of cancer immunotherapy and regenerative medicine.

Cancer immunotherapy / Cell therapy

MHC tetramers

Growth factors / cytokines for cell culture



Organoids

Niche factors for 3D cell culture



Basic research tools

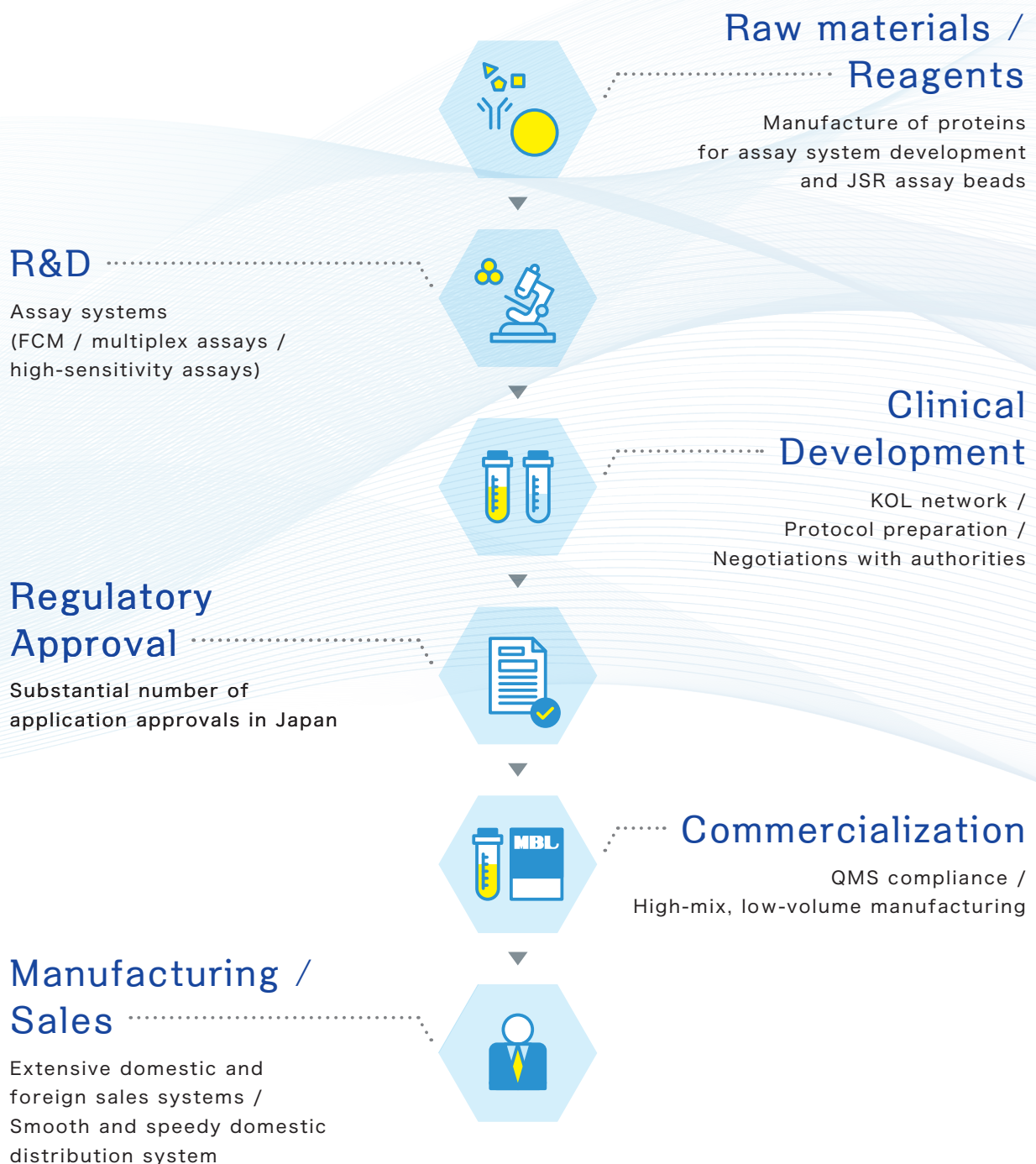
Antibodies / ELISA kits

Fluorescent proteins



Our Development System

We carry out the whole process of R&D, raw material production and reagent manufacturing, clinical performance study, regulatory applications, manufacturing, and marketing in-house. This has allowed us to build relationships of trust with researchers and key opinion leaders (KOLs), enabling speedy commercialization of products. We not only market reagents following commercialization but also market raw materials and play a role as an OEM supplier.



Antibody Development

Abundant of Experience and Expertise Amassed Since the Birth of the Company

MBL was founded as Japan's first antibody manufacturer, and antibody manufacturing technology has remained a core technology and source of value creation for us. We assembled an elite team that brings together all the technology, expertise, and human resources we have accumulated since MBL was founded to create the antibodies needed for all our businesses. As well as components for basic research reagents and clinical diagnostics, we also create our own antibodies for use in in-house manufacturing and product quality testing, and thus are also making indirect contributions to our businesses from various different angles.

Numerous Antibodies Acquired

Products developed

Over **4,000**

Number of contract services

Over **10,000** (results over 18 years)



Wide-Ranging Antibody Development Technology and Ability to Respond to Diverse Needs

Animal species for monoclonal antibodies

8

Number of antibody-related proprietary licenses

Over **20**



Results Derived from Therapeutic Antibody Seeds

Number of proprietary patents out-licensed

6

Number of target molecules for development and implementation

Over **200**



External Certification Obtained for Animal Experiment Facilities

We have received accreditation from the Center for Accreditation of Laboratory Animal Care and Use, which is under the umbrella of Japan Pharmaceutical Information Center, that animal experimentation at our facilities is implemented correctly in accordance with the Basic Policy on Animal Experimentation Performed at the Institutions under the Jurisdiction of the Ministry of Health, Labour and Welfare.

Development of Reagents

From the perspective of patients and healthcare professionals, we will develop clinical diagnostics that meet specific medical needs in cooperation with KOLs.

Clinical Diagnostics

Immunology / Serology Test Reagents: Autoimmune Test Reagents

Working in collaboration with Japanese KOLs in the field of autoimmune diseases, we have launched numerous new products. With polymyositis and dermatomyositis/autoimmune bullous disease in particular, Japanese researchers have taken a global lead in both treatment and testing and have drawn up diagnosis standards and treatment guidelines for Japan. The infrastructure is therefore in place for the production of world-class products.



Molecular diagnostic Reagents

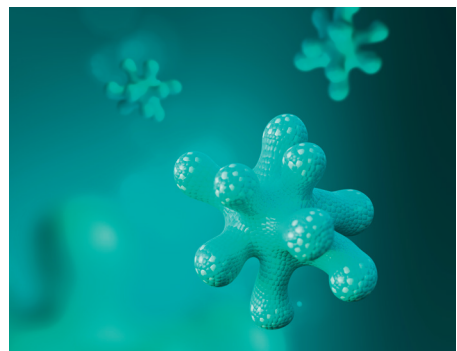
In the development of genetic diagnostics, we have installed cutting-edge technology such as next-generation sequencers to enable us to provide the medical community with rapid and highly sensitive clinical diagnostics that provide genetic information that can aid in the diagnosis of cancer or infectious diseases and is useful in the development of personalized medicine.



Reagents for Research Use

Niche Factors for 3D Cell Culture

Organoids are miniature organs developed *in vitro* from pluripotent stem cells such as stem cells derived from the living organism and iPS cells. Organoid technology has started to be used in basic research, drug discovery research, and regenerative medicine. We have developed and marketed organoid-related products such as growth factors for addition during organoid culture.



Clinical Development

To provide the required diagnostics to the medical industry as soon as possible, we carry out the series of tasks from planning clinical performance study and application for approval of *in vitro* diagnostics to procedures for insurance coverage as a unified process.

Through close cooperation with the medical community, we strive to make innovative diagnostic reagents a reality.

MBL's Strengths

Links with KOLs

Autoimmune Diseases

We have collaborated with domestic KOLs to launch numerous products in the field of autoimmune diseases. With polymyositis and dermatomyositis / autoimmune bullous disease in particular, Japanese KOLs have taken a global lead in both treatment and testing and have drawn up diagnosis standards and treatment guidelines for Japan.

Genes

MBL is the only *in vitro* diagnostics manufacturer to participate in SCRUM-Japan*. With the advice of medical doctors who have a wealth of experience in new drug development, we will be able to develop IVD / CDx products to obtain approval and insurance coverage from regulatory authority.

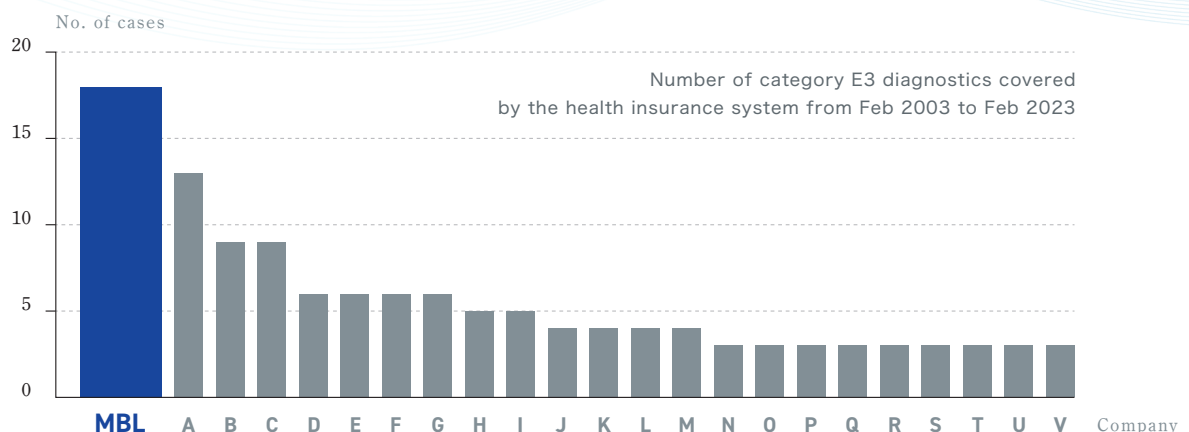
*SCRUM-Japan is the first ever nationwide cancer genome screening project carried out through industry-academia collaboration. It came about through the merger of LC-SCRUM-Japan, a genetic screening network for rare lung cancers, and GI-SCREEN-Japan, a genetic screening network for bowel cancer.

MBL's Strengths

New Product Development

Number of Clinical Diagnostics Covered by the Japanese Health Insurance System

Applications for diagnostics to be covered by the health insurance system fall into three categories: E1, E2, and E3. E1 is diagnostics with previously existing measurement items and measurement methods, E2 is diagnostics with new measurement methods, and E3 is diagnostics with new measurement items. At MBL, we work with all three categories, but we are particularly strong in E3.

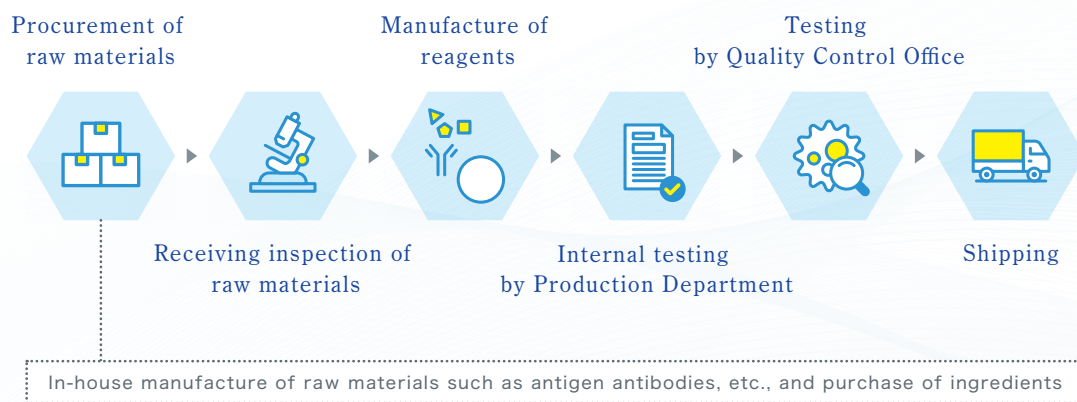


Manufacturing

Stable Supplies of High-Quality, Safe, Reliable Products

Our R&D division and Production divisions collaborate to develop and improve manufacturing methods and to ensure high productivity in the manufacture of in vitro diagnostics and their raw materials. With this manufacturing technology infrastructure as a base, we are able to ensure stable supplies of our products. We presently have a lineup of around 75 in vitro diagnostics on the market, and we conduct over 1,000 performance tests every year.

Basic Process for Production of *In Vitro* Diagnostics



Quality Management System

MBL has obtained ISO13485 certification, and constantly strives to improve product quality through the following quality policies:

- 1** We shall maintain and continually improve the effectiveness of the quality management system and deliver customer-oriented quality.
- 2** We shall listen to the information from customers and carefully and promptly make responses.
- 3** We shall give first priority to the compliance with the laws and regulatory requirements and deliver safe and secure products and services.



MD 763057 / ISO 13485

Academic Support

Symposiums

Autoantibodies and Autoimmunity Symposium

We have hosted this symposium 30 times since 1993, inviting participants from Japan and overseas.

Takato Molecular Cell Biology Symposium

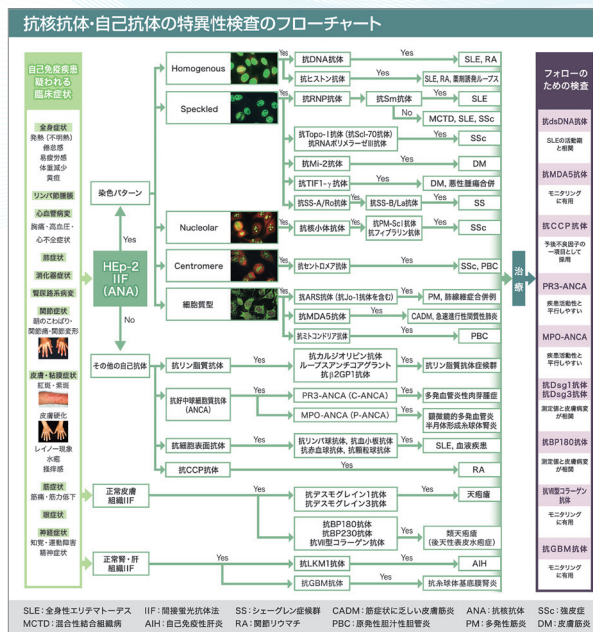
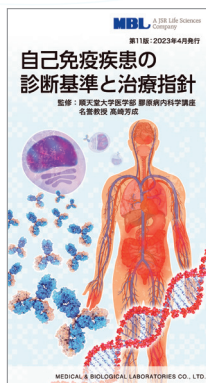
We have hosted this symposium every August since 1989, with the 34th symposium in 2023.



Publications

Diagnostic Criteria and Treatment Guidelines for Autoimmune Diseases

We have published a booklet with the latest information on diagnostic criteria and treatment guidelines for autoimmune diseases. The booklet includes a test flowchart, a checklist of the main clinical symptoms, and autoantibody test items, which are all presented in a way that can be readily understood by doctors who do not specialize in collagen-vascular diseases. The booklet will serve as a guideline for medical treatment and is intended to be useful for clinical practice.



Corporate History

Events

Products

1969 Company founded with the aim of becoming Japan's first antibody manufacturer (Start of antiserum business)

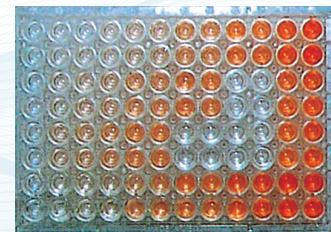
1975 Expansion into clinical diagnostics field

1977 Commenced development of autoimmune disease diagnostics

1987 Expansion into field of reagents for basic research

Development and marketing of Enzyme ANA Test, the first domestically produced antinuclear antibody (ANA) detection reagent

Development/marketing of first ELISA reagent for autoantibody testing



MESA series EIA reagent

1999 Entry into molecular diagnostics field

2005 G&G Science Co., Ltd. founded
 Joint corporation, Beijing B&M Biotech Co., Ltd. founded in Beijing, China. (as of now MBL Beijing Biotech Co., Ltd.)

2010 Development / marketing of STACIA MEBLux™ Test

2015 MBL came under umbrella of JSR Group

2018 Launch of MEBGEN RASKET™-B kit

2020 MBL Shenzhen Biotech Co., Ltd. founded in Shenzhen, China



2021 MBL became fully owned subsidiary of JSR Corporation Strengthening of drug discovery support field

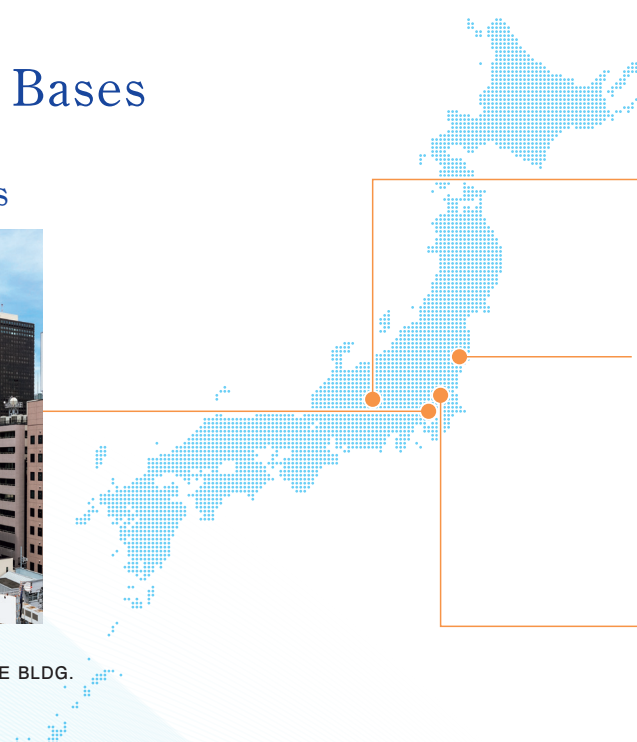
Bases

Domestic Bases

Headquarters



SUMITOMO FUDOSAN
SHIBADAIMON NICHOME BLDG.



Ina Laboratory

(1st Manufacturing Facility /
2nd Manufacturing Facility)



Fukushima Laboratory

(Gene reagent development)

Tsukuba Laboratory



Overseas Bases

Products and services are provided in collaboration with overseas Group member companies and affiliates.

MBL Beijing

Sales of raw materials for
in vitro diagnostics

MBL Shenzhen

Manufacturing and sales of
in vitro diagnostics

JSR Life Sciences

Polymer-based diagnostics
and particles for therapeutic
antibody purification business

Crown Bioscience

Global contract research
organization providing preclinical
and translational platforms to
support drug discovery

Company Overview

Company name : MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.

Headquarters : SUMITOMO FUDOSAN SHIBADAIMON NICHOME BLDG.
2-11-8 Shibadaimon, Minato-ku, Tokyo
105-0012 Japan

Telephone : +81-3-6684-6860 (Main)

Fax : +81-3-6854-3615

Founded : August 23, 1969

CEO : Hiroki Ito

Number of Employees : 474 (As of March 31, 2023)

SDGs

Our corporate policy is to contribute our innovative diagnostic technology to people's health and medical development. On this basis, we create value through our corporate activities, and we are committed to ensuring the sustainability of the environment and of society. We also promote activities that contribute to all our stakeholders—our customers and business partners, our employees and shareholders, society, and the environment. As a member of the JSR Group, we define sustainability as contributing to society by creating value through our corporate activities.

Providing Opportunities for Sharing Information

Every year we host the Autoantibodies and Autoimmunity Symposium in the clinical field and the Takato Molecular Cell Biology Symposium in the basic research field. We invite not only doctors but also high school and university students aspiring to become doctors to participate in these symposiums, and thus provide forums for the development of medicine and communication with the next generation of medical professionals.



Comfortable Work Environment

We have many female employees playing active roles in the company. There is a 50-50 gender ratio at all our business facilities, with women accounting for 60% of staff at Ina Laboratory. In addition, 23% of management staff are women. The average number of hours of overtime in fiscal 2022 was below the legal limit of 45 hours per month.



Operation of Environmental Management Systems

We have received stepwise certification under the Ministry of the Environment's Eco-Action 21 environmental management system, and by putting the environmental management set out in the guidelines into practice, we are achieving a high level of environmental friendliness in our corporate activities.



Laboratories/ manufacturing plants : [Ina Laboratory]
< 1st Manufacturing Facility >
1063-103 Terasawaoka, Ina, Nagano
396-0002 Japan
< 2nd Manufacturing Facility >
1018-1 Terasawaoka, Ina, Nagano
396-0002 Japan
[Tsukuba Laboratory]
JSR Tsukuba Research Laboratories
25 Miyukigaoka, Tsukuba-shi, Ibaraki
305-0841 Japan

Delivery Center : 3F Stage 3 North Building,
Goodman Business Park
2-2 Kaguro Minami, Inzai City, Chiba
270-1369 Japan

Group companies : [China]
< MBL Beijing Biotech Co., Ltd. >
< MBL Shenzhen Biotech Co., Ltd. >
[Japan]
< G&G Science Co., Ltd. >
< Crown Bioscience & MBL Co., Ltd. >

MBL MEDICAL & BIOLOGICAL LABORATORIES CO., LTD.
A JSR Life Sciences Company