We Solve Resource Gaps.

As a Contract Diagnostics Organization (CDO), we provide resources and expertise for pharmaceutical and diagnostics industries.

As your complete diagnostics partner, we offer a comprehensive range of \textit{in vitro} diagnostic services and capabilities to augment your needs, such as:

- Integrated discovery, development, validation through regulatory approval
- Custom projects, all IVD diagnostic areas
- CLIA-certified clinical/molecular laboratory-based testing services
- Complete clinical trial services
- GMP/ISO 13485 manufacturing

Your project is unique—we tailor to fit your needs.

Communication, speed and efficiency are just a few of the benefits gained through dedicated project management in a controlled, quality-compliant environment.

Your project is in capable hands.

With scientific and medical expertise to support all areas of IVD diagnostics, we ensure your project is designed, implemented and on-target with your goals and schedules.
Service Areas

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

Research & Development

• Biomarker discovery (molecular, protein, other)
• LDT/custom development/clinical validation
• Molecular IVD development and validation
• Platform evaluation and automation
• Studies to establish biological baseline
• Broad, multi-platform technology capability

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
• ISO 13485 compliance
• OEM reagents, kit components or assays
• Certificates of Analysis (COS)
• Sample collection kits

Clinical Laboratory

• CLIA, CAP, GLP, state and regulatory certification and accreditation
• High-complexity specialty testing resource
• Broad, multi-platform capability (non-bias)
• Pre-inspection auditing/readiness
• Complete new start-up resource/consulting
• Mock inspections (CLIA, CAP, ISO)
• Inspection audit responses (CLIA, CAP, ISO)
• Provision of standard laboratory documentation (CLIA, CAP, ISO)

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 local, state and federal laws.

ResearchDx

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