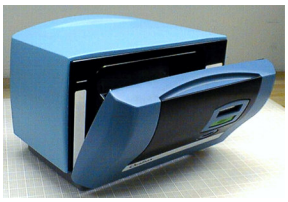
OMNICA CORPORATION
Product Development
Engaging Views and OMNInews
DESIGN AND ENGINEERING NEWSLETTER

Practice makes perfect in IVD instrumentation development

The Omnica technical staff has been involved in the development of laboratory IVD instrumentation for much of their careers. We have worked with chemiliuminescense, photometric, amperiometric, and fluorescence technologies, and are versed with clinical and immunoassay analyzers, immunoassay washers, and liquid handling devices.

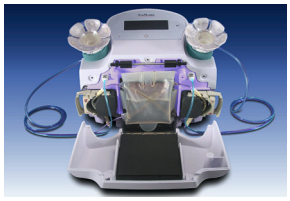
Our experience with chemiluminescence includes a POC instrument for measuring PSA levels. The project featured a patented, fluid-filled assay pack we developed for the client. Omnica performed all the product development for the device and devised a novel manufacturing process to construct and fill the consumable reagent packs. The tabletop POC device is a model of simplicity and efficiency. At the push of a single button the FastPak® system provides laboratory precision immunoassay results in a few minutes.



For another project, the in-house team designed a novel lateral flow electromagnetic immunoassay analyzer using paramagnetic particles as the biomarker label carrier. The biologic and chemical agent identification system utilizes a lateral-flow consumable cassette we designed, engineered, and prototyped at our facility. The current generation of the product has broad applications in medical diagnostics, food safety testing, veterinary health, biodefense, and environmental testing.

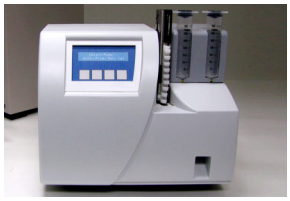
Omnica has performed mechanical and firmware troubleshooting and development on multiple liquid handling projects. For one well-known firm we successfully identified a manufacturing fault that was causing the system to fail prematurely.

For a start-up firm we developed a liquid-handling POC device (for breast cancer risk assessment). One of the challenges was to identify polymers for the fluid barrier that exhibited durability, and also served as a vapor barrier. Urethane was tested as tough, but ineffective for the application. We solved the problem by using EVA, a waterproof, resilient, and flexible thermoplastic as the barrier material. Our team proceeded to construct 12 working prototypes of the tabletop device.



In the last few years we have worked on two diagnostic systems that included a mass spectrometry component. One is a complex TOF mass spectrometer-based system that uses distributed architecture with a controller area network (CAN bus). All firmware and system control software (excluding the pathogen DNA database) was developed by Omnica. In the course of the project we obtained six patents for the client in the field of electrospray ionization and other areas.

Our R&D Group collaborated with Purdue University on a mass spectrometry project that combined paper chromatography and electrospray ionization. We performed the design and engineering for the entire system including the cassette, reagent injectors, high-voltage system, automated magazine, status display, and the Graphical User Interface. The result of the work was the first commercial product to use a PaperSpray ionization source.



Omnica continues to develop IVD devices, instrument systems, and consumables for clients in the areas of real-time PCR laser-induced fluorescence, magnetic particle-based PCR assay technology, and other POC platforms. Presently we are working on a project that involves a custom cartridge with an amperiometric sensor probe.

Ron Sully is Omnica's Director of Marketing
He can be reached at: materialize@omnica.com