

## **Chapter 3**

# **Corporate Members**

### 3.1 LIST OF ADDRESSES

The named Corporate Member representatives have been appointed to facilitate liaison with IFCC. For general inquiries to a listed Corporate Member, it is recommended to use the listed website as the first point of contact.

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#### Becton Dickinson

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#### The Binding Site Group, Ltd.

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**3.2 PROFILES OF IFCC CORPORATE MEMBERS****Abbott**

Abbott is a global healthcare leader that helps people live more fully at all stages of life. The company's portfolio of life-changing technologies spans the spectrum of healthcare, with leading business and products in diagnostics, medical devices, nutritionals, and branded generic medicines. The company employs nearly 107,000 people and markets its products in more than 160 countries. Abbott is a global leader in in vitro diagnostics and offers a broad range of innovative instrument systems and tests for hospitals, reference labs, molecular labs, blood banks, physician offices and clinics. Abbott's diagnostic solutions offer customers automation, convenience, bedside testing, cost effectiveness and flexibility.

Website: [www.abbott.com](http://www.abbott.com)

**Agappe Diagnostics Ltd.**

Manufacturers of complete range Diagnostic Reagents like Biochemistry kits, Serology, Immuno Turbidometry, Coagulation, Hematology reagents and system packs for Biolis series. Products carry CE Marking. ISO 9001-2008 and 13485 - 2003 certified company. Also deals in a range of Fully Auto and Semi Auto Analyzers for various applications. We are exclusive distributors for world famous brands Like Tokyo Boeki Biolis Series and Mindray.

Web site: [www.agappe.com](http://www.agappe.com)

**Asahi Kasei Pharma Corporation**

We are growing as a specialty pharmaceutical firm with a global presence by focusing on the development of new world-class drugs in selected therapeutic fields. In diagnostics, management resources are concentrated on products with strong growth prospects. The Diagnostics Department develops and manufactures enzymes for clinical chemistry use, reagents, diagnostic kits, and human enzyme calibrator for standardization, employing state-of-the-art biotechnology, for marketing to reagent manufacturers, OEM reagent manufacturers, and hospital and commercial laboratories. Our focus is on value-added, continuous innovation and quality improvement of enzymes and enzyme-

related products to meet the increasing demands for greater measurement accuracy and product-handling flexibility in the clinical chemistry marketplace.  
Website: [www.asahi-kasei.co.jp/asahi/en/index.html](http://www.asahi-kasei.co.jp/asahi/en/index.html)

### **Becton Dickinson**

BD is a global medical technology company that is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care. BD leads in patient and healthcare worker safety and the technologies that enable medical research and clinical laboratories. The company provides innovative solutions that help advance medical research and genomics, enhance the diagnosis of infectious disease and cancer, improve medication management, promote infection prevention, equip surgical and interventional procedures, and support the management of diabetes.

The company partners with organizations around the world to address some of the most challenging global health issues. BD has more than 70,000 associates across 50 countries who work in close collaboration with customers and partners to help enhance outcomes, lower health care delivery costs, increase efficiencies, improve health care safety, and expand access to health.

For more information please visit: [www.bd.com/](http://www.bd.com/)

### **Beckman Coulter, Inc.**

Improving Patient Health and Reducing the Cost of Care.

Beckman Coulter is an organization with one of the most comprehensive product portfolios in both life sciences and clinical diagnostics. When laboratories choose Beckman Coulter as their partner, they receive distinct advantages: a legacy of quality, superior brand equity, and a highly capable team of professionals with a single focus - making laboratories more efficient and productive. We are able to design, develop, manufacture, sell and support testing systems that simplify and automate complex biomedical testing.

Our customers include hospitals, physicians' offices, diagnostic reference laboratories, pharmaceutical and biotechnology companies, universities, medical schools and research institutions. In fact, Beckman Coulter has placed more than 200,000 clinical and research instrument systems in laboratories around the world. Our diagnostic systems are found in hospitals and other critical care settings around the world and produce information used by physicians to diagnose disease, make treatment decisions and monitor patients.

Instruments for life science research are used by scientists as they study the causes of disease, identify new therapies, and test new drugs.

Headquartered in Orange County, California, Beckman Coulter employs about 12,000 people worldwide, operating in more than 50 sites on six continents.

By offering laboratories the tools that increase the accuracy of test results and velocity of decision-making, Beckman Coulter is dedicated to improving patient health and reducing the cost of care.

Website: [www.beckmancoulter.com/](http://www.beckmancoulter.com/)



### The Binding Site Group Ltd.

Binding Site is a British-based company specialising in the research, development and production of immunodiagnostic kits and reagents. Binding Site manufactures a wide range of high quality and innovative products used in clinical laboratories world-wide. International support is provided in the UK, USA, Canada, Germany, Austria, France and Spain from Binding Site offices and a network of distributors in over 60 other countries.

The origins of the company go back to the early 1960's when antisera were produced to meet the needs of the Immunology department within the University of Birmingham Medical School. The range of antisera produced was small but novel and of a very high quality, leading to numerous requests for material from Immunology groups around the world. During the ensuing years the range of antibodies grew rapidly and in the early 1980's a commercial immunodiagnostic company, Binding Site, was founded.

Expertise in immunisation and processing techniques has enabled us to build a range of immunodiagnostic products aimed at fulfilling the needs of commercial and government funded laboratories in a range of markets - Hospitals, Reference Centres, Universities, Pharmaceuticals, Therapeutics - whatever their size or complexity.

Innovative new products and improved product performance are the benefits of our collaborations with numerous centres of excellence, coupled with a highly professional scientific and technical manufacturing staff.

Our product portfolio has grown to include the most comprehensive range of assays for Primary Immunodeficiency in the world. We have also been able to develop the Freelite assays, the first nephelometric tests for measuring free immunoglobulin kappa and lambda light chains in serum. These assays give a sensitivity, accessibility, and consistency never before achievable, allowing significant improvements in laboratory and clinical practice for the detection and monitoring of B cell malignancies. Rigorous quality assurance procedures help ensure that we provide only products of the very highest standard and with technical support and educational programmes offered world-wide we are able to offer all of our customers the benefits of our technical expertise and knowledge. Website: [www.bindingsite.com](http://www.bindingsite.com)

### Bio-Rad Laboratories

Founded in 1952, Bio-Rad has its headquarter based in Hercules, California. It has remained at the centre of scientific discovery for more than 50 years by providing a broad range of innovative tools and services.

Bio-Rad employs more than 6,800 professionals worldwide within a network of more than 30 wholly owned subsidiaries serving more than 150 countries. Its two primary businesses include Clinical Diagnostics and Life Science research.

Bio-Rad serves more than 100,000 research, industry, and clinical laboratories around the globe. It is world renowned within its core industry segments with customers in hospitals, universities, research institutions, microbiological and environmental inspection agencies, pharmacological and biological research and private industry laboratory.

Bio-Rad is the number one specialty diagnostics company. It holds leadership positions in quality control management, diabetes monitoring, blood virus testing and detection, blood typing and autoimmune disorders testing

Website: [www.bio-rad.com/](http://www.bio-rad.com/)

## **C.P.M. Diagnostic Research SAS**

Since 1986 we have been involved in hospital sanitation projects both in Italy and abroad promoted by the Cooperazione Italiana, the European Union and the Vatican Foreign Mission. Our teamwork attitude has gained us loyal customers in the construction industry, oil industry (Agip Researches) and ONG, the Italian Red Cross, in the construction of hospital and medical centers, like the hospital in Quelimane in Mozambique, the hospital in Sidone Lebanon, the hospital in Thaoua and Zinder in Niger, the San Juan de Dios hospital in Colombia and pharmaceutical products, diagnostic material, medical supplies and hospital facilities to Bosnia, Sierra Leone, New Guinea, Haiti, the Ukraine, Angola, Guatemala, Tanzania and other countries as part of programs operated by the E.C.H.O and EU program.

On behalf of the United Nations and in collaboration with LIFE Rome, we built a totally solar powered mobile health-care unit which was been to Salvador.

To K.P.O - Karachaganak Petroleum Operating - B.V. have been supplied emergency and intensive care ambulances where these vehicles were able to offer their service above where the climatic conditions and temperature are exasperated (+50°C / -38°C). Moreover, since 15 years, C.P.M. SAS have a branch office in the Republic of Cuba recognized by the local government and where we are one of the most important distributor in Chemical Chemistry and Microbiology sector with a wide range of products registered near the local Health Authority.

C.P.M. SAS thanks to its efficiency in quality and manufacturing process have obtained the ISO 9001:2008 and ISO 13485:2004 certifications.

Website: [www.cpmas.it/](http://www.cpmas.it/)

## **DiaSys Diagnostic Systems GmbH**

DiaSys Diagnostic Systems is a leading specialist in development and manufacturing of diagnostic system solutions of high quality combined with ease of use and reduced environmental burden. Focusing on clinical chemistry and immunoturbidimetric tests, DiaSys has introduced more than 90 optimized reagents in user-friendly kits for manual or automated use. The products give reliable results in routine and special diagnostics as e.g., in diabetes, metabolic syndrome, lipid disorders, iron metabolism, pancreatic, kidney or liver diseases. The analytical instrumentation portfolio comprises automated clinical chemistry system analyzers for small to mid-size labs (respons®, BioMajesty®/JCA-BM 6010/C), semi-automated analyzers, POCT instruments (InnovaStar®) as well as glucose/lactate analyzers (SensoStar®). Additionally, DiaSys offers a broad range of quality control material (TruLab®). DiaSys is an ISO certified company since 1996 (ISO 13485:2003, ISO 9001:2000). To date, customers and partners in more than 100 countries around the world rely on DiaSys quality.

Website: [www.diasys-diagnostics.com](http://www.diasys-diagnostics.com)

## Diatron

Diatron specializes in the development, manufacturing, and marketing of hematology analyzers, reagents (both for our own and other manufacturers' analyzers) and hematology control material as well as clinical chemistry analyzers, clinical chemistry reagents and controls for human medical and veterinary use. The brand name of Diatron has been established throughout the world as a result of our capability for manufacturing high quality and extremely reliable instruments, which has resulted in our products being sold and marketed in more than 100 countries. Today, there are more than 30,000 Diatron clinical chemistry and hematology analyzers in laboratory use, and our customer base continues to grow strongly year after year. All of our products have CE marking with some having FDA clearance, thus allowing sale to the USA market. Website: [www.diatron.com](http://www.diatron.com)

## ET Healthcare Inc.

ET Healthcare Inc. is an IVD Company initially focusing on the China clinical market. We offer a POCT/near patient system, Pylon, for cardiac and inflammation markers. Website: [www.ethealthcare.com.cn](http://www.ethealthcare.com.cn)

## FUJIFILM Wako Pure Chemical Corporation

Wako Pure Chemical Industries, Ltd. was established in 1922 as a predecessor of Takeda Chobei Shoten (currently, Takeda Pharmaceutical Company Limited) pharmaceutical department.

Interest in healthcare continues to grow. High hopes are now pinned on the diagnostic tests to enable prevention of diseases, as well as their early detection and treatment. Wako Pure Chemical Industries, Ltd. is engaged in the research, development, and manufacturing of a diverse range of products, such as assay kits for the diagnosis of cancer and life-style related diseases, and infectious disease assays.

We are also steadfastly fulfilling our mission as a comprehensive diagnostic reagent manufacturer by developing assays that integrate reagents and instruments, and by promoting comprehensive total solutions for medical management and operations.

We will contribute to the advancement of the quality of medicine by continuing to develop valuable assays in cutting-edge areas, supporting future medicine such as disease prognosis and diagnosis, and predisposition detection.

Website: [www.wako-chem.co.jp](http://www.wako-chem.co.jp)

## Fujirebio Europe

Fujirebio is a global leader in the field of high-quality in vitro diagnostics (IVD) testing. It has more than 50 years' accumulated experience in the conception, development, production and worldwide commercialization of robust IVD products.

Founded in 1950 in Tokyo, Japan, Fujirebio has over the years concluded a number of successful acquisitions of best-in-class IVD companies. Examples include Centocor Diagnostics in 1998, CanAg Diagnostics in 2006 and Innogenetics in 2010. Today, Fujirebio's global presence includes offices in the United States, Latin America, Europe, and Asia as well as a vast international distribution network.

Fujirebio has a strong and long-lasting tradition of collaborating with experts in the worldwide clinical community in the development of high-quality routine and truly novel

biomarkers that cover a variety of disease states. Its IVD product lines span the range from specialized manual and automated testing to fully automated routine clinical laboratory testing solutions.

Fujirebio is today an H.U. Group company (listed on the Tokyo Stock Exchange – TYO: 4544) and employs more than 1.200 people in Asia, Europe, and America.

Website: [www.fujirebio.europe.com](http://www.fujirebio.europe.com)

### **Gentian AS**

Gentian develop, manufacture and market IVD products based on proprietary technology for flexible, high speed, high sensitivity testing.

The Gentian Cystatin C Immunoassay provides standardised and precise measurement of kidney function, which has allowed Gentian to become a leading force in introducing this novel renal marker in routine diagnostics in clinical laboratories worldwide.

Gentian's product development focuses on enhancing the assay signal strength of current particle enhanced turbidimetric and nephelometric methods for more sensitive, precise results. Following the success of this technology in the Cystatin C Immunoassay, it is now being utilized in the areas of cardiovascular, cancer, inflammation and veterinary diagnostics. Gentian is located in Oslo, Norway and Beijing, China. Valid certificates include ISO 13485:2012 and ISO 9001:2008.

Website: [www.gentian.com](http://www.gentian.com)

### **Helena Biosciences Europe**

Helena Biosciences is a leading medical diagnostic company with an international reputation comprising two flagship business divisions that specialise in the design, manufacture and support of Clinical Electrophoresis and Haemostasis systems and tests. For over three decades, the company has been a market leader in clinical electrophoresis technology, pioneering advances in the design of instrumentation, applications and software for acetate, agarose and since 2009, fully automated Clinical Capillary Electrophoresis.

Website: [www.helena-biosciences.com](http://www.helena-biosciences.com)

### **Hemas Hospitals (PVT) Ltd.**

Hemas Hospital (Pvt) Ltd., Wattala is one of the largest private Hospitals in Sri Lanka with 135 beds, catering for over 15,000 admissions and 250,000 outpatient attendances each year.

Hemas Hospital Laboratory Services – Wattala, being a part of the Hemas Hospital, Wattala recognizes its responsibility as a provider of quality services and has developed and documented a quality management system to better satisfy the needs of its customers and to improve management of the organization. The quality system complies with the international standards ISO 15189:2012.

Laboratory Diagnosis is divided into following disciplines, Hematology, Clinical Biochemistry, Chemical Pathology, Clinical Pathology, Microbiology, Serology, Histology and Phlebotomy services.

## HyTest Ltd.

HyTest produces antibodies and antigens for the IVD industry for use as key components of various laboratory assays and kits. The company has gained a market leading position in several key market segments, including cardiac markers and infectious diseases testing reagents. HyTest is a leading provider of several reagents such as antibodies and antigens of the troponin I and troponin complex. HyTest's products are sold in no less than 50 countries throughout the world. Its success has been based on significant R&D investments combined with a strong sales and marketing mix. More information at: [www.hytest.fi](http://www.hytest.fi)

## Immunodiagnostic Systems - IDS

IDS is a leading in-vitro diagnostic solution provider to the clinical laboratory market. We develop, manufacture and market innovative immunoassays and automated immunoanalyser technologies to provide improved diagnostic outcomes for patients. Our immunoassay portfolio is a combination of an endocrinology specialty testing menu and assay panels in complementary fields. The portfolio is available as a combination of tests available for use on our fully-automated systems, or as stand-alone test kits. This complete offering meets the needs of both clinical and research laboratories of all types and sizes, with their diagnostic testing requirements.

Our IDS heritage within certain endocrinology fields, including vitamin D testing, offers a solid platform on which to develop a market-leading endocrinology menu for Bone Metabolism, Calcium Metabolism, CKD-MBD (Chronic Kidney Disease & Mineral Bone Disorders), Fertility, Growth Disorders and Hypertension. Through partnership, we develop a broader complementary menu, extending into other clinical areas such as Allergy, Autoimmunity, and Infectious Disease.

Website: [www.idsplc.com/](http://www.idsplc.com/)

## Instrumentation Laboratory

Instrumentation Laboratory is integral part of Werfen, a worldwide leader in *in vitro* diagnostics (IVD) in the specialties of Hemostasis, Acute Care Diagnostics and Autoimmunity. IL develops, manufactures, and distributes instruments, related reagents, and data management solutions for hospitals around the world-at the point of care and in the laboratory. IL solutions include Hemostasis and Acute Care Diagnostics systems and services, all designed with a common goal: to help healthcare providers enhance patient care and efficiency.

Website: [www.instrumentationlaboratory.com](http://www.instrumentationlaboratory.com)

## Labtronic

Labtronic was established in 2009 to promote clinical diagnostic laboratory equipment and reagents. We work only with trusted manufacturers of laboratory equipment and reagents who have established themselves as leaders in the field of in-vitro diagnostics: Boule Medical AB (Sweden), Diasys Diagnostic Systems GmbH (Germany), 77 Elektronika Kft (Hungary), Beckman Coulter (USA), Helena Biosciences Europe (Great Britain), Sartstedt (Germany), Eschweiler GmbH & Co. KG (Germany), DRG Instruments GmbH (Germany), Biotek Instruments Inc (USA), Gold Standard Diagnostics Corp (USA), Erma (Japan).

Website: [www.labtronic.me](http://www.labtronic.me) and [www.labtronic.eu](http://www.labtronic.eu)

## **LumiraDx**

LumiraDx develops, manufactures, and commercialises an innovative point-of-care diagnostic Platform. The LumiraDx Platform is designed to deliver lab comparable diagnostic results at the point of care in minutes. It is designed to be affordable and accessible for healthcare providers globally, and to strengthen community-based healthcare.

Website: [www.lumiradx.com](http://www.lumiradx.com)

## **Maccura Biotechnology Co., Ltd.**

Maccura Biotechnology Co., Ltd. was incorporated in 1994. Maccura is a hi-tech enterprise certified by relevant departments. Maccura has past the CMD ISO13485, CQC ISO14001, TUV ISO13485 as well as CE Certification of some products and obtained the CNAS Medical Reference Laboratory Accreditation. Maccura is an In-Vitro Diagnostic integration company of research & development, production, sales and services. We become the first enterprise member at IFCC. As an IVD company, Maccura is the first batch to build the enzymatic reference laboratory, and traceable results of maccura's diagnostic products have reached the international advanced level. Maccura has been transformed into one of the leading IVD companies in China. Today, Maccura continues to grow with innovation and provide top quality IVD products and services to the world.

Website: [www.maccura.com](http://www.maccura.com)

## **MedicalSystem Biotechnology Co., Ltd.**

Ningbo MedicalSystem Biotechnology Co., Ltd., as a leading company in the field of clinical chemistry in China, specializes in the development, manufacturing, and marketing of diagnostic system solutions. MedicalSystem is certified by Quality Management System ISO 9001: 2008 and ISO 13485: 2012.

MedicalSystem focus on providing IVD products and the third-party clinical diagnosis services to hospitals and other medical institutions.

MedicalSystem is committed to build the business model of “taking the diagnostic products as the core, integrating diagnostic product and service” to fulfill the needs of customers. MedicalSystem has a first-grade R&D team and obtained more than 128 in-vitro diagnostic reagents registration certificates licensed by CFDA covering most of the clinical chemistry test and becomes one of the manufacturers which offer the largest range of chemistries in China. Additionally, MedicalSystem has 4 automatic biochemistry analyzers registration certificates. The analyzers could meet customers' requirements completely. MedicalSystem is one of the largest manufacturers in Chinese IVD industry who could provide diagnostic reagents and instruments together. MedicalSystem has established a high-level reference laboratory for standardization of their IVD products since 2009, the quality of measurement services was assured through compliance with ISO 15195: 2003 and ISO 17025: 2005 and through regular participation in appropriate EQAS. In RELA 2014, the reference laboratory (Labcode 087) has participated 19 measurands (including Enzymes, Proteins, Electrolytes, etc.) with satisfactory results. In order to improve the accuracy of patient results in clinical laboratories, MedicalSystem has developed the first EQA scheme (MSEQA) launched by Chinese IVD manufacturer which provides a means of assessing the analytical performance of a laboratory compared to others.

Website: [www.nb-medicalsystem.com/](http://www.nb-medicalsystem.com/)

## Megalab, JSC

Megalab was founded in 2017 by “Georgian Healthcare Group”. It is the first multidisciplinary laboratory in the region, combining clinical and pathological departments. The laboratory is designed according to the JCI (Joint Commission International) standard, which is the highest accreditation body for medical institutions in the United States. 20 million GEL was invested in the creation of Megalab.

Foreign partners took part in the creation of “Megalab”, which will continue to actively participate in the process of quality development and maintenance. Among them, are such international brands Labpon (Netherlands), BioLab (Jordan).

In Megalab you can find equipment from well-known manufacturers such as Siemens, Leika, Carl Zeiss, Thermofisher, BioMérieux and more.

It is a laboratory hypermarket where it is possible to perform any test necessary for humans, including newly introduced high-tech areas: digital and molecular diagnostics. Also analysis of any type of biological material.

The laboratory has about 150 highly qualified staff. Among them are leading Georgian specialists working in Europe. Megalab constantly strives to improve the qualifications of its staff with the help of various international or local trainings. In addition, Megalab promotes the upbringing of the next generations, the education and employment of students and residents, as part of the development of corporate social responsibility.

Since January 2019, the laboratory has been cooperating with about 100 medical institutions, including leading hospitals. Today Megalab already serves more than 3.000 patients a day, although the capacity of the laboratory exceeds 6 million different profile tests per year.

Website: [www.megalab.ge](http://www.megalab.ge)

## A. Menarini Diagnostics

Born as a division of pharmaceutical A. Menarini Industrie Farmaceutiche Riunite, headquartered in Florence and with over 17.000 employees in 70 countries, A. Menarini Diagnostics is a healthcare company with more than 30 years of experience in developing and leading the European market of prevention and diagnostics.

For the European healthcare community we are a dynamic and reliable partner providing innovative diagnostic solutions thanks to our deep relation with the market, and therefore, knowledge of its needs. All therapy decisions are based on reliable informed diagnosis as well as quality of life is related to prevention. These are the main reasons for our daily committed work. By focusing on well-defined and selected diagnostic areas, we create value for the society as a whole. Extensive investments in research, strategic alliances, and a constant, close, and intelligent presence into the healthcare community, allow us to be a leading European company and a trustful partner for both patients and professionals. Our aim is to make diagnostics management easier, more effective and result cost efficient.

All over Europe each client can be supported by one of our more than 700 skilled scientific consultants. In fact we are one of the diagnostics company with the most capillary presence in Europe, with our 14 fully owned subsidiaries, covering with our own network 90.3% of the population and serving a market of 300 million people. We have a leading position in the Diabetes monitoring and our activities also cover Urinalysis, Autoimmune diseases, Hematology, Immunology, Immunohistochemistry, Wet and Dry Chemistry systems.

Website: [www.menarinidiagnostics.com](http://www.menarinidiagnostics.com)

## Mindray

Mindray is a leading global developer of medical devices and solutions, dedicated to making better healthcare more accessible to humanity. Since its foundation in 1991, Mindray has been exclusively focused on the medical industry in the fields of Patient Monitoring & Life Support, In-Vitro Diagnostics, and Medical Imaging. In 2006, Mindray was listed on the New York stock exchange under the ticker symbol MR.

Headquartered in Shenzhen China, Mindray is a multinational corporation with subsidiaries in 33 countries in North and South America, Europe, Africa, and the Asia-Pacific region. The company's products and services can be found in healthcare facilities in over 190 countries.

Driven by innovation, Mindray has built up a global R&D network with 10 research centers in the US, Europe, and China. Focused on fully understanding the needs of both patients and practitioners, Mindray's insightful innovation produces ergonomically optimized medical devices that are readily accessible by the healthcare practitioner, allowing doctors and nurses to focus on the patient, not the machine.

Mindray closely controls all aspects of R&D and production, from design through to manufacturing of the final product. An integrated in-house production facility ensures the highest quality and also reduces costs, maximizing value for customers and ultimately making healthcare accessible to more people.

For detailed information please visit our web site: [www.mindray.com](http://www.mindray.com)

## Mitsubishi Chemical Europe GmbH

Mitsubishi Chemical Medience is a subsidiary of Mitsubishi Chemical Corporation. For more than 40 years now, it provides biological and medical/clinical labs with fast and highly precise analysis methods from its extensive and continuously expanded test portfolio. The outstanding quality of its appliances, reagents and service are the basis and the future perspective of the Japanese cooperation with its decades-long success story. Already back in 1982, Mitsubishi Chemical Corporation was the first company worldwide to develop the LPIA (latex photometric immunoassay) method to market maturity. Latest innovative product is PATHFAST® a fully automated chemiluminescence immuno analyser platform for the determination of biomarkers for fast differential diagnosis in central labs and at the point of care. The Mitsubishi Chemical Medience Group is aiming for further development under the management vision of "Good Health Creator, MEDical+sciENCE: Creating a Healthy and Safe Society through Medical Science." Its core business today comprises the development, production and distribution of analysis devices and reagents sets based on the patented LPIA technology on the one hand, and a significant engagement in the "theranostics" sector on the other. In this sector, the company maintains global connections and co-operations with research companies and internationally operating university factories and labs today. Its major focus on research will also guarantee products with the highest possible state of development in the future. Mitsubishi Chemical Europe GmbH is the representative of diagnostic business in EMEA.

Website: [www.mitsubishichemical.com](http://www.mitsubishichemical.com)



### **Nittobo Medical Co. Ltd.**

Nittobo Medical Co. Ltd., based in Koriyama, Japan, was established in 1987. We have been focusing on developing immunoturbidimetric and colorimetric reagents for IVD, as well as functional polymers, which are industrial specialty chemicals.

Our IVD reagents are distinguished by both high quality and stable supply, due to their production, from the main raw materials to the finished products, being completely managed within the Nittobo Group, in an integrated manner. Under the “N-assay” brand, we offer a rich product line-up to meet clinical needs, such as CRP, IgG, IgA, IgM, C3, C4, Urinary albumin, PreALB, RBP, etc. Further, we have developed the new ELISA kit for the “TRAP-5b (TRACP-5b)” bone resorption marker, which is used as a supplementary indicator for treatment of metabolic bone disease such as osteoporosis. Recently, we added “Rapid BACPro™ II” to our product list. This is a completely novel preparation kit for rapid identification of bacteria, using proprietary cationic polymer technology.

We will continue to contribute to the creation of a prosperous society by increasing the value of our social presence.

For more information about our products, visit: [www.nittobo-nmd.co.jp/english/top.html](http://www.nittobo-nmd.co.jp/english/top.html)

### **Nova Biomedical Corporation**

Nova Biomedical is a world leader in point of care and critical care whole blood diagnostic testing. The company’s products are marketed in six worldwide market areas—Hospital, Clinic/Physician Office, Ambulance and Emergency, Veterinary, Blood Bank, and Self-test. Hospital and veterinary products include StatStrip® point-of-care meters for glucose, ketone, creatinine, and lactate testing as well as Stat Profile critical care blood gas analyzers with no-maintenance cartridges and MicroSensor technology. Nova’s Allegro™ analyzer for primary care settings is a fast, simple, capillary whole blood analyzer providing HbA1c, lipids, urine albumin/creatinine, blood creatinine, hemoglobin and hematocrit in 5 minutes. StatStrip EM™ is a portable, system for ambulance use that provides rapid glucose, ketone, lactate, hemoglobin, and hematocrit testing using tiny capillary blood samples. Nova also markets the Nova Max Plus self-test meter for glucose and ketone testing.

Website: [www.novabiomedical.com/](http://www.novabiomedical.com/)

### **Oneworld Accuracy Collaboration**

We invite leading clinical and research groups around the world to become Science Architects in the Oneworld Accuracy Collaboration. We embed their science in programs that assess, improve, and standardize test results. We add those programs to OASYS - Oneworld Accuracy System. OASYS is an online system that can connect anyone in the world that has Internet access. We invite national groups to own the challenge of achieving testing accuracy in their countries. We empower them as Collaboration Members. We give them the tools they need: programs, online system, training, and the collective experience of their Collaboration peers. We invite laboratories, doctors, clinics, and pharmacies to participate in our EQA and Standardization programs. Oneworld Accuracy currently has 30 Collaboration Members who provide 25,000 program subscriptions every year to 5,000 participants in 55 countries.

Website: [www.oneworldaccuracy.com](http://www.oneworldaccuracy.com)

## Ortho-Clinical Diagnostics, Inc.

Ortho-Clinical Diagnostics For nearly 70 years, Ortho Clinical Diagnostics has provided the global healthcare community with the means to make better informed decisions. We have pioneered some of the most important, life-impacting advances in diagnostics - from our earliest work in blood typing to the latest developments in laboratory systems. Today, we serve the clinical laboratory and transfusion medicine communities worldwide. We are a leading provider of laboratory solutions as an aid in the diagnosis and treatment of disease. For more information please visit:

Website: [www.orthoclinical.com](http://www.orthoclinical.com)

## PerkinElmer

PerkinElmer is a global company committed to innovating for a healthier world. Our dedicated team of employees worldwide is passionate about helping customers work to create healthier families, improve the quality of life, and sustain the well-being and longevity of people globally.

PerkinElmer Diagnostics Segment:

- Test expectant mothers for pregnancy-related health risks and fetal abnormalities
- Screen newborn babies for genetic mutations that are associated with life-threatening disorders
- Accelerate detection of rare diseases, autoimmune disorders, allergies, and infectious diseases. Together, we are making a difference for the better.
- Last year, 35 million babies in over 90 countries were screened using PerkinElmer tests, saving the lives of more than 70 babies each day on average.

To date, more than 700 million babies have been tested for life-threatening diseases using PerkinElmer's newborn screening tools.

Website: [www.perkinelmer.com](http://www.perkinelmer.com)

## Radiometer Medical ApS

Radiometer is a leading provider of technologically advanced acute care solutions that simplify and automate all phases of acute care testing. Radiometer's solutions cover blood sampling, blood gas analysis, transcutaneous monitoring, immunoassay testing and related IT management systems and help healthcare professionals get fast and accurate information on the most critical parameters in acute care testing. At Radiometer, our mission is to help caregivers make diagnostic decisions that save lives. Add to that our vision of improving global healthcare with reliable, fast, and easy diagnoses. This is the foundation for making immediate and well-informed decisions on the treatment of critically ill patients in clinical settings such as emergency care, intensive care, anesthesiology, cardiac surgery, neonatal intensive care, and wound care.

Founded in 1935 and headquartered in Copenhagen, Denmark, Radiometer was a pioneer in blood gas testing, introducing the world's first commercially available blood gas analyzer in 1954. Today, Radiometer's products and solutions are used in hospitals, clinics, and laboratories in over 130 countries, to provide information on the most critical parameters in acute care testing. In fact, seven samples are performed every second on a Radiometer analyzer somewhere in the world. That is 420 samples a minute, 25, 200 samples an hour, 604, 800 samples a day. That is 220, 752, 000 samples every year performed on a Radiometer analyzer somewhere in the world.

For more information about blood gas analyzers, immunoassay analyzers, transcutaneous monitoring solutions or IT management systems, visit [www.radiometer.com](http://www.radiometer.com).

com. For information about the latest trends in acute care testing, visit [www.acutecaretesting.org](http://www.acutecaretesting.org), Radiometer's knowledge site.

### **Randox Laboratories Ltd.**

For almost 40 years Randox have been at the forefront of clinical diagnostics, leading the way with our disruptive technology and versatile product offering. With speed, accuracy and reliability at its core, our product range comprises; third party quality controls, the world's largest EQA scheme, over 113 diagnostic reagents and clinical chemistry analysers ranging from low throughput to high throughput.

With applications in molecular diagnostics, immunoassay, and forensic toxicology testing, Randox patented biochip technology is capable of simultaneously detecting hundreds of targets from a single patient sample. Complete patient profiling in this way facilitates faster patient testing, earlier diagnosis and improved patient pathways. Our commitment and significant re-investment in R&D mean that Randox have more new tests in development than any other manufacturer. Novel assays for stroke differentiation, Alzheimer's Disease risk, Acute Kidney Injury, Chronic Kidney Disease and Bladder Cancer are among just some of the niche tests available.

Website: [www.randox.com](http://www.randox.com)

### **Roche Diagnostics**

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology, and neuroscience. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. Roche's personalised healthcare strategy aims at providing medicines and diagnostics that enable tangible improvements in the health, quality of life and survival of patients. Founded in 1896, Roche has been making important contributions to global health for more than a century. Thirty-two medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and chemotherapy.

In 2019 the Roche Group employed approximately 100,000 people worldwide, invested more than 11 billion Swiss francs in R&D and posted sales of approximately 60 billion Swiss francs. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan.

For more information: [www.roche.com](http://www.roche.com)

## Sebia S.A.

Sebia a global specialty diagnostic company, develops, manufactures, and commercializes IVD tests and analyzers dedicated to the in vitro diagnosis of cancer, inflammatory diseases, diabetes and hemoglobin disorders. Sebia's focus on electrophoresis techniques enables it to maintain a sustained R&D program, providing access to genuine innovations in any lab. Both agarose gel and capillary assays, and their dedicated automation, are designed to be integrated into the same routine workflow; for gel (Assist, Hydrasys 2 Scan) and for capillary electrophoresis (Capillarys 3 TERA, stand alone or in work cell configuration up to three instruments with tube loader, Capillarys 2 Flex Piercing, Minicap Flex Piercing). More recently Sebia completed its Myeloma product line, with two important additions, Hydrashift daratumumab, reagent to be used with the Hydragel IF test to mitigate the DARZALEX(R) interference, and two new generations sFLC assays, Seralite serum and Sebia FLC kappa and lambda kits. Website: [www.sebia.com](http://www.sebia.com)

## Sekisui Diagnostics

For 40 years SEKISUI Diagnostics has been committed to providing innovative medical diagnostics to physicians and laboratories. We develop, manufacture, and supply billions of tests each year to the global healthcare market through our sales channels and our distribution/business partners. Our product lines include clinical chemistry reagents, coagulation systems and reagents, point-of-care molecular, rapid tests and immunoassay system as well as enzymes and specialty biochemicals Website: [www.sekisuidiagnostics.com](http://www.sekisuidiagnostics.com)

## Sentinel CH. SpA

Sentinel CH SpA is an Italian company founded in 1983.

For over twenty years Sentinel has been committed to the development of innovative IVD devices in the bid to make clinical diagnosis ever more reliable.

In 2006 Sentinel moved to new high-tech premises covering a total area of about 10.000m<sup>2</sup>.

The company is ISO 9001:2000, ISO 13485:2003 and ISO 13485:2003 CMDCAS certified.

Sentinel is compliant with the European Directives (98/79/CE), 21C CFR 820 "Code of Federal Regulations" FDA (U.A. Food and Drug Administration), SOE-98-282 (Canadian Medical Devices Regulations) as well as with directives of other countries, including Canada (CMDCAS). The facility, equipment and Quality System are regularly audited by Certification Body, Registrar Body and by customers and inspected by the National Competent Authority and FDA.

Sentinel's commitment to comply with IVD regulations has facilitated and supported successful partnerships in the industry as well as the distribution of Sentinel's products in over 70 countries worldwide.

Sentinel has an active presence at the major international congresses, presenting posters written by its specialised scientists. Sentinel is an active partner of IRMM projects for the release of new References Preparations for proteins.

The Technical and Manufacturing departments count for 70% of the company.

More than 100 different assays, under our own brand and also as customized kits, are manufactured in contamination-free clean rooms (ISO 8 and ISO 7 qualified).

The company's main areas of activity are:

- Clinical Chemistry
- Immunoturbidimetry
- Calibrators, controls
- Fully automated systems for Clinical and Immunochemistry, Fecal Occult Blood (FOB) testing and Coagulation.

The new Molecular Biology department initiated in 2008 has its own Production clean rooms (ISO 7) as well as R&D laboratory.

Sentinel Diagnostics: "Watching over Life"

Website: [www.sentinel diagnostics.com](http://www.sentinel diagnostics.com)

### **Shanghai Kehua Bio-Engineering Co., Ltd.**

Shanghai Kehua Bio-Engineering Co., Ltd. (KHB) was founded in 1981, focusing on the IVD business. In July 2004, KHB listed on the Shen Zhen Stock Exchange and is now one of the largest developers, manufacturers and marketers of in vitro diagnostic products in China, offering products mainly in two primary business segments: Diagnostic Reagents and Diagnostic Laboratory Instruments.

Based on the innovation center and post-doctoral workstation with excellent R&D professionals and talents, we have built a world class R&D platform.

We have successfully broadened our market reach by introducing more advanced products and new product lines that address different end-user segments. To date, KHB was obtained registration certificates (SFDA) for 180-plus products and 67 have been CE-marked.

Website: [www.skhb.com](http://www.skhb.com)

### **Shanghai Zhicheng Biological Technology Co., Ltd**

Shanghai Zhicheng is an innovative Chinese company devoted to manufacturing and marketing in vitro diagnostic (IVD) tests for use in clinical laboratories. We have been focusing on promoting the quality of our products by serious and pragmatic R&D, strict QC according to ISO 13485 and ISO 9001 since the company was founded by Mr. Wanghui in 1995. Now our products were distributed more than 1000 laboratories in China with famous brand of DENUO.

Website: [www.shzhicheng.com](http://www.shzhicheng.com)

### **Shenzhen YHLO Biotech Co., Ltd**

YHLO (EST. 2008) is an innovative and steadfastly growing company headquartered in Shenzhen, China.

To be a reliable and respected IVD enterprise, YHLO has put extensive investments in R&D and firmly associated with the top-tier universities, medical schools, and research institutes worldwide on scientific studies. With over a decade's continuous development expertise in immunoassays solution, YHLO provides a broad range of instruments (based on Chemiluminescence, ELISA, Immunoblot and Immunofluorescence methodologies) with patented technologies and outstanding features, as well as a comprehensive total solutions with portfolios in fertility and reproductive health, diabetes, infectious diseases, autoimmune disorders and other novel assays on rare diseases analysis. Since the COVID-19 pandemic outbreak, YHLO has taken a fast response and launched series of assays to assist people around the world in large

scale screening test.

Thanks to its premium quality management, YHLO has complied by international standards, ISO 9001:2015, ISO 13485:2016, KGMP of Korea, TGA of Australia, etc. To date, YHLO has a global presence by over 85 countries around the world, our strategic alliances with multinational corporations enable us to be more competitive.

Moreover, YHLO has in-depth cooperation with global research partners in Europe, USA, Japan and Australia, with aim of developing advanced technologies and create more medical value for health and vitality of people all over the world.

Website: [www.szyhlo.com](http://www.szyhlo.com)

### **Siemens Healthcare Diagnostics**

Siemens Healthcare Diagnostics provides healthcare professionals in hospital, reference, and physician office laboratories, and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. The company's innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

The company serves 30,000 customers in more than 120 countries and offers solutions for immunoassay, chemistry, automation, hemostasis, hematology, blood gas, diabetes, urinalysis, microbiology, and molecular testing, and also offers a comprehensive diagnostics IT portfolio. As a global leader in clinical diagnostics, Siemens' forward-thinking products and services are helping clinicians deliver better care so people around the world can lead healthier lives.

To learn more about Siemens Healthcare Diagnostics, please visit our Web site at [www.siemens.com/diagnostics](http://www.siemens.com/diagnostics)

### **Snibe**

Shenzhen New Industries Biomedical Engineering Co., Ltd (briefed as Snibe) is a leading global in-vitro diagnostic biomedical company. Snibe has focused on the Chemiluminescent immunoassay (CLIA) field for more than 26 years. We are providing customized diagnostic solutions to laboratories for more than 145 countries and regions. Over 15000 units of Snibe's products have been installed in hospitals and labs worldwide, including global chain labs like Synlab, Eurofins, Cerba, Synevo, etc. Snibe established 4 core R&D centers, including reagent, instrument, magnetic microbead, and reagent raw material to lay a solid foundation for developing the broadest range of CLIA analyzers and test menu. We successfully developed one of the fastest CLIA analyzer in the world - MAGLUMI X8 with the throughput of 600T/H in 2018. In order to meet the demand of mega-laboratories, Snibe announced a strategic partnership with Thermofisher and Hitachi to launch the Total Laboratory Automation solution in 2019. Moreover, to help the fight against COVID-19, Snibe successfully developed the 2019-nCoV (SARS-CoV-2) CLIA Kits in 2020, the first of its kind in the world to received CE mark.

Our Mission is "Creating value for human health through continuous innovation".

Find out more at: [www.snibe.com](http://www.snibe.com)

## **Sysmex Europe GmbH**

Sysmex supports healthcare professionals around the world in lighting the way with diagnostics by providing a broad range of medical diagnostics products and solutions. In the fields of haematology, urinalysis, haemostasis, oncology, flow cytometry and essential healthcare, we combine highly dependable, multi-functional and easy-to-operate instruments, a variety of reagents and software, plus reliable service, and support.

Sysmex Europe GmbH, located near Hamburg, Germany, is a subsidiary of the Sysmex Corporation from Kobe, Japan. From our Hamburg offices, we serve our affiliates, distributors and customers throughout Europe, the Middle East, and Africa (EMEA). For more information on how we are shaping the advancement of healthcare, visit: [www.sysmex-europe.com](http://www.sysmex-europe.com).

## **Technogenetics**

Technogenetics is an innovative company that has been operating for over 30 years in the fields of diagnostics research and biotechnologies.

Technogenetics mission is to contribute every day to medical and scientific progress by developing cutting-edge solutions and producing public and private test laboratories.

Website: [www.technogenetics.it/en](http://www.technogenetics.it/en)

## **Thermo Fisher Scientific**

Thermo Fisher Scientific is the world leader in serving science. Thermo Fisher Scientific is a driving force in the research, healthcare, industrial and applied markets, generating more than USD 20 billion in annual revenue. No other company can match our range of customer touch points – technologically, geographically, or commercially. We help our customers in finding cures for cancer, protecting the environment, making sure our food is safe and moving forward with thousands of important projects that improve millions of lives. At Thermo Fisher Scientific, each one of our 65,000 extraordinary minds has a unique story to tell. Our four premier brands - Life Technologies, Thermo Scientific, Fisher Scientific and Unity Lab Services - offer an unmatched combination of innovative technologies, purchasing convenience and comprehensive support. Our mission is enabling our customers to make the world healthier, cleaner, and safer. For more information, please visit: [www.thermofisher.com/](http://www.thermofisher.com/)

## **Tosoh Corporation**

Tosoh's diagnostic systems feature advanced immunoassay technologies such as the AIA & AIA-CL series of automated immunoassay analyzers, G series of glycohemoglobin analyzers, and molecular testing solutions that support the monitoring of such life-threatening disease as diabetes, certain cancers, and microbial infections.

They also feature integrated essential hardware and software uncompromising value through global customer support that includes ensuring the ready availability of the systems' consumable items, namely AIA-PACK & AIA-CL-PACK reagent cups.

Website: [www.tosohbioscience.com/clinical-diagnostics](http://www.tosohbioscience.com/clinical-diagnostics)

### **Labor Dr. Wisplinghoff**

Wisplinghoff diagnostic services are backed by a strong team of 29 medical doctors and scientists in Cologne.

contribute to the overall progress of healthcare by leading collaborations with industry and academic institutions in order to develop new techniques, carry out research and promote synergies between our scientists, academics and colleagues in the industry.

Website: [www.wisplinghoff.de/en](http://www.wisplinghoff.de/en)

### **Wuhan Life Origin Biotech Joint Stock Co., Ltd. – Szybio**

Wuhan Life Origin Biotech Joint Stock Co., Ltd. is a high-tech enterprise specialized in research and development, production and sales of IVD reagents for medical clinic. Our company owns research and development technology platforms such as chemiluminescence, conventional chemistry, latex turbidity and POCT. Our company has more than 300 employees, more than 30 masters and doctors, and has built a nearly 1000 squares of “clinical in vitro diagnostic reagent research and development center” and purification plant. Our company has more than 80 item of medical device registration certificate, covering cardiac, renal, blood lipid, liver function and so on.

Website: [www.szybio.com/](http://www.szybio.com/)