

Monobind Fact Sheet

Contact: Alicia Jerome Volkov, Director & Corporate Officer, aliciajerome@monobind.com

Headquarters

Lake Forest, CA, USA

Website

www.monobind.com

Year Established

1977, Privately Held

Employees

40+

Markets Served

100+ Countries

Products Delivered

200M+ Kits
100M T4 Tests in USA
40M Tests/ Year

Product Lines

AccuBind® ELISA
AccuLite® CLIA
VAST®
QSure® Controls
Instruments
Biomaterials

Product Focus

Immunology
Hormones
70+ Analytes
150+ Kits

Certifications

ISO 13485 MDSAP
CE Marked
GMP Facility
FDA Registered

Manufacturing

Reagents, Dispensing
100 N. Pointe Dr.,
Lake Forest, CA, 92630 USA
30K+ Square Feet

Plates

103 N. Pointe Dr.,
Lake Forest, CA, 92630 USA
10K+ Square Feet

Kitting/ Warehouse

103 N. Pointe Dr.,
Lake Forest, CA, 92630 USA

The Company

Experts in Assay Development, Monobind ranks among the largest *in-vitro* diagnostic (IVD) producers. As an established industry player, it held the #1 position in the USA for 18 years with its RIA Thyroid tests, then flourished into a global brand across 100+ countries with its Assays, Controls, Instruments and Biomaterials through a skilled network of distributors, laboratories, and manufacturers.

All Monobind Assays, Controls and Biomaterials are developed and produced in-house from raw materials (never OEM-sourced) as backed by Monobind's pioneering R&D authority which has realized IVDs for 70+ Analytes and 100's of Biomaterials. Monobind is laser-focused on raising the bar for patient diagnostics with quality products that are Accurate, Stable, Reproducible and Well-Correlated.

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 AccuBind® ELISA and AccuLite® CLIA products (70+ Analytes) compete with market leaders in the diagnostic areas of Anemia, Allergy, Bone, Cancer, Cardiac, Endocrine, Fertility, Prenatal, Growth, Infectious, Infectious TORCH, Inflammation, Neonatal, Steroids, Thyroid, and Thyroid Autoimmunity.

With the innovative VAST®, in ELISA & CLIA, labs gain the convenience and ability to measure 2 to 4 analytes per kit, choosing one per well, with CombiCal® a multi-analyte matrix in panel-focused products.

Formatted on the 96-well microplate, Monobind Assays, work in open-system manual to automated analyzers. The market need for complete systems: integrated platforms with value-added features led to Monobind Instruments. Likewise, the need for external controls has propelled Monobind QSure® Controls.

In addition to finished IVDs, Monobind processes Biomaterials for several of the world's largest closed-system Diagnostic and Molecular companies, providing reagent-grade fractionated human blood-products, purified-human plasma, serum, and urine, as well as custom R&D projects such as calibrators and controls.

Our Facility & Production

Designed for GMP and ISO 13485 requirements, Monobind's 40K+ square-foot facility houses state-of-the-art equipment and automation that supports large-scale production: Annually approx. 4M vials via 4 dispensing-lines and 500K plates via 3 coating-lines using a single shift, with more capacity through additional shifts. Biomaterials process 30+K liters of Plasma annually, many of which are found in Monobind products. The use of proprietary systems wed QC, Production, and Fulfillment for **Total-Quality Management** -- from incoming raw-materials, lot-assignment, label creation, batch records, in-process QC, to reagent dispensing and final product release.

Our Distributors

Monobind partners with reputable organizations to bring quality products to market with regional expertise, as well as skilled sales- and technical-support. Flexible design cycles allow Monobind to respond quickly to meet market needs with new or refined products. Together, Monobind and its distributors enjoy a robust and unlimited future in the biomedical industry!

Our Staff

Monobind employees a knowledgeable staff of renowned scientists, QC, production, QA/ regulatory, and administrators. Spanning 45+ years, efficiency is gained by the cross-training of departments, an advanced manufacturing system, ERP and other technology investments to network our operations and markets.

Dr. Rick Jerome, PhD Organic Chemistry, Founder and CSO, *a widely regarded expert in immunoassays.*