

Accelerate Your Commercial Success: Become a Luminex Licensed Technologies Partner

When Luminex signed its first Partner in 1998, few would have expected that almost 20 years later, Luminex's Partners would generate for themselves more than \$3.5 billion in kit and testing services revenue.

Are you interested in developing, manufacturing, and commercializing a multiplexed assay on a platform that is efficient, flexible, and widely-adopted? Learn how Luminex xMAP® Technology can be right for your business. This case study highlights three companies that demonstrate the diversity of market segments, company size and geographic presence of Luminex Partners who are successfully leveraging Luminex's xMAP Technology to grow their business:

- NMI TT Pharma Services
- Myriad RBM
- Beijing Unionluck Biological Technology Company

xMAP is a versatile bead-based technology with an open architecture design that supports a wide range of nucleic acid and protein applications. The color-coded microspheres enable the detection of up to 500 analytes simultaneously using a single aliquot of sample per reaction well. Other benefits of adopting xMAP multiplexing technology include the ability to create assays that optimize sample volume and reduce time to actionable results.

When selecting a multiplexing technology platform for your business, other considerations are equally important contributors to success. "You won't go it alone when you partner with Luminex," notes Tom Copa, Vice President of the Licensed Technologies Group. "Luminex offers a robust toolkit of resources to enable the development and commercialization of your xMAP-based assay."

"Partnering with Luminex provides companies with a proven path to enable their innovation. We do this by offering a cost-effective platform, a flexible licensing model, and a track record of successful Partner relationships." adds David Bourne, Vice President of Business Development and Strategic Planning.

When you become a Luminex Partner you join part of a community that spans the life science research, drug and vaccine development, clinical diagnostic, agricultural, and biodefense spaces. There are currently more than 60 Luminex Partners worldwide who have launched thousands of analytes formatted into commercially available kits and testing services. Luminex Partners include industry leaders such as Thermo Fisher Scientific, EMD Millipore,

Bio-Rad and Bio-Techne, as well as companies that operate in niche markets providing differentiated products and specialized laboratory services.

Luminex Partner Toolkit

- **Unmatched Expertise** — Manufacturing consultation from the undisputed multiplex assay marketing leader with more than 20 years of experience, and a history of continuous quality improvement from material specification development, through to finished goods quality control, and every step in between
- **Proven Reagents** — Full menu of microspheres, an antibody coupling kit, and ancillary instrument control reagents
- **Unparalleled Adoption** — More than 14,000 xMAP instruments sold globally
- **Technical Training** — In-person and online classes to enhance your knowledge of Luminex technology and systems
- **Bench-side Assistance in Your Lab** — Field Applications Scientists are available to aid in the development and optimization of your assays
- **Proven Protocols** — Take the guesswork out of getting started with the [xMAP Cookbook](#), a collection of proven protocols and reagent recommendations
- **Marketing Support** — Opportunities include access to our digital presence, display space in our trade show booth and collateral, and participation in webinars and xMAP-related scientific symposia
- **Global Presence** — Support from Luminex's Business Managers worldwide, who are in the field talking to your representatives and potential customers every day

A conversation with Dr. Thomas Joos of NMI Natural and Medical Sciences Institute at the University of Tübingen

Can you tell us about NMI and your role?



The NMI Natural and Medical Sciences Institute at the University of Tübingen is a non-profit organization, a private foundation, which undertakes applied research and development at the interface of life sciences and material sciences. It is involved in application-oriented research at the interface between life

and material sciences. An interdisciplinary team of scientists is performing research and development projects for companies and public research sponsors in the areas of pharma and biotechnology, biomedical technology, and surface and materials technology. The NMI and is located in Reutlingen, Germany.

I am dedicated to developing new technologies, specifically high-throughput protein immunoassays. Nearly two decades ago, I simultaneously began my career at NMI and my relationship with Luminex. Holding roles of increasing responsibility during my tenure, I am currently the Head of the Biochemistry Department and Deputy Managing Director of NMI.

Who are your customers and what products and/or services does NMI offer?

We are offering development of multiplexed sandwich immunoassays and sample testing services. In addition, we are running antigen assays to profile the serological response to HCV, TB, and other pathogens. Recently my colleague Markus Templin invented the DigiWest protein profiling approach. Here, we use the Luminex platform in our DigiWest High Content Protein Profiling service for our customers in the pharma and biotech industry. DigiWest is a novel proprietary immunoassay technology that is very robust and allows measurement of up to 600 analytes from <math><50\ \mu\text{g}</math> of protein. It is fully customizable based on a list of over 1,000 antibodies (and validated antibody lists for human, mouse, rat, dog, minipig, and cyno). DigiWest is a versatile platform that enables comprehensive analyses from limited samples, for pathway profiling, drug MoA studies, lead characterization, predictive toxicity, and biomarker screening. It also quantifies post-translational modifications, including phospho-epitopes.



Why the Luminex xMAP Technology?

We have been collaborating with Luminex since 2001, and we have 12 Luminex instruments including Luminex® 100/200™, MAGPIX®, and FLEXMAP 3D®. Without Luminex, I wouldn't have been as successful within the field of immunoassay technologies. In 2015 we became an official Luminex partner to run our DigiWest Services in Reutlingen at our subsidiary at the CoLaborator in Berlin, Germany.

I received one of the first Luminex 100™ instruments in 2001. Within a few years, my group had run more than 30 feasibility studies for potential Luminex customers based in Europe. In between, NMI has more than 50 publications showing data generated with Luminex technology.

We have been pleasantly surprised by the ease with which we can switch from planar array to a Luminex bead-based assay. Our experience has been that capture and detection antibodies used on an ELISA plate can be transferred to xMAP format, and that assay development is accelerated using bead-based Luminex technology.

I appreciate that Luminex has continued to innovate the xMAP platform, introducing magnetic microspheres to the market that enabled us to remove wash steps in our assay workflow. We were an early testing site for this innovation and were able to improve the robustness of our assays. Also, the open architecture has been very beneficial for us.

I attribute Luminex's 20+ year staying power to the open architecture and dependability of the xMAP platform, as well as the value-based price point.

Can you share with us any other benefits of becoming a Luminex partner that might not be readily apparent?

In addition to strong support, the ability to simultaneously test up to 20 antibody pairs per analyte on xMAP provides a very efficient path to determine the optimum pair, and accelerate multiplexed assay development. This is a big advantage of the Luminex technology. Besides this, the Luminex technology is outstanding to run serological assays, whether you have only a few antigens, or whether you run a multipathogen assay with more than a hundred different antigens. Assay performance and throughput is outstanding.

A conversation with Sam LaBrie, Senior Vice President of Corporate Development at Myriad RBM, Inc.

Sam, can you tell us about Myriad RBM and your role?



Founded in 2002, Myriad RBM, Inc. is the world's leading multiplexed immunoassay testing laboratory, providing comprehensive protein biomarker services based on its Multi-Analyte Profiling (MAP) technology platform. This platform provides pre-clinical and clinical researchers with reproducible and quantitative data for a

few or hundreds of proteins in a cost-effective manner. All services are performed in our CLIA certified biomarker testing laboratory, located in Austin, Texas.

Myriad RBM is a wholly owned subsidiary of Myriad Genetics, Inc. (MYGN), a leading molecular diagnostic company based in Salt Lake City, Utah which develops and markets novel predictive medicine, personalized medicine and prognostic medicine tests. Myriad Genetics was founded in 1991, has approximately 2,600 employees and had 2016 revenue of \$754M.

I have been with the company for nearly a decade and manage the development of new products through collaborations and strategic partnerships.

Who are your customers and what products and/or services does Myriad RBM offer?

Myriad RBM offers biomarker testing services that support diagnostic science and clinical trials. Its customers include pharmaceutical companies and researchers in academic and discovery laboratories.

Identification of biomarker patterns in a biological sample, such as serum or plasma, can dramatically increase the success of almost any drug development program. Our MAP approach provides investigators with a reliable platform that allows discovery, validation and clinical use of these patterns in a cost-effective and efficient manner.

Myriad RBM has earned CLIA licensure of accreditation from COLA, participates in external proficiency testing programs from the College of American Pathologists (CAP), and is capable of supporting Good Laboratory Practice (GLP) studies. Standardized procedures, instrumentation, and quality controls are used to ensure quality throughout all aspects of the laboratory from sample receipt



to results reporting. By continuous quality improvement, Myriad RBM ensures that customers are satisfied with the products and service they receive.

Human MAPs represent the most comprehensive menu of quantitative, multiplexed immunoassays commercially available. The Human MAPs provide insight into multiple pathways to help better understand the underlying biology. I'll briefly describe DiscoveryMAP and CustomMAP, although numerous other Human MAPs are available.

DiscoveryMAP v. 3.3 is a comprehensive, quantitative, immunoassay service product, measuring our complete menu of more than 300 human assays. It is the culmination of 15 years of assay development for cytokines, chemokines, metabolic markers, hormones, growth factors, tissue remodeling proteins, angiogenesis markers, acute phase reactants, cancer markers, kidney damage markers, CNS biomarkers, and other important circulating proteins. DiscoveryMAP v. 3.3 is for those who seek a thorough understanding of a compound's biological activity, efficacy, and safety profile as well as the disease or condition being addressed.

CustomMAP is the most popular service as more of Myriad RBM's business is coming from the processing of samples from early to late-stage clinical trials. Customers have the ability to select any assays from the DiscoveryMAP menu and receive those biomarker results along with results from other assays that are in the same set of multiplexes. Customers benefit from the efficient use of precious clinical trial samples and the additional biomarker data.

Why the Luminex xMAP technology?

Myriad RBM has been a Luminex partner since 2002 and has over 60 xMAP instruments. A reduced sample volume requirement and lower cost to generate more data are key benefits that attracted Myriad RBM to the Luminex platform. We appreciate the consistent quality of consumables and the high level of instrument service. As a service laboratory, our instruments must constantly be up and running.

Can you share with us any other benefits of becoming a Luminex partner that might not be readily apparent?

Continuity and consistency of supply from Luminex is excellent. Also, the longevity of the xMAP platform is rather unusual, but is understandable given that the technology works well, is priced right and has consistent quality.



A conversation with Zhiping Zhou, President, and Jianrong Wu, Associate Director of Research and Development, at Beijing Unionluck Biological Technology Company.

Mr. Zhou and Ms. Wu, Unionluck is one of Luminex's newest Partners in China. Can you tell us about your company and the products you offer?



Unionluck began operations in 1996 and we have been a Luminex Partner since 2015. We specialize in the research and development, manufacture, and commercialization of in vitro ELISA-based diagnostic products for the mainland China neonatal disease screening market.

In addition, with the rise of cardiovascular morbidity and mortality in the Chinese population, we initiated a program to expand our portfolio to include kits used to screen for cardiac, vascular and cerebrovascular disease.

The infrastructure to support our product offering includes an established sales team, a nationwide distribution network, and customer support department. Our customers are primarily comprised of hospital-based testing laboratories throughout China.

How did you come about adopting the xMAP Technology, and where are you in your commercial plan?

I [Ms. Wu] was first introduced to xMAP Technology through discussions with a Luminex sales representative who approached me to discuss our mutual interests in neonatal screening assays. We evaluated the technology and immediately determined it would be an excellent multiplex platform for our cardiovascular



assay development program versus other technologies such as chemiluminescence. The open architecture design of the xMAP platform and the ability to develop both protein and nucleic acid based assays were key selling points as we were looking for a technology solution that would support our entire product development strategy.

Efforts are currently underway to meet a target launch date in late 2017 for our first xMAP-based assay – a cardiovascular screening test. Of course this timeline is contingent on a successful clinical validation and approval by the China Food & Drug Administration. We are also on track to commercialize a diagnostic test late in the following year.

Can you share with us any other benefits of becoming a Luminex Partner that might not be readily apparent?

One of the greatest benefits Unionluck received was the onsite instrument and assay development training that was provided by Luminex. This activity was instrumental in quickly becoming proficient on the platform and in assay development.

Unionluck is the first Chinese company to partner with Luminex in the lucrative and competitive Chinese cardiovascular market. Many of our customers are familiar with the xMAP platform, and as we introduce our assays to that market, we are confident adoption will be very good and the products will be a commercial success.



Are you interested in developing, manufacturing, and commercializing a multiplexed assay on a platform that is efficient, flexible, and widely-adopted? Contact Luminex Business Development at: <http://info.luminexcorp.com/en-us/become-a-partner>