ResearchDX
Your Companion in Diagnostics®

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 *in vitro* diagnostic services and capabilities to augment your needs, such as:

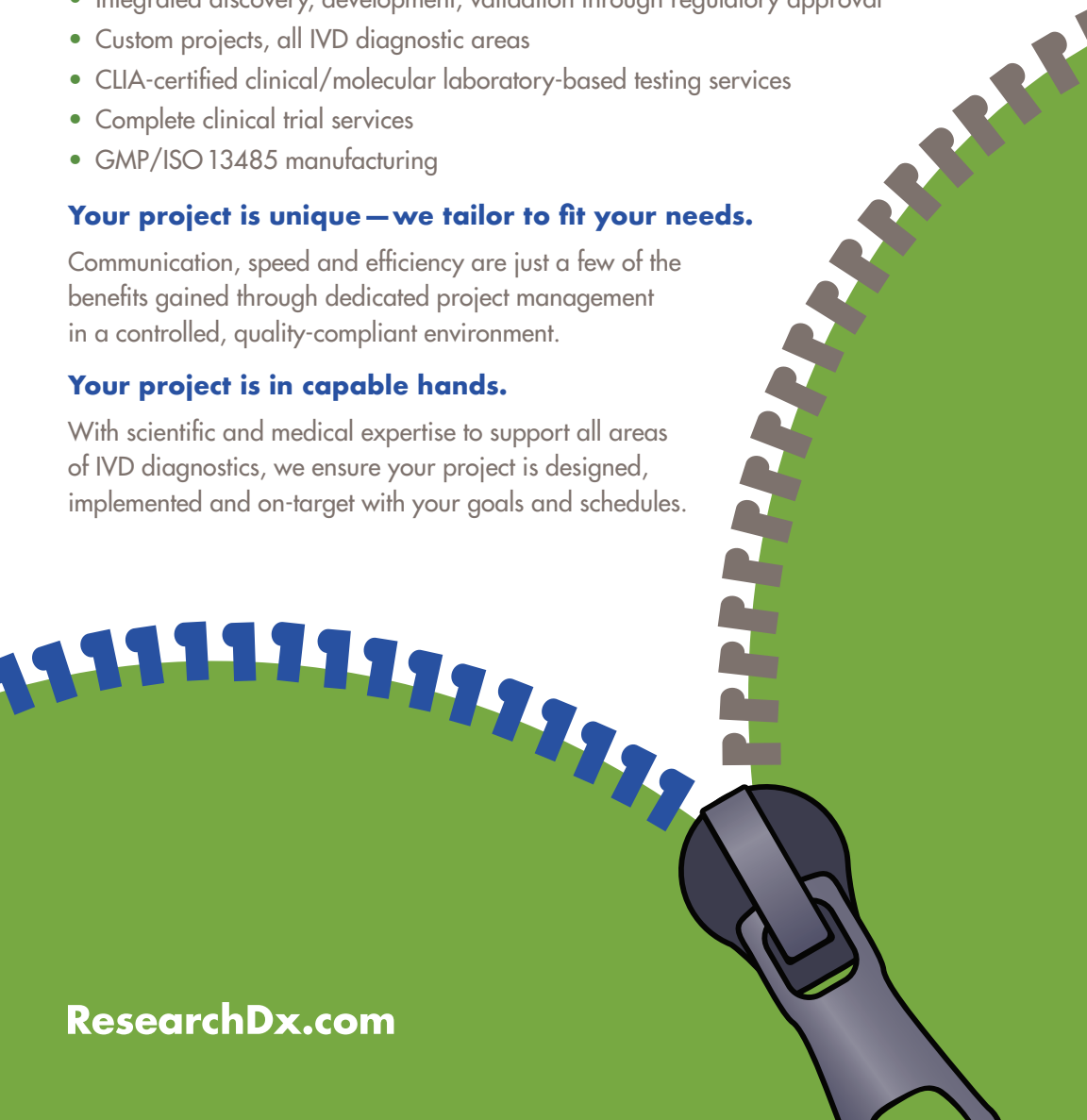
- Integrated discovery, development, validation through regulatory approval
- Custom projects, all IVD diagnostic areas
- CLIA-certified clinical/molecular laboratory-based testing services
- Complete clinical trial services
- GMP/ISO 13485 manufacturing

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.



ResearchDx.com

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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