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3.2 PROFILES OF IFCC CORPORATE MEMBERS

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Abbott is a global, broad-based health care company devoted to the discovery, development, manufacturing and marketing of pharmaceuticals and medical products, including nutritional, devices and diagnostics. The company employs nearly 90,000 people and markets its products in more than 130 countries. Abbott Diagnostics 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: http://www.abbott.com

AbD Serotec
AbD Serotec is the research and diagnostic antibody division of MorphoSys, one of the world’s leading antibody technology companies. The AbD Serotec brand was created in early 2006 to market the combined products and services of Antibodies by Design, Biogenesis, Serotec, and Oxford Biotechnology - more than 14,000 antibodies and immunological reagents, custom monoclonal antibodies developed from the MorphoSys HuCAL® library, and large and small scale antibody production and conjugation services. AbD Serotec prides itself on its commitment to providing its customers in research and industry with the highest quality products and services, from its ISO certified production facility in Kidlington, near Oxford, UK. This facility is the AbD Serotec headquarters, and supports sales offices in Raleigh, North Carolina and Düsseldorf, Germany. Custom monoclonal development services using the HuCAL® technology are performed in Puchheim, near Munich, Germany.
Website: http://www.abdserotec.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.
Website: http://www.agappe.com

ANALIS R&D Diag
For more than 25 years, the “ANALIS R&D Diag”, group specialized in electrophoresis, has developed kits for in vitro diagnostic, which have been distributed throughout the world. As a result of our long experience in designing kits for electrophoresis using agarose gels, Analis has developed kits for Capillary Electrophoresis. COfix™ kits for Capillary Electrophoresis presented here are for Clinical Routine as well as Clinical Research:
- Carbohydrate Deficient Transferrin kit is used to detect AUD (alcohol use disorder). The same kit has been used for Congenital Disorder of Glycosylation (CDG) and for transferrin in Cerebrospinal Fluid (CSF). This kit is FDA device listed and has CE-IVD label for Europe.

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• Hemoglobin analysis including variant analysis is possible using two buffer systems (alkaline and basic). The hemoglobin kits are CE-IVD labeled for Europe.
• More generic buffers are also available which allow analysis of proteins for example in CSF or for peptides such as glutathione (GSH-GSSG) in blood.
• Anions, organic acids or cations may also be analyzed using specific applications.
• And a special dynamic coating may be used to facilitate CE-MS applications for proteome biomarker.

"R&D Diag" is composed of highly trained people, who offer assistance including running customer samples. We welcome ideas and projects in developing new applications using the high resolution power of Capillary Electrophoresis.
Website: http://www.analis.com/ and http://ceofix.analis.be

Asahi Kasei Pharma Corporation
Asahi Kasei Pharma is the core operating company for all operations of the Asahi Kasei Group which serve the health care industries. The product range includes pharmaceuticals, medical devices, pharmaceutical intermediates, diagnostic reagents, nutritional products, and animal health products.
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: http://www.asahi-kasei.co.jp/asahi/en/index.html

Axis–Shield Point of Care Division
Axis–Shield is an innovative Anglo-Norwegian company focused on the development and manufacture of important in vitro diagnostic (IVD) tests for use in clinical laboratories and at the point of care. The Group comprises a Point-of-Care Division in Oslo, a Laboratory Division in Dundee and local distribution subsidiaries in the UK (Axis-Shield UK), in Norway, Sweden, Denmark and Finland (Medinor), in Switzerland (Axis-Shield AG) and in Germany (Axis-Shield GmbH) and most of these companies also sell third-party products and non-IVD medical devices. We also have a representative office in China and a growing organisation in the USA which is primarily charged with accelerating the Afinion placement programme.
At the point of care, our products include the NycoCard range and the Afinion. In the laboratory sector we specialise in proprietary markers for the early diagnosis and management of critical illnesses such as cardiovascular and neurodegenerative diseases, rheumatoid arthritis and diabetes. We are playing an increasingly leading role in the fight against the global diabetes epidemic, and the need to keep tight control over blood glucose levels to avoid serious clinical sequelae.

BD Diagnostics
BD is a leading global medical technology company that develops, manufactures and sells medical devices, instrument systems and reagents. The Company is dedicated to improving people’s health throughout the world. BD is focused on improving drug delivery, enhancing the quality and speed of diagnosing infectious diseases and cancers, and advancing research, discovery and production of new drugs and vaccines. BD’s capabilities are instrumental in combating many of the world’s most pressing diseases. Founded in 1897 and headquartered in Franklin Lakes, New Jersey, BD employs approximately 29,000 associates in more than 50 countries throughout the world. The Company serves healthcare institutions, life science researchers, clinical laboratories, the pharmaceutical industry and the general public.
Website: 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: 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: http://www.biocrates.com/

**BIOCRATES Life Sciences AG**

BIOCRATES Life Sciences AG is a leading biotechnology company focused on biomarker discovery and development of diagnostics for early disease detection (nephropathy, diabetes) and companion diagnostics. BIOCRATES’ unique targeted metabolomics platform enables a quick and cost effective way of identification and quantification of a broad range of endogenous metabolites in different body fluids and tissues. BIOCRATES sets the standard for targeted metabolomics by providing the most trusted and comprehensive research kits and IVDs for assessing disease, as well as understanding drug, food, and environmental effects.

Biomarker Diagnostics: Biocrates works on the identification, validation and commercialization of metabolic biomarkers for diagnostic products developed in-house or with strong partners. Biocrates focuses on indications with high medical need and attractive commercial potential, e.g. cancer, chronic kidney nephropathy or metabolic syndrome/Type II diabetes.

**TargetDQ™ Services:** Contract research services supports customers in identifying and quantifying hundreds of metabolites from a broad range of samples, ultimately revealing meaningful biomarkers.

**AbsoluteDQ™ Kits:** In 2008 the first metabolomic kit of its kind was launched which enables quick, accurate detection and quantification of over 180 metabolites from four classes from only 10 microliters of plasma.

**MetaDisI DQ™ Kit:** The MetaDisI DQ™ Kit is part of a new generation of research diagnostic tools providing metabolomics information that allows a comprehensive assessment of a person’s metabolic state.

**SteroI DQ Kit:** The Kit offers a unique experience in standardized, quantitative steroid hormone detection by simultaneously analyzing (multiplexing) 16 different steroid hormones with tandem mass spectrometry (LC-MS/MS).

Website: http://www.biocrates.com/

**bioMérieux S.A.**

A world leader in the field of in vitro diagnostics for over 45 years, bioMérieux provides diagnostic solutions (reagents, instruments and software) that determine the source of disease and contamination to improve patient health and ensure consumer safety. Our products are used for diagnosing infectious diseases and providing high medical value results for cardiovascular emergencies and cancer screening and monitoring. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products. Microbiology, immunoassays and molecular diagnostics

Our fully automated systems are constantly evolving and integrating an increasing number of parameters. bioMérieux is one of the few companies mastering the complete range of technologies essential for in vitro diagnostics:

- Microbiology
- Immunoassays
- Molecular diagnostics

Clinical diagnostics for infectious diseases

We are focused on diagnosing infectious diseases - in particular, sepsis, healthcare-associated infections, tuberculosis, AIDS and hepatitis.

Our primary goals:

- Reducing time to results to help clinicians choose the right treatment for their patient faster
- Delivering Full Microbiology Lab Automation™ to streamline laboratory workflow and boost efficiency with a complete range of automated platforms for blood culture, identification, antibiotic susceptibility testing and microbial strain typing

Website: http://www.biomerieux.com

**Bio-Rad Laboratories**

Founded in 1952, Bio-Rad has its headquarters 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: http://www.bio-rad.com/

**Care s.r.l.**

Care s.r.l. is an Italian Company dealing with the manufacturing and distribution of in vitro diagnostic devices and development and management of Internal and “External Quality Assessment Schemes” (EQAS) and Internal Quality Control (IQC) profiles for Laboratories all over Italy. Originally, CARE was focused on the production and development of Laboratory immuno-diagnostics, specializing in infectious diseases as development of reagents for the diagnostics of Hepatitis and HIV. In 1992 has focused its activity on the production of a complete line of ELISA Immunodiagnostics on microplate for Hepatitis B and Torch Group Diseases, starting to sell these products all over Italy and the world. As far as this activity is concerned, in 1993, CARE achieves the registration of the IVD Supermik (HbsAg ELISA kit) at the Italian Department of Health. Subsequently CARE focuses on the organization of External Quality Assessment Schemes (EQAS), which it supplies all over Italy. CARE has always oriented its productive and development activities to GMP and in June 24, 2004 CARE certified its own Quality System, according to UNI EN ISO 9001:2000 and from 2007 UNI EN ISO 13485:2003 having the following subject: “Design and manufacture of in vitro diagnostic reagents, internal quality control (IQC) materials and external quality assessment (EQA) schemes”

Website: http://www.dicocare.org
De Gruyter Publisher, Berlin/Boston/Beijing

De Gruyter is an international academic publishing house headquartered in Berlin, Germany, with a US branch based in Boston and a recently established second branch in Beijing. For more than 260 years the name De Gruyter has been synonymous with high-quality, landmark publications in the humanities and natural sciences. The scope of the publishing program includes theology and philosophy, biology, chemistry and material sciences, medicine, mathematics and physics, linguistics and literature, history and archaeology, and law. In all these areas De Gruyter has consistently partnered with exceptional scholars to establish itself as a key international publisher.

Annually, we publish more than 850 new titles, both in print and as ebooks, in both German and English, and we offer a backlist of 12,500 titles, all also available both in print and as ebooks. In addition, we offer more than 230 academic journals, as well as a variety of electronic media publications.

De Gruyter is widely recognized for its acclaimed Pschyrembel® series, the standard German medical reference book - a powerful and competent encyclopedia. We further have a strong reputation in scientific textbooks. In laboratory medicine, De Gruyter offers the textbook Renz: “Praktische Labordiagnostik” (practical laboratory diagnostics). Beyond works for students, De Gruyter publishes high quality handbooks for researchers, such as Kessler: “Molecular Diagnostics of Infectious Diseases”, Herrmann/Obeid: “Vitamins in the Prevention of Human Diseases”, Renz: “Autoimmune Diagnostics”, or Kazmierczak: “Diagnostic Enzymology”. De Gruyter has also launched the “Patient Safety” book series dealing with hot topics like Medical Errors and Patient Safety, Hemolysis, Herbal Supplements, Immunodiagnostics or POCT.

By acquisition and the foundation of new journals De Gruyter could increase its number of scientific journals from formerly 150 to now 230. Beside our traditional, long-standing journals in the biochemical and medical fields, like Clinical Chemistry and Laboratory Medicine (CCLM), LaboratoriumsMedizin (Journal of Laboratory Medicine), Biological Chemistry, Biomedical Engineering, or the Journal of Perinatal Medicine, we offer now additional journals as for example Drug Metabolism and Drug Interactions, Reviews in the Neurosciences, or Nanotechnology Reviews, each offering a high quality, international forum for scientists in the respective disciplines.

Website: http://www.degruyter.com

DiaSys Diagnostic Systems

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 introduced more than 80 optimised reagents for routine and special diagnostics in user-friendly kits for manual or automated use. Additionally, the programme includes a broad range of appropriate calibrators and controls.

The analytical instrumentation portfolio comprises automated clinical chemistry system analyzers, semi-automated analyzers, POC instruments as well as glucose/lactate/hemoglobin analyzers. The instrument line is completed by reverse osmosis systems for purified water.

DiaSys is an ISO certified company since 1996 (valid certificates ISO 13485:2003, ISO 9001:2000). To date, customers and partners in more than 100 countries around the world rely on DiaSys quality.
Website: http://www.diasys-diagnostics.com/

Drew Scientific Co. Limited

Drew Scientific designs, manufactures and sells a range of analytical instrumentation for clinical chemistry and haematology laboratories in both human and veterinary medicine. The company operates from three sites in Texas, Connecticut and England. Drew has distributors in 150 countries.

The company’s chemistry product range includes analysers for glycated haemoglobin, haemoglobinopathies and blood chemistry. For haematology the company has a range of systems for human, veterinary and research use, offering five part white cell differential counting and as many as 30 different species.

Both ranges of analysers are backed by a comprehensive range of reagents, calibrators and controls. Drew Scientific is a wholly owned subsidiary of Escalon Medical Corporation Inc.
Website: http://www.drew-scientific.com

Gentian AS

Gentian is a privately held company with products and patent protected technologies for chemical analysis of human and veterinary samples.

Gentian’s tests are based on particle enhanced turbidimetry and nephelometry. Focusing on precise measurements of kidney function, Gentian has become a leading force in introducing the novel renal marker Cystatin C in routine diagnostics in clinical laboratories worldwide. Superior to serum creatinine, MDRD and invasive renal diagnostic methods, Cystatin C is also an early risk marker for cardiovascular disease. However, the potential of this marker is dependent on a strong assay signal. The technology of enhancing assay signal strength is Gentian’s market advantage. Gentian is situated in Oslo, Norway and Beijing, China. Valid certificates include ISO 13485:2003 and ISO 9001:2000.
Website: http://www.gentian.no

HyTest Ltd.

HyTest Ltd., founded in 1994, offers innovative solutions for assay development and research applications by providing high-quality immunological reagents in such areas as cardiac markers, infectious, neuroscience, biological warfare agents and autoimmune disease reagents. HyTest is a leading provider of several reagents such as antibodies and antigens of the troponin I, troponin complex and Influenza A and B. HyTest offers also extensive customer services and has a certified ISO 9001:2000 quality system.
Website: http://www.hytest.fi
A. Menarini Diagnostics
Born as a division of pharmaceutical A. Menarini Industrie Farmaceutiche Riunite, headquartered in Florence and with over 13,000 employees in 70 countries, A. Menarini Diagnostics is a health care company with more than 30 years of experience in developing and leading the European market of prevention and focused on diagnostics. The company is an integral 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.

Immunodiagnostic Systems Ltd (IDS Ltd)
Immunodiagnostic Systems (IDS) is dedicated to the development and provision of innovative Immunoassays and automated immunoanalyser technologies for use in clinical and research laboratories worldwide. The company enjoys a dominant position in the provision of immunoassay kits for the determination of Vitamin D (both 25-Hydroxy Vitamin D, and 1,25-Dihydroxy Vitamin D). Website: http://www.idsl plc.com/

Innotrac Diagnostics Oy
Innotrac Diagnostics provide state-of-the-art immunoassay systems for cardiac markers and critical care diagnostics. Automated Innotrac AioFlex™ immunoanalyzers are truly easy-to-use, making them ideal both for critical care environment and for larger laboratories. Innotrac AioFlex™ is the only continuous and random-access immunoassay system giving rapid and fully quantitative results directly from whole blood, plasma or serum. Proven Innotrac AioFlex™ systems exploit both the benefits of non-enhancement time-resolved fluorometry and Innotrac’s patented dry chemistry technology to provide fast and simple assays with no reagent preparation. In addition to being highly sensitive, the 2nd generation Innotrac AioFlex™ cardiac troponin I assay brings increased diagnostic usefulness to troponin measurement by reducing interference from cardiac autoantibodies (improved immunoassay, patent pending), also known as interfering factor. Innotrac Diagnostics Oy, founded in 1995, is an experienced provider of immunoassay reagents and contract manufacturing services meeting the high requirements of clinical laboratories, diagnostics and pharmaceutical industry and research institutions. Innotrac's expertise in streptavidin plate coating and antibody biotinylation is used to provide both off-the-shelf products and products tailor-made to the individual needs of research and industrial partners. Website: http://www.innotrac.fi/

Labquality
Labquality is an impartial organization owned by Hospitals and associations. The aim of External Quality Assessment Schemes (EQAS) is to improve quality in clinical laboratories by supplying data to the laboratories on their performance compared with other laboratories. Labquality is a member of EQALM (External Quality Assessment in Laboratory Medicine) and cooperates with other EQA organizers in Europe. Website: http://www.labquality.ft/in_english/

Merck Millipore
Overview
Merck Millipore is the Life Science division of Merck KGaA of Germany and offers a broad range of innovative, performance products, services and business relationships that enable our customers’ success in research, development and production of biotech and pharmaceutical drug therapies. Through dedicated collaboration on new scientific and engineering insights, and as one of the top three R&D investors in the Life Science Tools industry, Merck Millipore serves as a strategic partner to customers and helps advance the promise of life science. Headquartered in Billerica, Massachusetts, Merck Millipore has around 10,000 employees, operations in 67 countries and 2010 revenues of EUR 1.7 billion. Merck Millipore operates as EMD Millipore in the U.S. and Canada.

Pure water expertise for biomedical laboratories
With over 50 years of experience in laboratory water purification and an installed base of more than 100,000 water purification systems worldwide, our long history of collaboration with biomedical laboratories has enabled us to develop our expertise concerning biomedical applications as well as water purification technologies. Merck Millipore offers a complete range of water purification systems designed to match the needs of small through large volume applications. Compatible with any analyzer, these direct-feed systems are economical, easy to use, save and improve productivity and results. Our portfolio includes the AFS®, Elix®, and Elix® Gulfstream Clinical product ranges.

Website: http://www.millipore.com/labwater

Mindray
Mindray was founded in 1991 with the goal of delivering high-quality, competitively priced medical devices to make healthcare more accessible and affordable around the world. In 2006, Mindray listed on the New York Stock Exchange. The company has three well-established business segments: Patient Monitoring and Life Support Products, In-Vitro Diagnostic Products and Medical Imaging Systems. Health care facilities equipped with Mindray’s products can be found in over 190 countries and regions. The IVD Mindray has a global R&D network with research centers in Shenzhen, Beijing, Nanjing, Seattle, New Jersey and Stockholm. Approximately 10% of total revenue has been consistently re-invested into R&D each year. An average of eight new products has annually been introduced to the market over the past seven years.

Website: 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, MEdition+sience: Creating a Healthy and Safe Society through Medical Science.” Its core business today comprises the development, production and distribution of analysis devices and reagents set 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 cooperations 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: http://www.mitsubishichemical.com

Nova Biomedical Corporation
Nova Biomedical’s clinical laboratory business comprises point of care iVd test systems used in hospital and primary care settings. These include innovative new hand held point of care sensors as well as an array of blood gas and critical care analysers offering a wide menu range. Website: http://www.novabiomedical.com/

Ortho-Clinical Diagnostics, Inc.
Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company, delivers the high quality in vitro diagnostic products that give healthcare professionals around the world the knowledge they need to make better treatment decisions sooner. The company serves the global transfusion medicine community with donor screening and blood typing products to help ensure every patient receives blood that is safe, the right type, and the right unit. Ortho Clinical Diagnostics also brings sophisticated information management, testing technologies, automation and interpretation tools to clinical laboratories worldwide to help them run more efficiently and improve patient care. Website: http://www.orthoclinical.com

PerkinElmer
PerkinElmer is a global company focused on improving the health and safety of people and their environment. From earlier medical insights and more effective therapies to cleaner water and safer homes, PerkinElmer touches the lives of millions of people around the world every day. At PerkinElmer, we’re taking action to make people healthier. Our Human Health business develops research and diagnostic instrumentation technologies as well as clinical resources and support services, all to fight illness proactively, provide medical insight more accurately and develop therapies more quickly. From preconception through early childhood PerkinElmer is actively committed to protecting the health and well-being of expectant mothers, babies and families. Through screening and diagnostic systems, clinical lab services and cord blood banking, we’re integral to the health of your family every step of the way. Website: http://www.perkinelmer.com

Phadia AB
Phadia develops, manufactures and markets complete blood test systems to support the clinical diagnosis and monitoring of allergy, asthma and autoimmune diseases. More than 3,000 laboratories in 60 countries use the company’s products. Supplying seven out of ten allergy laboratory tests worldwide, Phadia has remained the world leader in its field for more than 25 years. Our ImmunoCAP® symptom profiles provide allergists, paediatricians and primary care physicians with precise, quantitative measurements of specific IgE levels, supporting the prognosis, diagnosis and follow-up of allergic patients. Website: http://www.phadia.com

Philips
At Philips, we try to simplify healthcare through combining our unique clinical expertise with human insights to develop innovations that ultimately help to improve the quality of people’s lives. With a growing presence in cardiology, oncology, and women’s health, we focus on the fundamental health problems with which people are confronted, such as congestive heart failure, lung and breast cancers and coronary artery disease. Our focus is to deliver value throughout the complete cycle of care: from disease prevention to screening and diagnosis through to treatment, monitoring and health management. Philips is dedicated to making an impact wherever care happens, within the hospital - critical care, emergency care and surgery – and, as importantly, in the home. Philips Handheld Diagnostics focuses on developing innovative solutions to revolutionize point of care testing with a fully-automated rapid diagnostics testing platform that will deliver lab-equivalent test results at the point of care – within minutes. Website: http://www.philips.com/magnotech

Radiometer Medical ApS
Radiometer is a leading provider of technologically advanced solutions that simplify and automate all phases of acute care testing. Radiometer offers solutions for blood gas analysis, immunoassay testing and transcutaneous monitoring. By providing fast and accurate acute diagnostic results, healthcare professionals can make immediate and well-informed decisions that enable them to improve patient care and optimize patient flow in all acute care settings – intensive care units (ICUs), emergency departments (EDs) and operating rooms (ORs). 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. A long series of new product platforms have been developed since then making Radiometer the ‘gold standard’ in blood gas analysis. Also today, Radiometer is focused on innovation and invests heavily in research and development of new and improved acute care solutions that enable fast and accurate diagnosis and treatment of critically ill patients. At Radiometer, we pride ourselves on having both international scope and local reach, closely supporting entire multi-hospital networks, individual hospitals and small community clinics in over 100 countries around the world. For more information about blood gas analyzers, immunoassay analyzers or transcutaneous monitoring solutions, visit http://www.radiometer.com. For information about the latest trends in acute care testing, visit http://www.acutecaretesting.org. Radiometer’s knowledge site.
Chapter 3: Corporate Members

Randox Laboratories Ltd.
Randox Laboratories, a market leader within the in vitro diagnostics industry, has 30 years experience in developing and manufacturing high quality products for laboratories worldwide. Our extensive product portfolio offers complete solutions within the fields of clinical chemistry, forensic toxicology, veterinary, drug residues, life sciences, oncology, molecular diagnostics and internal and external quality control.

Our innovative approach to diagnostics has enabled the development of a wide range of products including our benchtop clinical chemistry analysers, the RX daytona, RX imola and RX monza. The advanced functionality of each analyser ensures outstanding flexibility, optimum reliability coupled with a comprehensive test panel and cost saving features. The most recent addition to the RX series, the RX suzuka, offers high quality testing for the larger throughput laboratory.

Randox has also developed a full range of immunoassay analyser systems. The Evidence family of analysers include the Evidence, Evidence Investigator, Evidence MultiStat and Evidence Evolution. Each system incorporates revolutionary Biochip Array Technology that allows simultaneous detection of multiple analytes from a single patient sample.

Rapid effortless testing, advanced consolidation and high quality results are a few of the many benefits of the Evidence analysers. The extensive biochip test menu includes both protein and DNA biochips, expanding the range to over 215 different biomarkers.

Our goal is to ‘revolutionise healthcare through continuously improving diagnostic solutions’. We continue to achieve this year after year due to our commitment and significant re-investment in Research and Development. Our large support network of staff allows us to develop and perfect revolutionary products, specifically designed to provide more efficient, higher quality and reliable results, ensuring patients receive the right diagnosis at the right time.

Website: http://www.randox.com/

Response Biomedical Corporation

Responde Biomedical develops, manufactures and markets rapid on-site diagnostic tests for use with its RAMP® platform for clinical and environmental applications. RAMP® represents a new paradigm in diagnostics that provides high sensitivity and reliable information in minutes. It is ideally suited to both point of care testing and laboratory use. The RAMP® system consists of a Reader and single-use disposable test cartridges, and has the potential to be adapted to more than 250 medical and non-medical tests currently performed in laboratories. RAMP® clinical tests are commercially available for the early detection of heart attack and congestive heart failure.

Website: http://www.responsebio.com/

Roche Diagnostics GmbH

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, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche’s personalised healthcare strategies aim at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients.

In 2008, Roche had over 80,000 employees worldwide and invested almost 9 billion Swiss francs in R&D. The Group posted sales of 45.6 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan.

Website: http://www.roche.com

Scipac Ltd.

SCIPAC provides a wide selection of human proteins, disease plasma and depleted sera and antibodies for the worldwide clinical diagnostics manufacturers.

Diagnostics assays are a major component of modern medical examination and many hospital laboratories across the world use diagnostics kits containing SCIPAC components. With “Raising the Standard” as a key pursuit they have ISO 9001 and 13485 registration and a constant striving for better standards of production and customer service.

This is appreciated by SCIPAC customers and reflected in the company’s expansion and reach. Their products are now used by assay manufacturers in over 30 countries with 60% of sales to the USA. Sales expansion in both bulk sales and increased product range have meant steady growth with sales have doubling in the past three years. The aim of the founders to provide the complete SCiScientific PAKcage has been fulfilled very successfully.

The link with academia has always been highly valued and has been expanding over the past few years. Sunny-Lab.com is a new business venture which enables the researcher to obtain smaller packages by direct credit card purchase. This e-commerce site also encourages academics to share information and get feedback on their work.

An exciting new venture for a visionary, outward looking company. SCIPAC is situated at Sittingbourne, 40 miles southeast of London.

Website: http://www.scipac.com

Sebia S.A.

Develops, manufactures and commercializes protein electrophoresis tests and analyzers, dedicated to the in vitro diagnosis of cancer, inflammatory, metabolism and hemoglobin disorders.

SEBIA’s focus on electrophoresis techniques, allows a sustained R&D program, providing to any type of labs access to genuine evolution. 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) and for capillary electrophoresis, (CAPILLARYS™ 2, MINICAP™).

SEBIA has recently diversified its activity by introducing Capillaries 2 Flex Piercing, the most advanced capillary technology, providing high level of performance, bringing complete walk-away automation. Tests available are serum proteins, urine proteins, Immunotyping, high resolution electrophoresis, CDT, and haemoglobinopathy screening from whole blood in primary capped tubes. Recently, SEBIA has diversified its activity in the field of diabetes, to fulfill the growing worldwide demand for more accurate and reproducible methods for HbA1C measurement.

Website: http://www.sebia.com

Sekisui Diagnostics (UK) Limited

In 2011 Sekisui Diagnostics was created from the acquisition of Genzyme Diagnostics by Sekisui Chemical.

We offer a unique product portfolio for diagnostic manufacturers and healthcare professionals worldwide, comprising of Critical Raw Materials, Clinical Chemistry Reagents, and Point of Care Rapid Tests.

Our competency in microbial fermentation, purification, and reagent formulation allows us to supply more than 50 intermediate products to clinical chemistry manufacturers and over 60 formulated reagents to chemistry instrument manufacturers and clinical laboratories worldwide. These portfolios are focused on diagnostic solutions for Cardiovascular disease, Diabetes, and Renal disease.
Our OSOM® branded Rapid Tests for infectious diseases and women’s health are developed for use in the point-of-care setting, designed to help physicians quickly and accurately diagnose their patients in order to provide the most appropriate treatment. Sekisui Diagnostics also has active research programs in a variety of different clinical areas.

Website: 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 10,000m². 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), 21 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, equipments 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: http://www.sentineldiagnostics.com

Sysmex Europe GmbH
SYSMEX EUROPE GMBH, Germany-based daughter company of SYSMEX CORPORATION, Kobe, Japan, is responsible for customer and sales support for Sysmex’s in vitro diagnostic systems and reagents as well as manufacture and sales of reagents for Sysmex’s in vitro diagnostic systems in the European, African and Middle East markets.

Sysmex, a manufacturer of comprehensive clinical testing, is engaged in clinical laboratory testing of blood, urine and other specimens, covering the areas of haematology, haemostasis, immunochemistry, biochemistry, urinalysis and faecal occult blood testing.

In the field of haematology, Sysmex holds the global market leader position. In addition to providing instruments and reagents for clinical laboratory testing, Sysmex is also developing a broad range of laboratory information systems and application software, thus offering information technology as part of its comprehensive service and support system. Integration of those various technologies is the driving force behind Sysmex’s business activities.

Sysmex is also developing these technologies and expertise to expand its areas of business. For example, it is expanding into such fields as point of care (POC) testing - clinical laboratory tests conducted on the spot, such as in the hospital operating room, intensive care unit, or at the clinic - to enable faster diagnoses, centralized test data management for improved testing efficiency, and the establishment of local healthcare networks to link hospitals and clinics.

At the same time, Sysmex is also creating new core technologies to address the challenges of disease prevention and early cancer detection. By expanding its business into these healthcare testing fields, Sysmex intends to contribute to the creation of a vibrant and healthy society. In addition, Sysmex is applying the technologies that it has devised in the field of clinical laboratory testing to industry, sports, and other new business fields.

At Sysmex, we have adopted two commitments to the future: to continually develop advanced technologies and create value with the aim of serving our customers and society at large; and to play a key role in contributing to the health and vitality of people the world over. It begins with close attention to the voices of our customers.

Website: http://www.sysmex-europe.com
Thermo Fisher Scientific
Thermo Fisher Scientific Inc. (NYSE: TMO) is the world leader in serving science. Our mission is to enable our customers to make the world healthier, cleaner and safer. We have approximately 37,000 employees and serve customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as in environmental and process control industries. We create value for our key stakeholders through two premier brands, Thermo Scientific and Fisher Scientific, which offer a unique combination of continuous technology development and the most convenient purchasing options. Our products and services help accelerate the pace of scientific discovery, and solve analytical challenges ranging from complex research to routine testing to field applications.

Unilabs
Unilabs is a leading clinical European supplier of laboratory medicine and radiology services with operations in 12 European countries.
Unilabs supplies diagnostics services to:
- Public and Private healthcare units
  - Hospitals
  - Outpatient clinics
  - GPs
  - Occupational health units
- County councils
- The general public
- Insurance companies
Unilabs also provides Laboratory and Logistics services for drug development companies & CROs.
Website: http://www.unilabs.com/

Wako Pure Chemical Industries, Ltd./Wako
Wako Pure Chemical Industries, Ltd. is a leading provider of clinical chemistry reagents and systems. Since 1922, Wako has devoted itself to pioneering the research, development, and manufacturing of high quality reagents since 1922. Headquarters in Osaka, Japan, Wako is an, becoming a international global in vitro diagnostic company with research, manufacturing, and sales offices and marketing in Japan, the United States and Germany. Wako is committed to the development of novel diagnostic and research reagents in the life sciences. Through intensive studies in clinical chemistry, immunoassay and microfluidics, Wako keeps abreast of the latest provides state-of-the-art diagnostic developments in medical science, systems in order to develop products tailored to the sophisticated requirements of our clients in various medical fields. Wako has developed a wide range of liquid chemistry reagents designed for use in the clinical laboratory. They include innovative reagents assays that use microfluidics (AFP-L3% and des-carboxy Prothrombin), liposome technology, the reagent for total complement activity (CH50), and the a micro-organism detection system using LAL and SLP to detect endotoxin, glucan, and peptidoglycan. Wako provides advanced assays for Free Fatty Acid (NEFA), enzymatic Creatinine, hyaluronic acid, as well as superior reagents for standard clinical chemistry analytes.
Wako has a consistent focus on the development of new and important tests for the diagnostic community. For example, Wako now provides a test that includes both novel chemistry and instrumentation for the measurement of AFP-L3%, a test that will improve the chances for finding liver cancers at an earlier and more treatable stage. Recently, Wako has also introduced a bench top clinical analyzer that utilizes many of these chemistries at the point of care in the physician's office, bringing the value of testing closer to the patient. As one of the industry's leading pioneers, Wako will continue to develop and supply chemicals, reagents, and instruments of the highest quality to meet the growing and changing needs of the diagnostic and research communities.
Website: http://www.wako-chem.co.jp

Wiener Lab
Wiener lab. develops, manufactures and markets FDA approved diagnostic reagents since 1960. It is also the distributor of technical equipment from international renowned companies. It is located in Rosario, Argentina, in a crossroads of the Mercosur. It is the leading manufacturer of diagnostic reagents in Latin America and its sales network includes six associated companies in Brazil, Chile, Colombia, Mexico, Peru and Venezuela, and has sales representatives in the other countries of the region. Its exports operations for Eastern Europe and the Middle East are performed through its associate company Wiener lab. Switzerland.
Wiener lab. products are focused on clinical analysis and specialisation hospital laboratories. Its products are based on the research, development and production of monoclonal antibodies to manufacture several tests: Hepatitis, Pregnancy, Blood Typing; production and purification of antigens for the detection of parasitic (Chagas’disease, Toxoplasmosis), bacterial (Brucella, Salmonella) or viral (Hepatitis, AIDS) diseases; applied research on recombinant nucleic acids and nucleic acid probes, as well as PCR (Polymerase Chain Reaction) procedures; design of recombinant proteins and synthetic peptides with antigenic activity; and research on different branches of Biotechnology. The leading edge technology in the research and development of diagnostics kits for Chagas’disease have earned Wiener lab. an outstanding position within the diagnostic market.
Some of Wiener lab. products are the result of joint projects with renowned research centres. Along with the Programme for Appropriate Technologies in Health (PATH-Seattle, USA), Wiener lab. has developed a high sensitivity, non-instrumental procedure for HIV carriers screening, the D.I.A. (Dot Immuno Assay) HIV 1+2, which has been evaluated and approved by the World Health Organisation.
Wiener lab. keeps up to date in scientific research and manufacturing technologies in order to improve and develop products of advanced technology.
Website: http://www.wiener-lab.com.ar