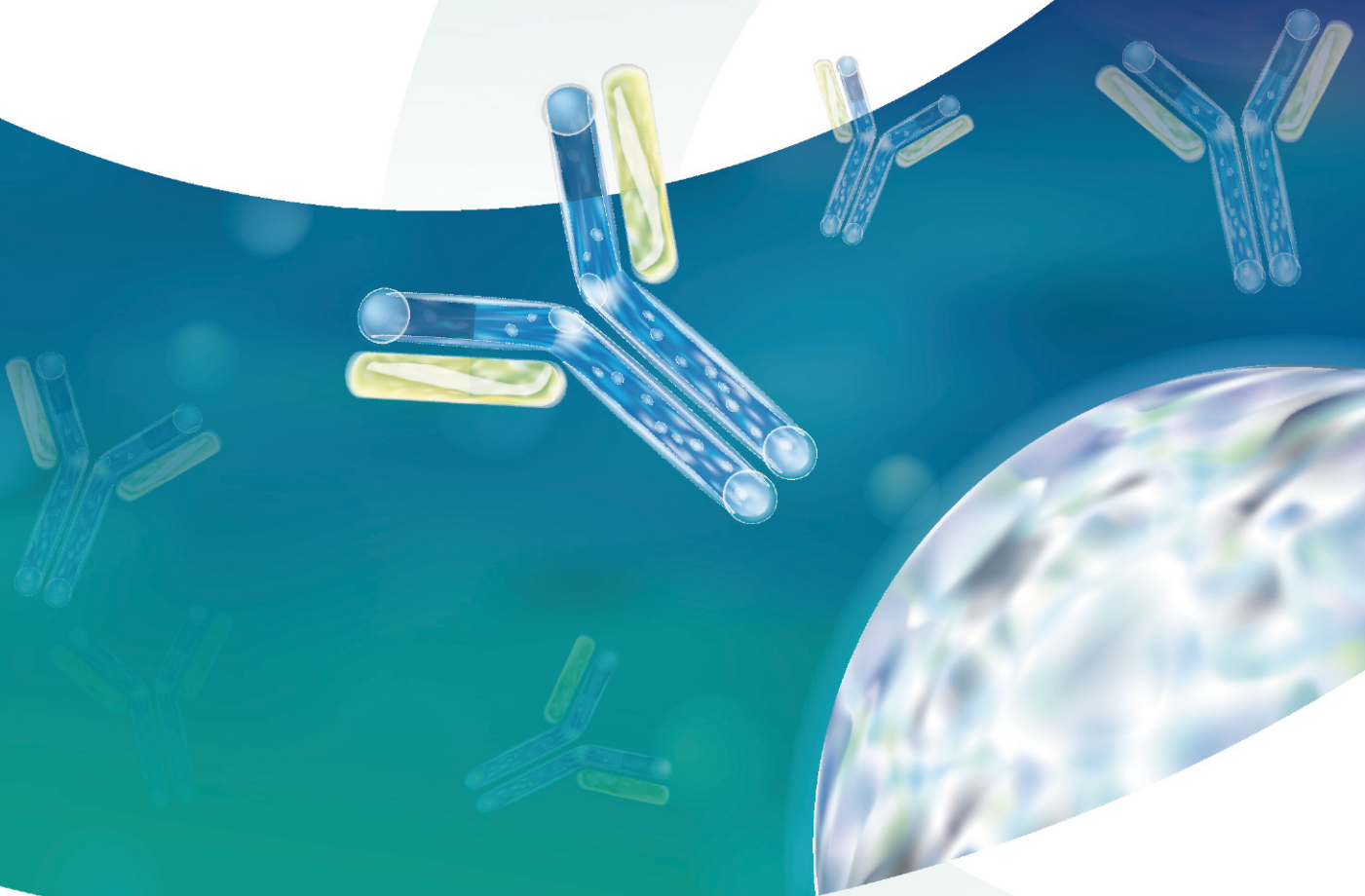


金漫利医药 临床试验生物分析服务

KingMylab Clinical Bioanalytical Services



全球高标准·一站式生物分析平台

Global Standard · One-Stop Bioanalytical Platform

金埭利医药生物分析服务致力于为全球客户提供科学、合规、一站式临床生物分析解决方案，覆盖细胞基因治疗药物、大分子药物及疫苗等前沿领域。依托专业技术团队和先进检测平台，可高效完成符合临床试验要求的分析方法学开发、验证及样本检测，提供可信赖的生物分析数据。

KingMylab BioA Services is dedicated to providing scientific, compliant, and one-stop clinical bioanalytical solutions focused on cell & gene therapy, large-molecule, and vaccines. Leveraging a professional technical team and advanced testing platforms, we efficiently perform analytical method development, validation, and sample testing that meet clinical trial requirements, delivering reliable bioanalytical data.

26,000m²
+9,000m²

实验室面积
Central + R&D & BioA labs space

800+

全球合作客户
Pharma & biotech, local and global

50+

临床试验方法学验证与确定
Method validations & qualifications

10+

核心技术团队平均经验
Average experience of the core technology team

100+

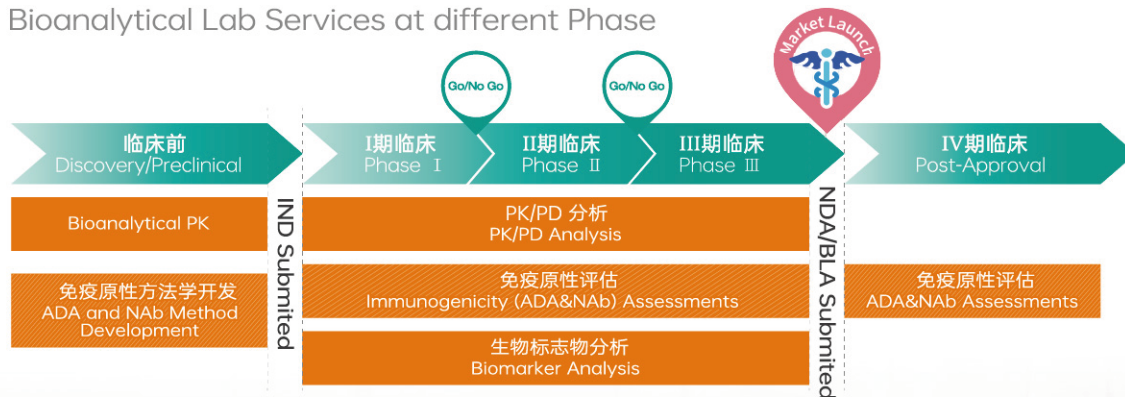
承接大分子药物注册临床试验
Clinical Trials Projects (LM)

30,000+

每年样本量
Samples tested annually

临床各期的生物分析服务

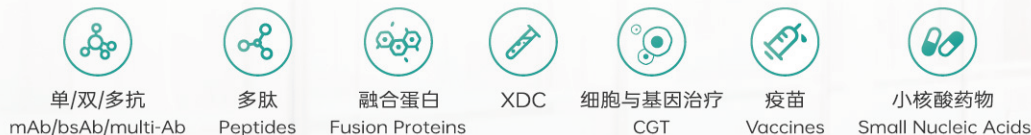
Bioanalytical Lab Services at different Phase



对于生物制品和其他先进疗法，可能需要进行额外的评估
Additional assessments may be required for biologics and other advanced therapies

覆盖药物类型

Drug types covered



全面的分析能力

Comprehensive Solutions

50+ PK

50+ADA

20+NAb

300+Biomarkers

20+RO

遵循全球高质量监管标准

Adhering to Global High-Quality Regulatory Standards

遵循NMPA、FDA、EMA的GxP法规及ICH M10等生物分析指导原则，确保检测结果的准确、合规与可靠，为全球客户提供值得信赖的生物分析数据。

Fully complying with GxP clinical trial quality management regulatory requirements of the NMPA, FDA, EMA as well as bioanalytical guidance such as ICH M10, we ensure the accuracy, compliance, and reliability of every test result, delivering trustworthy bioanalytical data to global clients.

国际质量体系标准 Global Quality System Standards

实验室于2008年和2009年通过CAP和ISO 15189
双认可

The laboratory achieved dual accreditation of
CAP and ISO 15189 in 2008 and 2009.



临床试验质量管理法规 Clinical Trial Quality Management Regulations

全面遵循全球主要监管机构的GxP法规要求

Fully comply with GxP regulatory requirements of major global regulatory agencies.



国家药品监督管理局药品审评中心
CENTER FOR DRUG EVALUATION, NMPA



FDA U.S. FOOD & DRUG
ADMINISTRATION



EUROPEAN MEDICINES
SCIENCE MEDICINES HEALTH



PMDA

核心指导原则与白皮书 Core Guidelines and White Papers

严格遵循行业最新指导原则

Strictly adhere to the latest industry guidance principles

- ICH M10
- 中国药典2025版9012 Chinese Pharmacopoeia 2025, 9012
- FDA Bioanalytical Method Validation
- EMA Immunogenicity Assessment
- NMPA Guideline on Immunogenicity Studies of Drugs

大分子药物

Large-molecule

针对单/双抗、多抗、ADC及融合蛋白等大分子药物，金埭利医药依托多技术平台与完善的质量体系，构建了涵盖药代动力学（PK）检测、免疫原性评估及生物标志物分析的全方位临床生物分析解决方案。平台依托LBA（包括ELISA、MSD、Luminex等）、流式细胞术（FACS）、Cell-Base、qPCR/ddPCR, LC-MS/MS等主流技术，已开发并验证了多种符合GLP法规要求的分析方法，精准满足各类药物的临床生物分析需求。

For large-molecule, KingMylab leverages its multi-technology platforms and robust quality system to establish a comprehensive clinical bioanalytical solution covering pharmacokinetic (PK), immunogenicity and biomarker analysis. Relying on mainstream technologies such as LBA (including ELISA, MSD, Luminex, etc.), flow cytometry (FACS), cell-based assays, qPCR/ddPCR, and LC-MS/MS, the platform has developed and validated a variety of analytical methods compliant with GLP regulations, precisely meeting the clinical bioanalytical needs of diverse drug types.

15 years

抗体类药物临床试验项目经验

Experience in Antibody-based Drugs



	Tests	LBA	Cell-base	qPCR/ddPCR	FACS	LC-MS/MS	Project Experience	
单/双抗体 mAb/BsAb	PK	●				●	HER2	EGFR/c-MET
	抗药抗体(ADA)	●					EGFR	PD-L1/CTLA4
	中和抗体(Nab)		●		●		CD38	PD-L1/VEGFA
	生物标志物(Biomarker)	●					PD-(L)1	PD-1/LAG3
	受体占有率(OR)				●		VEGFA	PD-L1/TIGIT
							FcRn	PD-L1/CD47
							CTLA4	CD3/CD20
							TNF-α	B7H4/4-1BB
							RANKL	

20+ mAb/BsAb、5+ Fc Fusion、3+ ADC

过往助力上市药物

Supported for Approval



	Tests	LBA	Cell-base	qPCR/ddPCR	FACS	LC-MS/MS	Project Experience	
ADC	PK	●				●	Trop2	EGFR
	ADA	●					HER2	c-MET
	NAb		●		●		CLDN18.2	BCMA
							HER3	CD20
							Nectin-4	CD19
							payload	
							MMAE	DXd
							DM1	DM4
							MMAF	

Cell and Gene Therapy

针对细胞治疗药物，我们提供覆盖PK检测、免疫原性及功能性评估的全方位GLP合规分析方案。已验证流式细胞术与qPCR方法，经验涵盖CAR-T、TCR-T、NK、MSC及in vivo CAR-T等，靶点包括CD19、BCMA、Claudin 18.2。曾成功支持国内首款CAR-T上市及多项在研产品的临床生物分析。

For CGT, we provide a comprehensive GLP-compliant analytical solution covering PK assessment, immunogenicity evaluation, and functional analysis. Validated flow cytometry and qPCR methods have been established, with experience spanning CAR-T, TCR-T, NK, MSC, and in vivo CAR-T, targeting CD19, BCMA, and Claudin 18.2. We have successfully supported the clinical bioanalysis of the first CAR-T product approved in China as well as multiple investigational cell therapy products.

Tests	LBA	qPCR/ddPCR/NGS	FACS	LC-MS/MS
目的基因 Target Gene		●		
参比基因 Reference Gene		●		
复制型慢病毒/转逆病毒 RCL/RCR		●		
细胞因子/生物标志物 Cytokine / Biomarker	●			
抗药抗体/中和抗体 ADA/NAb	●		●	
免疫细胞分型 immunophenotyping			●	
CAR药代动力学 CAR PK		●	●	
阳离子脂质 Cationic Lipid				●

承接细胞类型

Cell Types Covered

CAR-T、TCR-T、NK、stem cells、in vivo CAR-T

承接靶点经验

Targets Covered

CD19、BCMA、Claudin 18.2、GPC3、CD30 等

团队项目成功经验

Project Experience

助力国内首款获FDA批准的CAR-T

Supported the first China-originated CAR-T approved by the FDA

疫苗类药物

Vaccine

在疫苗类药物领域拥有超10年临床试验项目经验，依托LBA、Cell-Based、流式细胞术及ELISPOT等多技术平台，可对体液免疫原性、细胞免疫原性及分子水平开展全面评估。平台严格遵循GxP及ICH M10等法规质量体系，累计承接肺炎链球菌多价疫苗、呼吸道合胞病毒（RSV）疫苗、HPV二/四/十一价疫苗及肿瘤疫苗等10余款疫苗临床生物分析项目，为各类疫苗研发提供一站式、合规的免疫原性与生物分析解决方案。

With over 10 years of experience in vaccine clinical trial projects, we leverage multiple technology platforms including LBA, cell-based assays, flow cytometry, and ELISPOT to comprehensively evaluate humoral immunogenicity, cell-mediated immunogenicity, and molecular-level endpoints. Our platform strictly adheres to GxP and ICH M10 regulatory quality systems, and has successfully conducted clinical bioanalysis for more than 10 vaccines, including multivalent pneumococcal vaccines, respiratory syncytial virus (RSV) vaccines, HPV bivalent/quadrivalent/11-valent vaccines, and tumor vaccines, providing one-stop, compliant immunogenicity and bioanalytical solutions for diverse vaccine development programs.

承接疫苗类临床试验项目经验

Vaccine Clinical Trial Project Experience



HPV多价预防性疫苗
Multivalent HPV Vaccines



肺炎链球菌多价疫苗
Multivalent Pneumococcal Vaccines



VZV预防性疫苗
VZV Vaccines



RSV预防性疫苗
RSV Vaccines



肿瘤治疗性疫苗
Tumor Vaccines

体液免疫：假病毒中和抗体、功能性中和抗体及结合抗体评价

Humoral Immunity: Evaluation of Pseudovirus Neutralizing Antibodies, Functional Neutralizing Antibodies, Binding Antibodies

细胞免疫：细胞免疫功能评价（T/B细胞）

Cell-Mediated Immunity: Evaluation of Cellular Immune Function (T/B Cells)

黏膜免疫：总sIgA和特异性sIgA评价

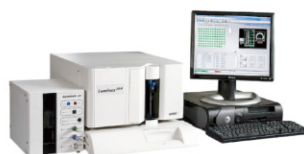
Mucosal Immunity Assessment: Evaluation of Total sIgA and Specific sIgA



ELISA



MSD



Luminex



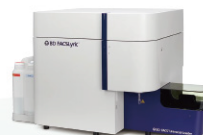
Cytation 5



Microscope



ELISPOT



Flow

生物标志物检测项目经验

Biomarker Experience



100+

临床方法验证与确定
Clinical Method Validation



300+

生物标志物
Biomarkers



30+种

药物研究与开发
Drug R&D Projects

生物标志物项目经验覆盖疾病领域

Disease Areas Covered by Biomarker Projects



实体肿瘤
Solid Tumors



血液肿瘤
Hematological
Malignancies



感染性疾病
Infectious
Diseases



内分泌及代谢疾病
Endocrine and
Metabolic Diseases



免疫性疾病
Immune Diseases



神经与精神疾病
Neurological
Disorders



肾脏和泌尿系统疾病
Renal and Urinary
System Diseases



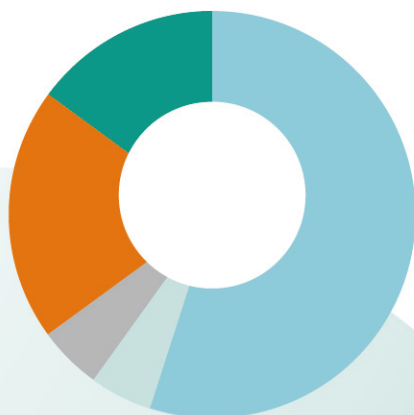
循环系统疾病
Cardiovascular
Diseases



遗传与罕见病
Gene & Rare Diseases

支持过的药物类型

Drug Types Supported





科学、合规、一站式临床试验中心实验室和数据服务平台

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



助力医药研发 造福人类健康

Accelerating drug development, advancing human health

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