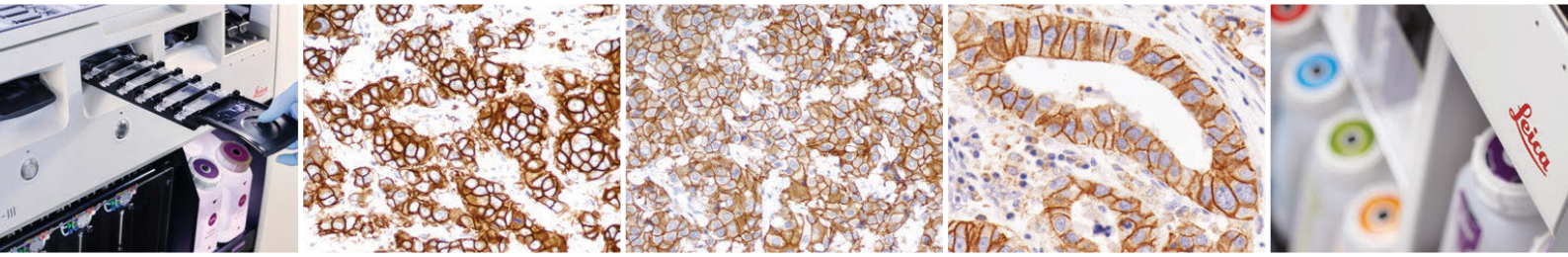
L E I C A B I O S Y S T E M S

CDx DEVELOPMENT SERVICES

SCALE ACCESS TO THERAPIES FASTER WITH OUR BROAD CDx CAPABILITIES



PARTNER WITH A GLOBAL LEADER IN ANATOMIC PATHOLOGY
TO TAP INTO ONE OF THE LARGEST GLOBAL INSTALLED BASES AND
150+ YEARS OF INNOVATION

Flexible CDx Development

- **Develop fit-for-purpose assays** leveraging our experience from 1300 IVDs globally, including IVDR compliance for multiple IHC products including CDx*
- **Minimize timelines** with flexible and modular development & robust QMS
- **Advance diagnostic programs** from research to clinical to commercial via our CAP/CLIA lab**

Fast Commercial Scale-Up

- **Enable patient access** to novel therapies via our 8,000+ IHC instruments & presence in all top US cancer centers
- **Accelerate adoption** by partnering with our 1,300+ commercial FTEs
- **Ensure CDx continuity** via our robust supply chain serving 100+ countries

Broad Research-to-Clinical Portfolio

- **Access to 11K antibodies** through Leica and Danaher's newest company, **Abcam**
- **Expand to multi-modal CDx** via access to other Danaher companies: Beckman Coulter and Cepheid
- **Reduce variability** by leveraging our leadership in digital pathology and AI partnerships

abcam progress happens together

BECKMAN COULTER

Cepheid A better way.

* Market transition ongoing
** Future CAP/CLIA lab under development

SUPPORTED BY PROVEN PROJECT MANAGEMENT EXCELLENCE

- Results delivered through our rigorous application of the Danaher Business System
- Culture of accountability, transparency, problem solving, and continuous improvement

CONNECT WITH US
CLICK OR SCAN

Advancing Cancer Diagnostics
Improving Lives

Leica BIOSYSTEMS

LeicaBiosystems.com

COMPREHENSIVE AND SEAMLESS CAPABILITIES TO SCALE NOVEL THERAPIES

		PHASE IA	PHASE IB	PHASE II/III PIVOTAL			
		ASSAY FEASIBILITY	ASSAY DEVELOPMENT	VERIFICATION & VALIDATION	TRIAL SUPPORT	SUBMISSION	LAUNCH
AGILE RESEARCH & DEVELOPMENT	Pioneering IHC assay development since 1987	Expertise in biomarker assay sensitivity and specificity Develop assays from a variety of detection technologies spanning plex-levels Collaborate and leverage diagnostic data to optimize therapies					
	Modular development to deliver required classification (RUO, IUO/ PEO, CDx IVD)	Optimize timelines based on pharma's requirements					
	Custom and recombinant antibody/probe development	Design assays to unique specifications or amino acid sequence Maximize antibody production yields					
EXPERIENCED CLINICAL & REGULATORY	CAP/CLIA certified lab*	Retrospective testing to support CDx go/no-go decision Eliminate risks from hand-offs between companies		Quickly transition from RUO to IUO			
	Dedicated local expertise across the globe (including China, Japan); supplemented by Danaher teams			Local clinical trial oversight to ensure quality and compliance Relationships with regulatory bodies from study design through approval		Predictable CDx approval timing	
	Experienced regulatory and clinical teams (1,300 IVDs globally including 140+ China IVDs)				Clinical trial support including in the EU & China	Global Regulatory experience and IVDR CDx approvals Coordinated co-submissions	Collaboration on reimbursement strategy
BROAD PRODUCT PORTFOLIO	11K primary antibodies through Leica Biosystems and Abcam	Access to the antibodies needed to answer complex questions	Leverage product portfolio to accelerate product development				
	BOND research and clinical instruments and reagents have shared technology	Simplest transition from research to clinical platforms More predictable timelines Robust biomarker characterization that holds up in later phases					
	Gold standard in clinical digital pathology with large installed base and AI partnerships	Leverage AI to identify more biomarker candidates		Potential faster data analysis for validation through image analysis AI			Opportunity to partner on AI scoring guide Be positioned for the future of digital pathology CDx
	A market leader in multiplex IHC technology: Cell IDx, partnerships, and IVD multiplex	Efficient identification of multiple biomarkers			Leverage IVD approved antibodies and detection systems in clinical trials		Enable adoption through seamless integration into laboratory workflow
	Multi- modality through Danaher companies						Expand diagnostic reach to PCR, clinical chemistry, multiplex IHC, ISH, FISH
GLOBAL COMMERCIALIZATION	Installed Base of 8K clinical BOND instruments and supply chain across 109 countries				More choices for clinical testing sites Reliable supply of assay to testing sites		Enable accelerated therapy adoption Easily integrate into a lab's routine workflow
	Global sales and service organization of 1,300+ associates						Drive customer awareness and usage Coordination between Rx and Dx teams for site expansion

*Future CAP/CLIA lab under development

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Leica Biosystems is a global leader in workflow solutions and automation. As the only company to own the workflow from biopsy to diagnosis, we are uniquely positioned to break down the barriers between each of these steps. Our mission of "Advancing Cancer Diagnostics, Improving Lives" is at the heart of our corporate culture. Our easy-to-use and consistently reliable offerings help improve workflow efficiency and diagnostic confidence. The company is represented in over 100 countries. It has manufacturing facilities in 9 countries, sales and service organizations in 19 countries, and an international network of dealers. The company is headquartered in Nussloch, Germany. Visit LeicaBiosystems.com for more information.