Partnering to Bridge Gaps

As a Contract Diagnostics Organization (CDO), we solve gaps in resources and expertise for biopharmaceutical and diagnostics industries.

By offering a comprehensive range of *in vitro* diagnostic services, we augment or integrate your project needs through outsourcing to a single partner.

- Integrated development from discovery through regulatory approval
- Discrete development projects in clinical, regulatory and laboratory services
- GMP manufacturing

As your complete diagnostics partner, we tailor to your project needs. Communication and speed efficiency are benefits gained through dedicated project management in a quality-compliant program and environment.

**Your project is in capable hands.**

We have scientific and medical expertise in all areas of IVD diagnostics to ensure your project is designed, implemented and stays on target with your goals and schedules.

**When your project timelines or priorities shift — we shift to meet your needs.**
Service Divisions

ResearchDx offers complete diagnostic development support. This listing highlights frequently utilized services; however, if you don’t see what you need, just ask.

Research & Development

• Biomarker discovery (molecular, protein, other)
• Assay/kit development and validation
• Platform evaluation and automation
• Studies to establish biological baseline
• Broad, multi-platform technology capability (no bias)
• LDT/custom development/clinical validation

Clinical Research

• Complete clinical trial services, program management and support
• Clinical trial strategic consulting
• Reference trial testing services
• Clinical primary site testing
• Analytical and clinical testing
• Complete data management program support

Regulatory & Compliance

• Strategy and FDA interactions
• IVD PRE-IDE, PMA and 510(k) filings
• International regulatory filings
• Compliance auditing and consulting
• Compliant labeling
• Software documentation
• Third party review by Accredited Persons (AP)

GMP Contract Manufacturing

• Custom reagents, assays, or final kits for research, clinical, final product
• Molecular/non-molecular IVD development
• OEM reagents, kit components or assays
• Certificates of Analysis (COA)
• Sample collection kits

Clinical Laboratory

• CLIA, CAP, ISO, GLP, state and regulatory certification, accreditation and compliance
• High-Complexity specialty testing resource (molecular/non-molecular)
• Broad, multi-platform capability (no bias)
• Pre-inspection auditing/readiness
• Complete resource and consulting for new start-up
• Mock inspections (CLIA, CAP, ISO)
• Inspection audit responses (CLIA, CAP, ISO)
• Provision of standard laboratory documentation (CLIA, CAP, ISO compliant)

GLP Diagnostic Services

• Non-clinical testing
• Pre-clinical testing
• GLP compliance consulting

ResearchDx maintains licensure, accreditation, certification and/or compliance where applicable to pertinent regulatory bodies and to local, state and federal laws.

ResearchDx

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