

KingMyLab
A Core Member of KingMed

Since
2008

Clinical Trial Central Pathology Solutions



Your Best Central Lab Partner for Clinical Trials in China

| About KingMylab

KingMylab is a leading provider of central laboratory services for clinical trials in China. Founded in 2008 as the Clinical Trial Department of Guangzhou KingMed Diagnostics—China's largest clinical diagnostics corporation—then became independent in 2020. We deliver scientific, compliant and one-stop comprehensive central laboratory and data solutions for clinical trials to our pharmaceutical and biotech partners locally and globally. Our services cover the entire drug development pipeline across a broad range of therapeutic areas—including but not limited to oncology, immunology, metabolism, neurology, infectious diseases, vaccines and cell&gene therapy, as well as the full clinical trial lifecycle and international multi-regional trials.

KingMylab's quality system complies with NMPA, FDA, EMA and GLP/GCP requirements, relevant three laboratories in Guangzhou, Shanghai and Hong Kong China have obtained CAP, CLIA and ISO 15189 accreditations. We are committed to building an integrated central laboratory service chain for clinical trials and expanding into diversified clinical trial CRO services.



4200+
Central Lab Tests



800+
Global Clients



80+
Technical Platforms



4500+
Clinical Trials



90+
Novel Drugs
Supported



160+
NMPA/FDA/EMA
Inspections

Central Pathology in Clinical Trials

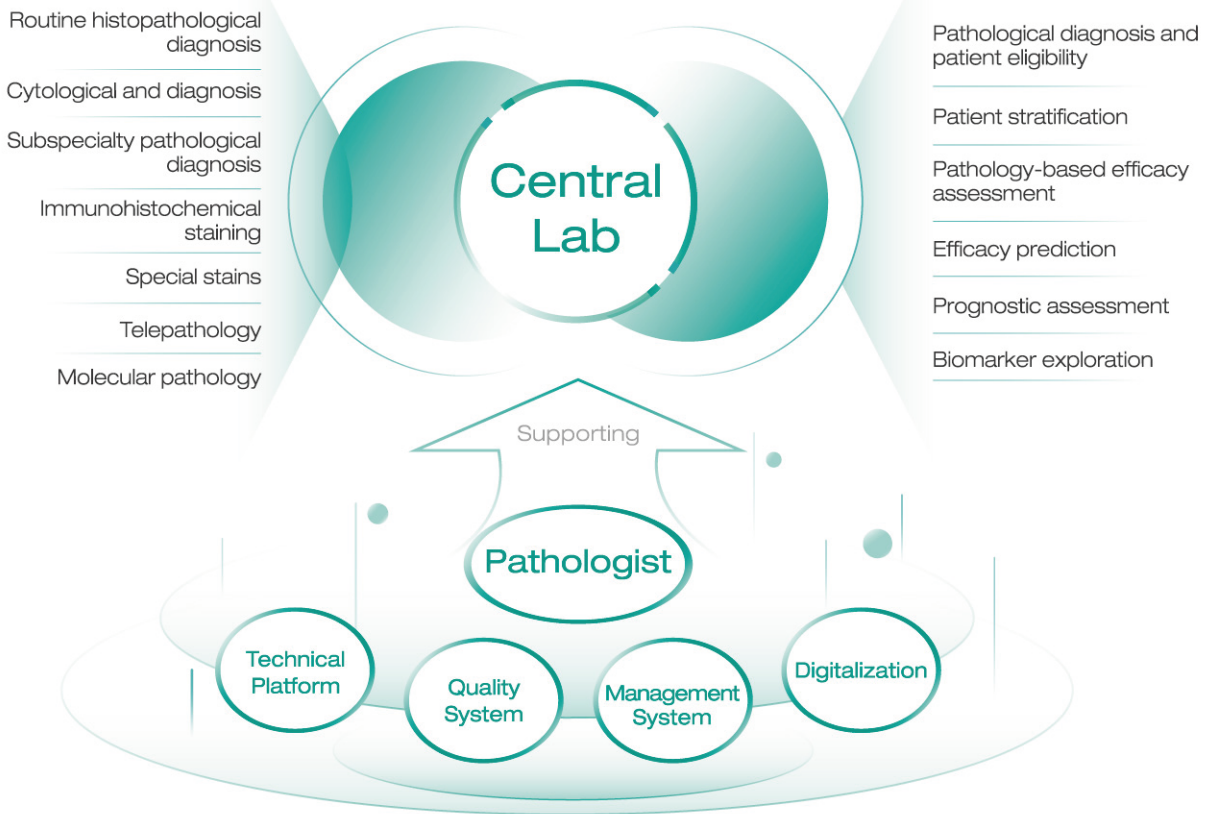
Pathology: The Gold Standard Across the Drug Development Lifecycle

Pathology provides the scientific foundation for innovative drug development. Recognized as the gold standard in oncology diagnosis, it delivers critical evidence across the entire clinical trial lifecycle—from precise subject enrollment and stratification to efficacy endpoint assessment, prognosis, and biomarker exploration. Its role is now expanding beyond oncology into inflammatory, immune, and metabolic diseases.

KingMylab's Central Pathology Platform

Our central pathology platform combines senior expert oversight with a rigorous, end-to-end management system compliant with international quality standards. With approximately 100 central pathology projects supported annually and over 30 innovative oncology drug approvals to date, KingMylab delivers proven pathological expertise and operational reliability to remain a trusted partner in empowering pharmaceutical innovation and advancing clinical development.

Scope and Application Scenarios of Central Pathology Services in Clinical Trials



Key Service Advantages of KingMylab Central Pathology



International High-Standard Central Pathology Quality System

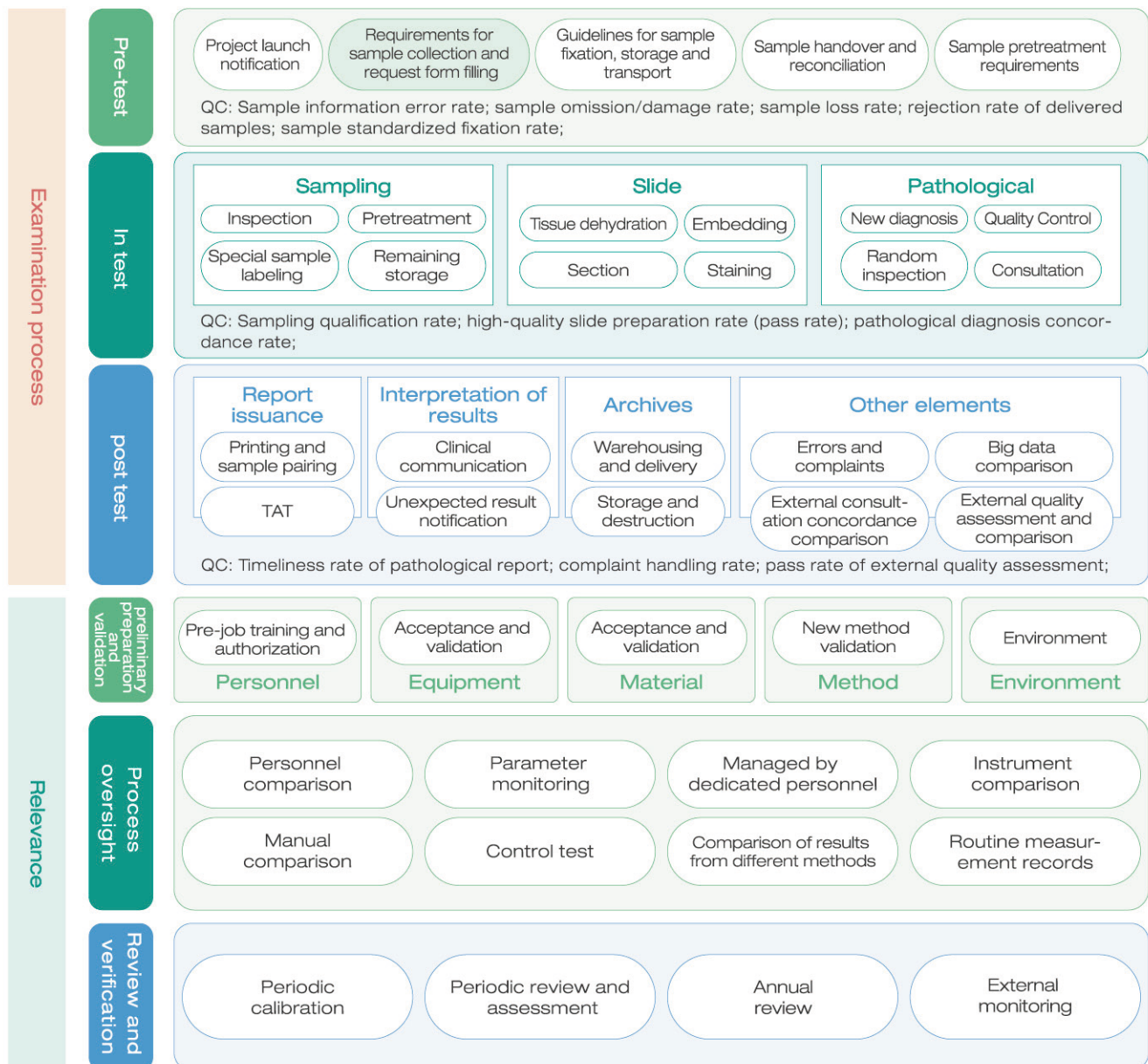
Built upon internationally recognized quality systems including CAP, CLIA, and ISO 15189; Full compliant with GCP/GCLP requirements for clinical trials under NMPA, FDA, and EMA. Our laboratories achieved dual accreditation from **CAP** in 2008 and **ISO 15189** in 2009



Quality management and routine quality control strictly aligned with **CNAS** and **CAP** standards
Regular participation in **CAP** continuing education programs

Annual participation in external quality assessment programs organized by National (PQCC, CCPI), Guangdong Pathology Quality Control Center, and professional societies

The Pathological Diagnosis Center implements a **three-phase quality management system** (pre-, during, and post-examination), with full-process oversight across five key elements: personnel, equipment, materials, methods, and environment



Pathological Diagnosis Center

Sample Volume



Histopathology
Over **500,000**
cases/year



Cytopathology
Over **500,000**
cases/year



Renal pathology
Over **50,000**
cases/year

Disease Areas

- Renal biopsy
- Liver biopsy
- Skin biopsy
- Nerve and muscle biopsy

Histopathological Diagnosis

- Pathological examination and diagnosis (HE)
- Sample inspection and sampling
- Immunohistochemistry, fluorescence, In situ hybridization
- Special stains

Cytopathological Diagnosis

- Liquid-based cytology(cervical)
- Liquid-based cytology(non-gynecological)
- Routine cytological smear
- Liquid-based cytology for fine needle aspiration biopsy

Ultramicroscopic Pathological Diagnosis

- Transmission electron microscopy
- Scanning electron microscopy
- Immunoelectron microscopy

Histopathology

Cytopathology

IHC/mIHC

Bone Marrow Pathology

FISH

Molecular Pathology

Ultrastructural Pathology

Digital /AI Pathology

Comprehensive Multi-Omics Platform Integration

Immunohistochemistry (IHC) Platform

300+

Immunohistochemical
antibody tests

50W+

Annual sample volume



DAKO Autostainer
Link48*2



Leica BOND-III*4



ROCHE VENTANA
BenchMark ULTRA*3

- Experienced Pathology Experts

- Globally Recognized Testing Platform

- Extensive Antibody Panels



Multiplex Immunohistochemical (mIHC) Platform

10+

Validated cancer types

≥2~6

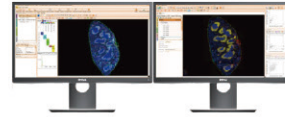
Multi-target labeling



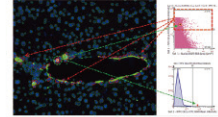
Leica BOND RX
Automated research-grade stainer



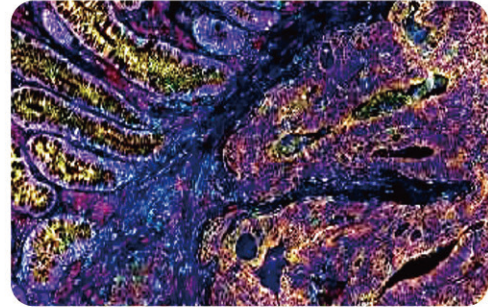
TissueFAXS SL Spectra S
High-throughput sample loading and slide scanning system



Tissue FAXS imaging & Strata Quest
Panoramic tissue multi-marker imaging and quantitative analysis system



- Compliance with International Quality and Validation Standards
- Development of Personalized Testing Solutions
- Rigorous and Comprehensive Data Analysis



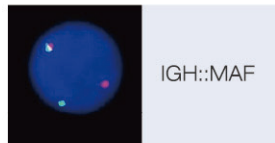
Fluorescence in Situ Hybridization (FISH) Platform

130+

Tests

3W+

Annual sample volume



IGH::MAF



p53 deletion

- Senior Specialist Team
- Comprehensive FISH Test Menu
- Development of Personalized Testing Solutions



Next-generation Sequencing (NGS) Platform

5W+

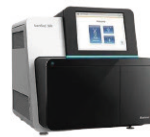
Annual sample volume of solid tumors

3W+

Annual sample volume of hematological Malignancies



Novaseq 6000*3



Nextseq 500*2



Miseq*1

- Professional Multidisciplinary Team
- Comprehensive Testing Projects
- Multi-Dimensional Variant Analysis Capability



Central Pathology IRC

Central Pathology IRC (Independent Review Committee) is the "gold standard" safeguard for ensuring objective and unbiased data in clinical trials. As a third-party evaluation body independent of the sponsor and clinical sites, it eliminates subjective bias through standardized slide review procedures and unified diagnostic criteria, providing independent, consistent, and scientific evidence for disease diagnosis, typing, grading, biomarker status, and efficacy assessment in oncology and other therapeutic areas. The entire operation and review process is fully traceable, serving as a critical quality control step to support the safe and effective approval of new drugs.

Central Pathology IRC Empowers Multi-disease Clinical Trials, ensuring independence, consistency, and scientific rigor of results

Patient
Screening

Precise "Gatekeeper"

- Evaluation of biomarker thresholds as inclusion and stratification criteria, e.g., PD-L1 and HER2 expression
- Morphological pathology diagnosis as enrollment criterion, e.g., central pathology diagnosis of diffuse large B-cell lymphoma

Endpoint
Assessment

"Final Verdict" of Pathology

- Use of pathology-related endpoints as primary study endpoint, e.g., in neoadjuvant clinical trials in breast cancer or non-small cell lung cancer



KingMyLab leads the development of consensus on central pathology IRC for clinical trials, filling key industry gaps

Standardized workflow control and electronic management throughout the process to enhance slide review efficiency and research quality

Comprehensive computerized system validation (CSV) ensures stable operation, complete data, and regulatory compliance throughout the system lifecycle

LAB-CTMS

- Full-cycle sample management
- Full-process project management
- Pathological report access



Independently developed LAB project management system

MyPathClair

- Full-process quality management
- Secure, independent, and accurate data
- Efficient transmission of pathological images

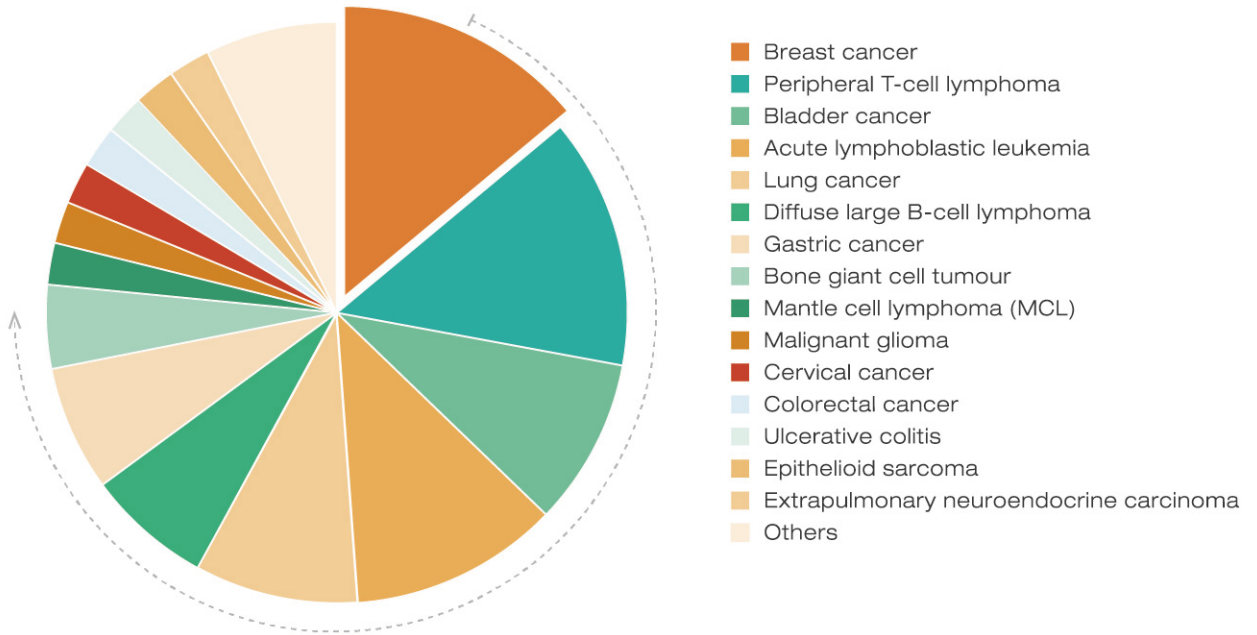


Independently developed central pathology IRC system

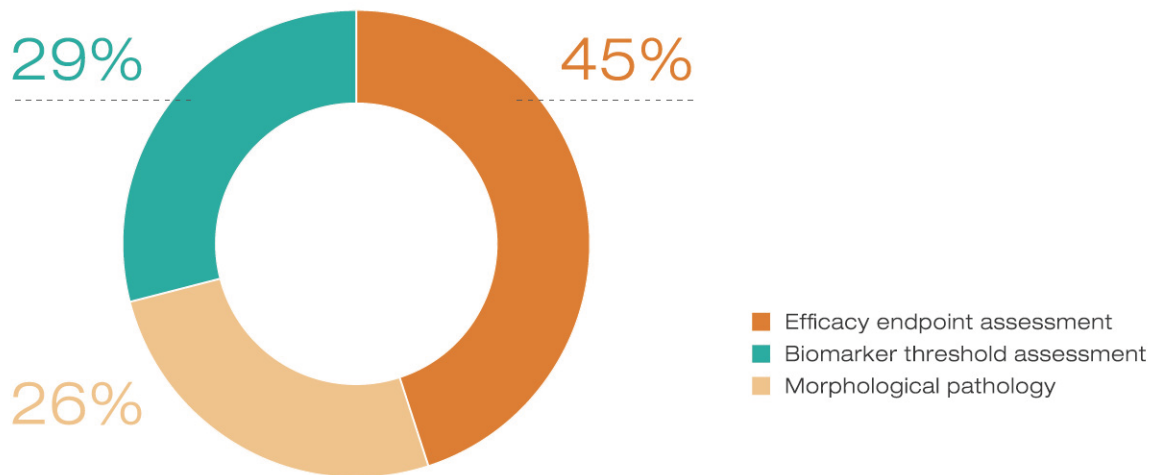
Extensive project experience, providing central pathology IRC services to multiple pharmaceutical companies

- As of now, KingMylab has conducted over 70 central pathology IRC projects, primarily focused on oncology pathological diagnosis.
- Cancer types coverage: breast cancer, peripheral T-cell lymphoma, bladder cancer, Acute lymphoblastic leukemia, lung cancer, DLBCL, gastric cancer, colorectal cancer, cervical cancer, et al.
- Supported 10+ oncology therapeutics approvals.

Cancer types covered by central pathology IRC projects



Project types covered by central pathology IRC

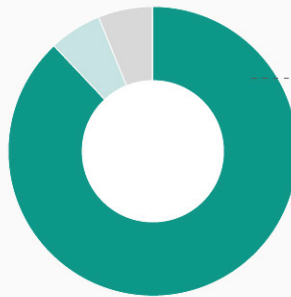




| Experienced Pathology Expert Resources

Experienced domestic and international pathology diagnosis and technical team

- Expert Scale: **80+** senior domestic and international pathology experts
- Qualification: **90%** with associate chief physician titles or above **100%** full-time at top-tier (tertiary) hospitals across key regions (Beijing, Shanghai, Guangdong, Jiangsu, Sichuan)
- Subspecialty Coverage: **10+** pathological subspecialties covered



90%

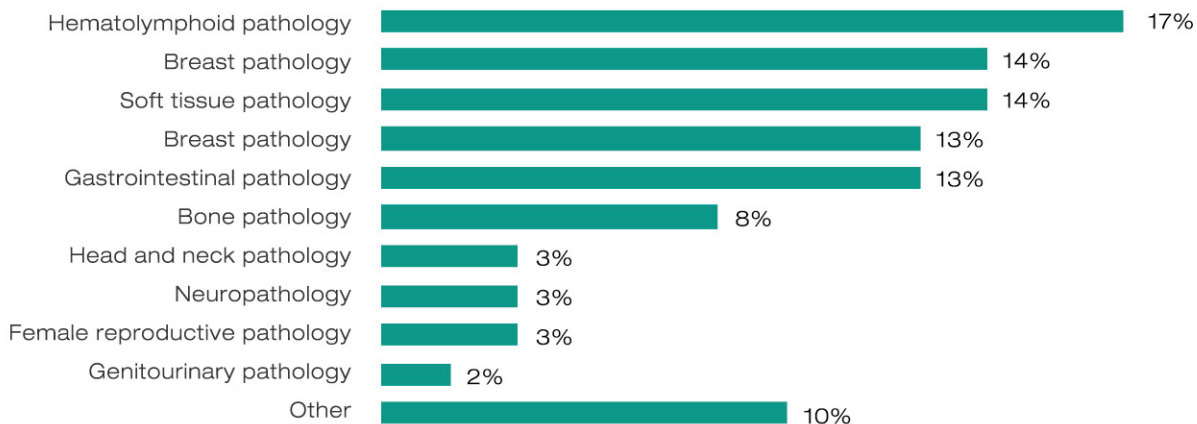
- Chief physician
- Associate chief physician
- Others

Subspecialties

16 subspecialties Dedicated teams of renowned domestic & international experts, Distinguished Expertise in Hematolymphoid · Dermatopathology · renal · hepatic

- | | | | |
|---------------------------------|------------------------|------------------------------|---|
| ◎ Soft tissue pathology | ◎ Bone pathology | ◎ Dermato pathology | ◎ Cardiovascular pathology |
| ◎ Hematolymphoid pathology | ◎ Infectious pathology | ◎ Gastrointestinal pathology | ◎ Head and neck pathology |
| ◎ Female reproductive pathology | ◎ Breast pathology | ◎ Renal pathology | ◎ Urological and male genitourinary pathology |
| ◎ Cyto pathology | ◎ Liver pathology | ◎ Thoracic pathology | ◎ Cranial nerve pathology |

Subspecialty Breakdown of Pathology Expert Team



AI-powered Digital Pathology Enablement

KingMylab is committed to advancing the long-term development and clinical application of artificial intelligence-driven pathological diagnosis to drive the field toward greater precision and standardization.

AI-Powered Quality Enhancement: Through AI-powered secondary validation of pathological diagnostic results, the platform effectively reduces inter operator variability and interpretation discrepancies, significantly enhancing diagnostic reliability.

Human-Machine Collaborative Diagnostics: For complex and challenging cases, a human-machine collaborative diagnostic system integrates algorithmic strengths with physician expertise, enabling bidirectional empowerment. This approach further improves diagnostic accuracy, delivering more efficient and precise diagnostic services for patients and clinicians.

Case



CCAP Cervical Cancer AI Diagnosis

1.2 million+

Annual screening volume

> 70%

Negative rate

> 99%

NPV



Pathological case repository

Leveraging years of professional pathology data accumulation and integrated technical capabilities, KingMylab has established a high-quality, multi-disease specialty case repository, providing a solid data foundation for clinical research and AI model development.

Specialized Disease Databases Dedicated disease-specific databases have been developed for cervical cancer, lymphoma, and renal pathology. These database encompass key data across screening, diagnosis, and testing processes, with a total data volume exceeding 70 GB (excluding pathological images).

Application & Value This repository provides multidimensional data support for clinical trial protocol optimization, rapid patient screening and enrollment, advanced data mining, and AI model training and validation, enabling efficient and high quality research advancement.

Cervical cancer-specific database

110 million

7.3 G (excluding pathological images)

Lymphoma-specific database

2.5 million

43 G (excluding pathological images)

Renal pathology-specific database

415,000 cases

200M (excluding pathological images)

Rich Central Pathology Experience and Full Lifecycle Project Management

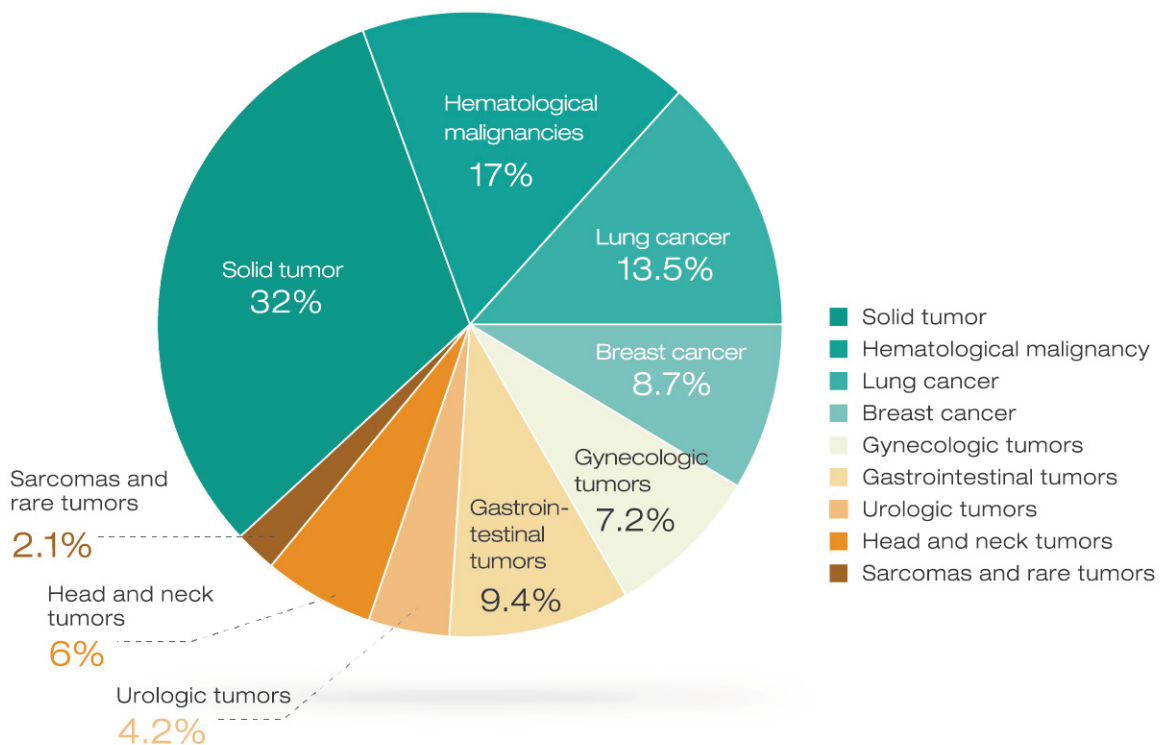
- To date, the central pathology platform has conducted over 500 clinical trial projects, with approximately 15% representing pivotal Phase III registration trials; around 100 new central pathology projects are added annually.
- 100% compliance in NMPA and EMA inspections: Nearly 40 NMPA and EMA inspections have been successfully passed for clinical trial projects undertaken by the platform, supporting the regulatory approval of approximately 30 therapeutic drugs.

Project Portfolio: Clinical stage & Disease area distribution

Solid tumor



Hematological malignancy





Scientific, Compliant & Comprehensive
Central Laboratory and Data Services for Clinical Trials



Accelerating drug development, advancing human health

www.kingmylab.com 

Address: [Hong Kong] Unit 1, 1F, Remington Centre, 23 Hung To Road, Kwun Tong, Hong Kong, P.R. China.
[GuangZhou] 6F, Building 2, Unit 2 Luoxuan 4th Road, GuangZhou International Bio Island, Guangdong, P.R.China;
[Shanghai] 5F, Building 3, 115 Xinjun Ring Road, Minhang District, Shanghai, P.R. China;
E-mail: kingmylab@kingmylab.com
Tel: 020-28330088