

Are Your Companion Diagnostics Needs Being Met?

ResearchDx provides integrated outsourcing solutions for all aspects of companion diagnostics development and regulatory approval.

ResearchDx is The Contract Diagnostics Organization (CDO) for the Biopharmaceutical and Diagnostic Industries.

ResearchDx was founded on the core principles and expertise that help biopharmaceutical companies accelerate, develop and manufacture their companion diagnostic products. As the **premier** CDO, ResearchDx has established integrated, turn-key, flexible services that are focused on our customer's objectives. We manage the entire diagnostic development process - from initial assay concept and discovery all the way through clinical research to regulatory approval. At ResearchDx we believe in bringing personalized medicine to the next level.



ResearchDx Supports Every Step of the Diagnostics Pipeline



Diagnostics/IVD Research

- Diagnostics Development Services
- Protocol Development and Sample Procurement
- Site Identification and Evaluation
- Clinical Trial Services and Consulting

CLIA/CAP Laboratory

- High Complexity Esoteric Testing
- Specialties: Cytogenetics, FISH, Molecular Diagnostics, Molecular Pathology, ELISA-based Applications and Next-Generation Sequencing
- Clinical Trial and Reference Testing Services
- Assay Development
- Rapid Validation of Custom or Client Specific Assays for Clinical Research and Clinical Trial Services

GMP Manufacturing

- Contract Manufacturing of Reagents, Assays and Kits
- Molecular Kit Development and Manufacturing
- Customization of Assay Kits for Research
- Rapid Production Schedules

Technical Consulting

- Assay Development
- Assay Platform Evaluation
- Assay Validation
- Laboratory Automation
- Workflow Optimization
- Assay Technical and Regulatory Compliance

Laboratory Consulting

- CLIA, CAP, ISO and State Licensure
- Regulatory Consulting, Audits and Submissions
- Lab Quality Management Services
- Send Out Practice Management Evaluation
- Inspection Readiness Services
- Laboratory Facilities
- Start Ups, Equipment Sourcing
- International CLIA and ISO Solutions
- Laboratory Design, Implementation and Management



INTEGRATED SERVICES
Seamless integration of all the services you need to develop a diagnostic product.



FLEXIBILITY
Adaptation to meet your complex and constantly evolving needs for diagnostic development.



FOCUS ON YOUR BUSINESS
Our sole focus is your diagnostic development.