ARUP's PharmaDx program develops companion diagnostics and provides testing services to meet the unique requirements of the pharmaceutical industry.

More Information

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PharmaDx

ARUP's PharmaDx program provides **custom test development and clinical trials testing services** to meet the unique requirements of the pharmaceutical industry. Our team has extensive experience managing complex laboratory testing projects that require customized solutions.

PharmaDx provides services in support of pharmaceutical clinical development and post-marketing activities, including:

- Companion and complementary diagnostic development, including assay development under design control and regulatory submission
- Assay development for patient eligibility, drug monitoring, immunogenicity, and therapeutic efficacy
- Laboratory testing in support of global clinical trials

Assay Development

Our team works closely with R&D and technical operations to offer customized assay development and validation services for our pharmaceutical and biotechnology partners. A variety of custom assay development services are available, including:

- Assay development under design control
- *De novo* assay design and development
- Assay transfer to ARUP
- Modification of existing ARUP assays to meet a sponsor's specialized needs

Companion Diagnostics

ARUP recently launched the **first laboratory-developed tests to be approved by the FDA under the Humanitarian Device Exemption (HDE) program**. Developed under our augmented quality management system and offered exclusively at ARUP, the *KIT* D816V and *PDGFRB* FISH tests determine Gleevec eligibility in multiple oncology indications.

Our augmented quality management system meets FDA requirements for medical devices under 21 CFR part 820. Regulatory oversight is included throughout the assay development lifecycle with regard to quality audits, document controls, design controls, purchasing controls, software validation, risk management, change controls, process controls, and corrective and preventive actions.

Clinical Trials

As a large, national reference laboratory with **more than 3,000 tests and test combinations**, ARUP has expertise with a broad range of technology platforms and instrumentation. PharmaDx leverages these capabilities to provide highly specialized and technically challenging assays that would not otherwise be available, even in a large reference laboratory.

PharmaDx makes both ARUP's broad test menu and assay development capabilities available to pharmaceutical partners to support clinical trials testing. Clinical trials testing at ARUP benefits from:

- Testing in CLIA/CAP-certified clinical laboratory
- GCLP available on case-by-case basis
- Custom-built automation system that ensures quality and rapid turnaround times
- Expertise in logistics that facilitates receipt of more than 50,000 specimens daily

Project Management

A PharmaDx project typically involves the collaborative efforts of a multidisciplinary team led by a project manager and may consist of members of R&D, technical operations, compliance and quality systems, and purchasing.

Our project managers are drawn from the manufacturing, pharmaceutical, biotech, and laboratory testing industries. Their experience allows them to:

- Deliver a high degree of customization and flexibility, greater than is typically available in a clinical laboratory setting
- Provide a **single point of contact** to ensure a successful partnership
- Manage the scope, time, quality, and budget of the project, as well as communicate with the pharmaceutical partner
- Handle logistical challenges and sponsor requests

www.aruplab.com/pharmaDx