

Company Description

Rules-Based Medicine® (RBM) is a CLIA-certified biomarker testing laboratory that spun off of Luminex in 2002. RBM uses multiplexed immunoassays to provide innovative products and services. Enabled by microsphere technology and decades of experience, our proprietary Multi-Analyte Profiling (MAP) platform makes drug discovery and development more efficient and effective. Using extremely small sample volumes, we provide discovery, pre-clinical and clinical researchers with reproducible, quantitative, multiplexed immunoassay data for hundreds of biomarkers.

RBM employs over 140 people at three facilities:

- **Austin, TX:** Corporate headquarters
- **Lake Placid, NY:** Multiplex assay development and manufacturing
- **Reutlingen, Germany:** TruCulture manufacturing and HOT cell culture services

Technology

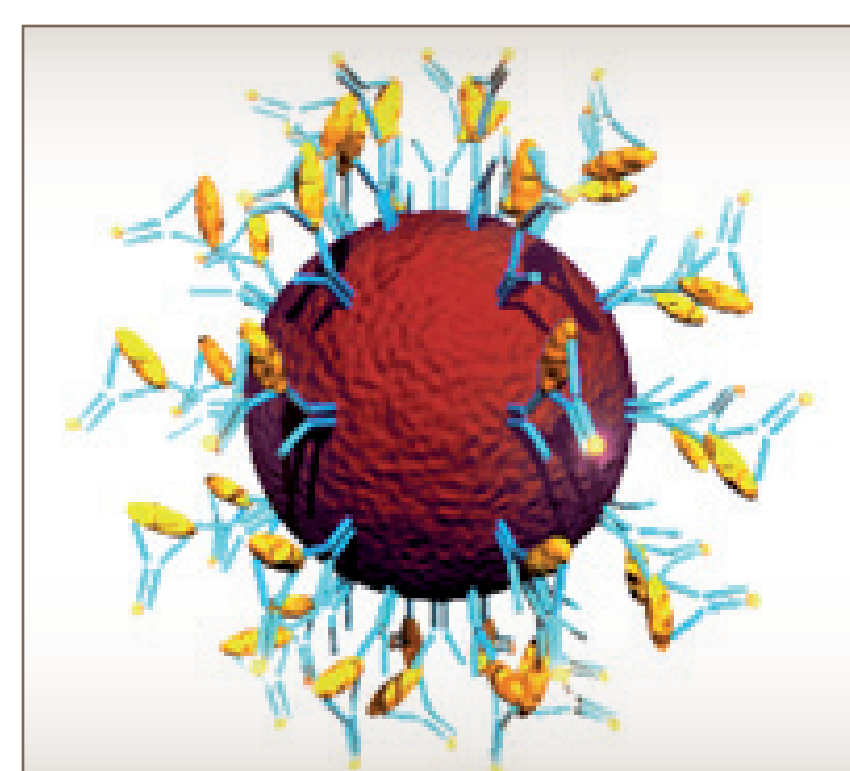


Figure 1A: Schematic of Capture Sandwich

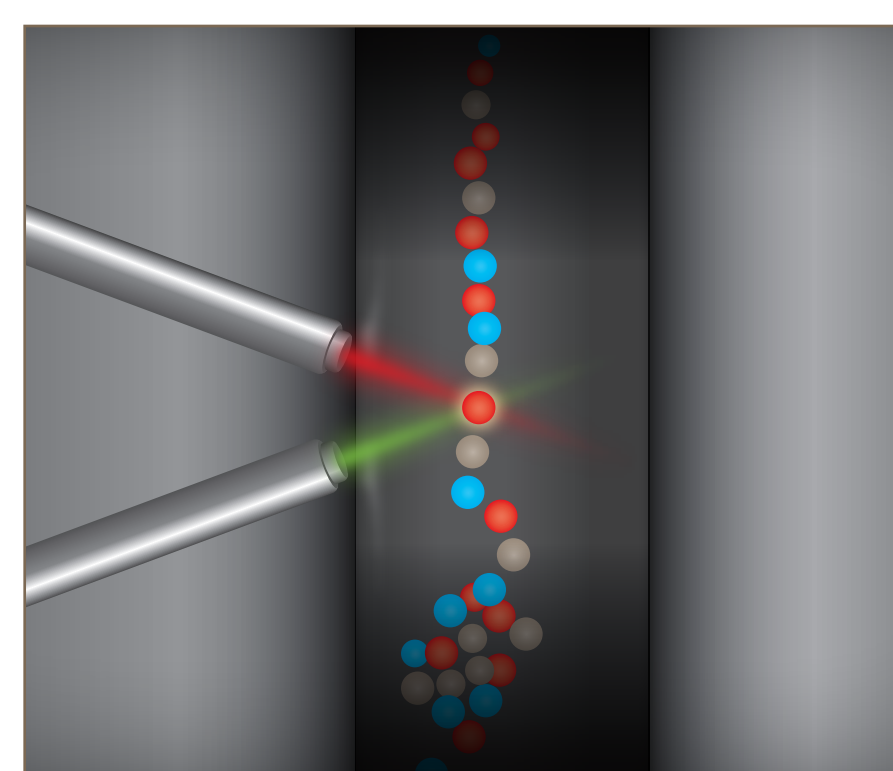


Figure 1B: Detection of Analyte Concentration

The Luminex instruments operate similarly to a flow cytometer, using the principle of hydrodynamic focusing to pass the microspheres, one at a time, along a path that is interrogated by two lasers (**Figure 1B**). The excitation beams measure the unique fluorescent signature of each bead, in addition to the amount of fluorescence generated in proportion to the analyte concentration in the sample, defined by the Median Fluorescent Intensity (MFI). Data are acquired and reported in real-time, giving us the ability to measure an analyte's concentration, many times over, per sample.

Platform

- Industrialized form of Luminex xMAP
- All liquid handling steps automated using the Tecan Genesis platform
- Proprietary blockers to handle most matrix effects
- Validated to clinical lab standards



Validation

Internal Assay Development

- Individually designed for every analyte
- Validated according to CLSI Standards
- Thoroughly tested at the simplex stage before multiplexing
- Key performance parameters such as LLOQ, LDD, and precision established prior to every kit release

Experimental Procedure

- LIMS provides chain of custody and data logging information for samples throughout the testing process
- Sample plating verified by two technicians
- Temperature controlled lab and storage
- Native controls run in duplicate alongside samples
- Automated sample plate processing - efficient and reliable throughput

Post-run Analysis

- Minimum of 50 beads analyzed per analyte
- 8-point Standard Curve fitting with advanced algorithms
- Controls follow Westgard rules to monitor unwanted trending
- Sample results manually reviewed for consistency
- Data backed up immediately on site with long-term off-site storage

Products and Services

HumanMAPs

- DiscoveryMAP® (189 analytes)
- OncologyMAP™ (102 analytes)
- HumanMAP® v1.6 (88 analytes)
- PsyMAP™ v 1.0 (51 analytes)
- CardiovascularMAP® (50 analytes)
- InflammationMAP® (46 analytes)
- MetabolicMAP® (21 analytes)
- KidneyMAP™ (16 analytes)
- CytokineMAP A & B
- CustomMAP (any combination of assays from our menu)

RodentMAPs

- RodentMAP® v2.0 (58 analytes)
- Rat MetabolicMAP™ (21 analytes)
- Rat KidneyMAP™ (12 analytes)
- Mouse CytokineMAP A, B & C
- CustomMAP



Human Orano-Typic (HOT) Co-Cultures
Co Gut, Co Skin, Co Lung, Co Joint, Co Vessel



TruCulture® Tubes
TruCulture® MAP (46 analytes)

Applications

DISCOVERY ➔ PRE-CLINICAL ➔ EARLY CLINICAL ➔ LATE CLINICAL

DISCOVERY	PRE-CLINICAL	EARLY CLINICAL	LATE CLINICAL
<ul style="list-style-type: none"> • The RBM Approach, casting a wide net • Hypothesis generating, data driven services • Over 400 quantitative immunoassays available • Proven success in gut, skin, respiratory, etc 	<ul style="list-style-type: none"> • A single platform from animal model to human • Broad rat, mouse and primate species coverage • Supports GLP studies • Unique sample types • Proven success, especially in toxicology 	<ul style="list-style-type: none"> • A leader in the development of better toxicology assessments • Innovative blood collection method for reproducible immune activity capture • Focused, therapeutic panels 	<ul style="list-style-type: none"> • A broad menu for custom MAP selection • Ability to test many sample matrixes • Cost effective over singleplex assays • Scientific expertise • High throughput capability

Conclusion

Our long history of developing and validating assays allows us to provide customers with unmatched expertise in the field of biomarker testing. The RBM platform combines the sensitivity and dynamic range of microsphere-based immuno-multiplexing with the precision and dependability of automated liquid handling. Together these features set RBM apart from other biomarker testing labs by offering high quality, cost-effective immunoassay measurements. Our expansive suite of solutions further distinguishes RBM as more than just a fee for service lab and helps establish RBM as the leading innovative biomarker solutions provider.