

Monobind Fact Sheet

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The Company

Experts in immunoassay development, Monobind has manufactured more than 200 million immunoassay kits since its inception in 1978 and currently produces 40 million tests per year — ranking it as one of the largest *in-vitro* diagnostic producers. As an established industry player and global brand, the company provides assays and biological raw materials to market-leading distributors, laboratories and manufacturers in more than 120 countries. Through its esteemed, internal R&D work and pioneering experience in reagent production, Monobind delivers products that set high quality standards for worldwide diagnostic healthcare.

Monobind is a privately held corporation led by its founder and headquartered in Lake Forest, California.

Our Mission

To enhance health in communities worldwide by supplying laboratory diagnostics which are innovative, simple to use, cost effective and vital for human-care.

Our Products

Monobind's ELISA and CLIA product lines, AccuBind® and AccuLite® compete with the market leaders in the *in-vitro* diagnostic areas of Thyroid & Endocrine, Neonatal Thyroid, Autoimmune Thyroid, Fertility, Growth Deficiency, Diabetes, Cardiac Markers, Infectious Disease, Cancer Markers, Allergy and Anemia. With our innovative VAST® product, in ELISA & CLIA formats, labs receive multiple analytes in one kit and can measure a panel of markers with just one calibrator set. This unique product line allow labs to select one of up to four analytes per break-away well. Monobind's flexible immunoassay systems work with manual to fully automated machines, including walk-away analyzers. Integrated equipment is sold by Monobind, and we offer applications for leading machines. Sophisticated GMP, Regulatory, and QC parameters guarantee reliable and reproducible products as demonstrated by our numerous FDA, ISO 13485 certification, CE Mark and vendor awards.

In addition to its immunoassay business, Monobind processes biomaterials for several of the world's largest diagnostic manufacturers, providing reagent-grade fractionated human blood-products (partnerships with Grifols, Baxter, CSL Behring), purified-human plasma, serum and urine, as well as many custom product development projects, including calibrators and controls.

Our Facility & Production

Designed to meet the GMP requirements and certified ISO 13485 and by the FDA, our 40,000+ square-foot facility incorporates state-of-the-art automated equipment and 24x7 monitoring to support large-scale production. A proprietary software system integrates our QC and production departments and enables total-quality management — from lot-number assignment and raw-material qualification, to in-process QC, batch analysis, and final release. Because a single human error would disable production, our sophisticated procedure of checks and balances greatly minimizes any compromise to quality.

Our Distributors

Without a direct sales-force, Monobind builds its success on relationships with key, reputable distributors located around the globe. This strategy promotes regional expertise and allows Monobind to offer products and formats tailored to the market conditions unique to the area of distribution. By providing quality-certified products and skilled technical support, Monobind and its distributors enjoy a robust and unlimited future in the biomedical industry.

Our Staff

Monobind employs a knowledgeable staff of renowned scientists, QC personnel, production experts, and supporting administrators. With more than 40 years of experience, our efficiency is underscored by the cross training of departments and an advanced online manufacturing system that networks all operations.

As CEO and founder, *Dr. Frederick R. Jerome, Ph.D.* is responsible for overseeing the design of Monobind's product line and the establishment of new markets. Dr. Jerome is a widely regarded expert in immunoassay development and manufacturing.