

ARUP INNOVATION CENTRAL LABORATORY

Your Strategic Partner To Transform Early-Stage Opportunities Into Commercially Viable Diagnostic Solutions

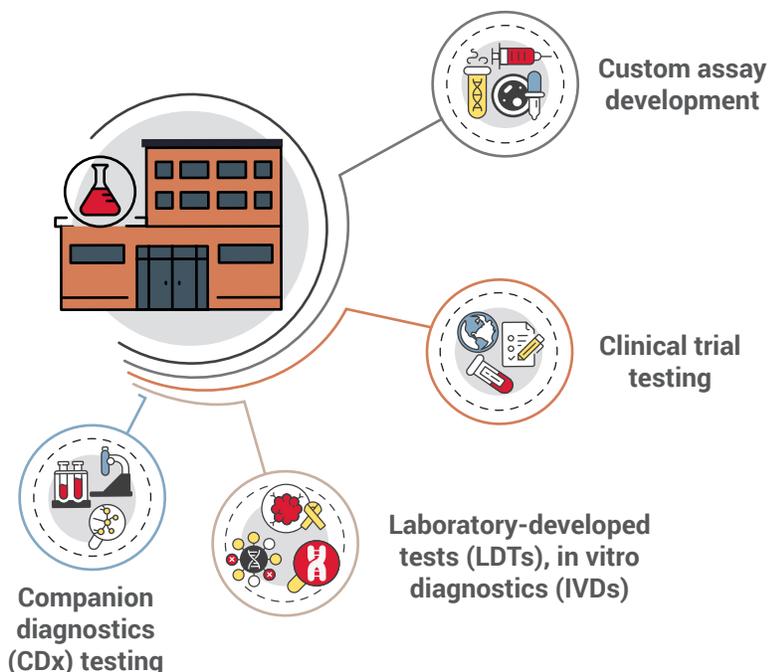


INNOVATION AT ARUP LABORATORIES

Introducing the Innovation Central Laboratory

The Innovation Central Laboratory enables ARUP and its pharmaceutical and biotechnology partners to engage in early-stage exploration that leads to accelerated deployment and refinement of new diagnostic concepts outside of routine clinical workflows.

Drawing from ARUP's deep clinical, scientific, and regulatory expertise and experience, this lab serves as an ecosystem for validating technologies and accelerating the development of next generation diagnostics from concept to commercialization.



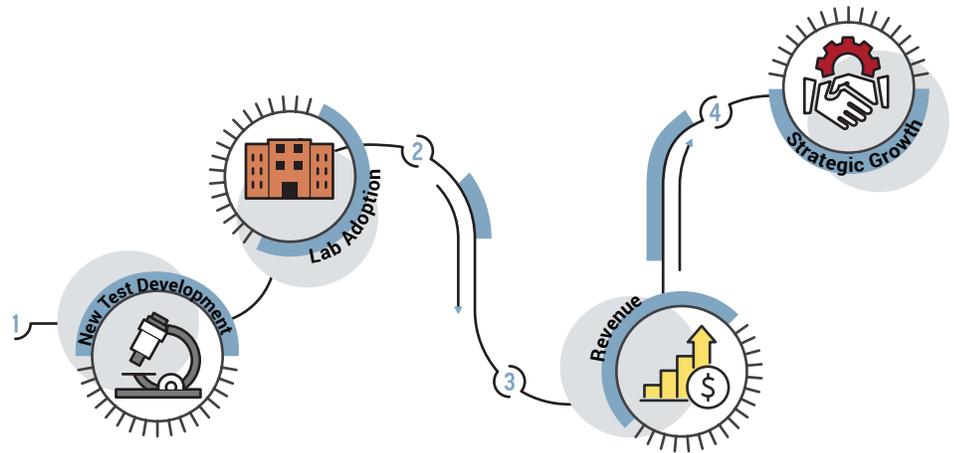
**SCHEDULE A
DISCOVERY CALL TO
PARTNER WITH ARUP'S
INNOVATION TEAM**



aruplab.com/discovery

SERVICES THAT ACCELERATE INNOVATION

Through full life cycle management, from feasibility exploration to commercialization, the ARUP Innovation Central Lab empowers partners to bring products to market efficiently and effectively.



COMPANION DIAGNOSTICS DEVELOPMENT

- Assay development, clinical trial and commercial testing in a Clinical Laboratory Improvement Amendments (CLIA)-certified, College of American Pathologists (CAP)-accredited, ISO 13485-certified laboratory
- Support of CDx experts in development of therapies for rare and common diseases
- In-house regulatory expertise with proven success in FDA and European Union (EU) clinical trial and marketing authorization applications

ARUP Firsts

First FDA-approved CDx immunoassay for a gene therapy:
[Read more.](#)

First CDx assays approved under the FDA's Humanitarian Device Exemption (HDE) program



Jay L. Patel, MD, MBA

Robert S. Ohgami, MD, PhD, MBA, FCAP

CLINICAL TRIALS TESTING

- **3,000+ tests,** comprehensive menu
- **High-quality, high-capacity, and quick-turnaround CAP/CLIA-compliant testing,** from research to primary endpoints
- Dedicated, experienced project managers from diverse industries
- Specialized, project-specific sample handling and processing

Central Pathology Review

Pioneered by Chief Scientific Officer Tracy George, MD, the central pathology review service provides an opportunity to partner with ARUP's expert pathologists to determine which patients are optimal candidates for inclusion in clinical trials and to monitor drug responses. Run by a highly collaborative, dedicated team, the service follows Good Clinical Practice (GCP) standards, from pathologic confirmation of diagnosis to response assessment. [Read more.](#)



Tracy George, MD, Peng Li, MD, PhD

CUSTOM ASSAY DEVELOPMENT

- Custom development of moderate to complex assays, including:
 - Research-use only (RUO) assays, LDTs, IVDs, CDx
- Assays validated on capillary blood microsamples
- Infrastructure to commercialize custom-built assays

Phospho-Tau 217 plasma test to detect Alzheimer's disease pathology: [Read more.](#)



APPLIED ARTIFICIAL INTELLIGENCE AND BIOINFORMATICS

- Expertise in digital pathology, machine learning, generative artificial intelligence (AI), and cloud computing
- Custom AI model development and applications
- Novel tools, algorithms, and software products

Automated grading of Castleman disease histopathology using an attention-based multiple-instance learning model: [Read more.](#)





ACADEMIC RESEARCH SUPPORT

- Investigator-initiated and key opinion leader (KOL) studies
- Grant application assistance and support
- Seamless data integration; secure data reporting via ARUP Connect™ portal or interface, including application programming interface (API) and secure file transfer protocol (SFTP), plus customizable reporting options for study electronic data capture (EDC) integration



OTHER LAB SERVICES

- Access to high-quality specimens and biorepository services for research and validation
- Long- or short-term sample storage via secure biorepository services
- Specialty processing of DNA/RNA and peripheral blood mononuclear cells (PBMCs), as well as buffy coat preparation
- Digital imaging and AI algorithm development to enable automated tissue classification, biomarker quantification, and diagnostic enhancement
- Instrument performance evaluations to support commercial use and regulatory requirements, including 510(k) submissions
- Consultation with more than **100 board-certified pathologists** who are faculty members at the Spencer Fox Eccles School of Medicine at the University of Utah

ACCOMPLISHMENTS WITH PARTNERS

1 FDA approves ARUP Laboratories' AAV5 DetectCDx[®], a first-ever companion diagnostic immunoassay for a gene therapy



2 ARUP offers clients a first-class central pathology review service for clinical trials



3 EU approval of AAV5 DetectCDx[®] provides access to companion diagnostic for hemophilia A gene therapy



4 ARUP's new Institute for Research and Innovation in Diagnostic and Precision Medicine™ is founded to help forge the future of laboratory medicine



5 ARUP launches pTau 217 blood test to detect Alzheimer's disease pathology



6 Pramana and ARUP Laboratories partner to digitize pathology slides and develop AI-powered hematopathology algorithms for deployment via edge AI



7 Tasso and ARUP Laboratories announce partnership, combined offering for decentralized clinical research biomarker testing



8 ARUP experts contribute to Castleman disease research showcased by Recordati at American Society of Hematology Annual Meeting



Schedule a discovery call to partner with **ARUP's Innovation team**



*ARUP is a nonprofit enterprise of the University of Utah
and its Department of Pathology.*

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