金域医药 KingMedLab

Core member of KingMed

Since 2008

Clinical Trials for Diabetes Mellitus

—— Central Lab Solutions

Your best central laboratory partner for clinical trials in China.

One-stop clinical trial laboratory and data service platform

The rapidly growing number of diabetic patients worldwide has stimulated the pharmaceutical industry to continuously enhance the research and development of antidiabetic therapies. The diabetes mellitus drug market has become the second-largest therapeutic segment after oncology. In recent years, new hypoglycemic agents, represented by GLP-1RA (glucagon-like peptide-1 receptor agonist) and SGLT2i (sodium-glucose cotransporter 2 inhibitor), have grown rapidly in the global market.

KingMylab offers a full range of validated assays for diabetes mellitus, and has accumulated extensive project management experience for clinical study projects involving different drug formulations and different administration frequencies. With a commitment to a scientific and rigorous quality management system, leading and comprehensive technical platforms, and rapid, high-quality delivery, we provide a one-stop clinical trial laboratory and data service platform, including central lab, bioanalysis, and translational medicine, to support the development of novel antidiabetic therapies and advance the future of diabetes care.

- A scientific and rigorous quality management system
- Extensive project management experience
- Leading and comprehensive technical platforms
- Rapid and high-quality delivery

Comprehensive central lab testing for diabetes mellitus

PD indicators

Category	Relevant indicators
Glucose metabolism indicators	HbA1c, fasting blood glucose, fasting insulin, glucagon, C-peptide, pro-insulin, fructosamine, glycated albumin, etc.
Lipid metabolism indicators	Total cholesterol, low-density lipoprotein (LDL), high-density lipoprotein (HDL), very low-density lipoprotein (VLDL), triglycerides, lipoprotein (a), apolipoprotein A1, apolipoprotein B, free fatty acids, etc.
Other indicators	Adiponectin, GLP-1, etc. (to support development of pharmacodynamic biomarker based on drug mechanism)

Safety indicators

Category	Relevant indicators
Routine testing	RBC, WBC, neutrophils, lymphocytes, monocytes, eosinophils, basophils, hemoglobin, hematocrit, platelets, HCT, MCV, MCHC, etc.
Biochemical testing	Blood sodium, potassium, calcium (total and albumin-corrected), alkaline phosphatase (ALP), ALT, AST, total bilirubin, direct bilirubin, blood urea nitrogen (BUN), creatinine, uric acid, creatine kinase, lactate dehydrogenase, albumin, lipase, amylase, cystatin C, etc.
Hormone testing	Thyroid stimulating hormone (TSH), follicle stimulating hormone (FSH), oestradiol, testosterone, human chorionic gonadotropin (hCG), parathyroid hormone (PTH), calcitonin (CT), growth hormone (GH), insulin-like growth factor (IGF-1), vitamin D, 25-hydroxyvitamin D, etc.
Bone metabolism	N-terminal telopeptide of type I collagen (NTX1), C-terminal telopeptide of type I collagen (CTX1), procollagen type I N-terminal propeptide (P1NP), bone alkaline phosphatase, osteocalcin (OST)

Other indicators

Category	Relevant indicators
Islet autoantibodies	Glutamic acid decarboxylase autoantibodies (GADA), protein tyrosine phosphatase autoantibodies (IA-2A), zinc transporter 8 autoantibodies (ZnT8A), insulin autoantibodies (IAA), etc.

International high-quality standards central lab

Based on CAP and ISO 15189 standards, strictly complies with GLP/GCP and regulatory requirements from NMPA, FDA, EMA, etc.

- CAP and ISO 15189 certification for 15 consecutive years.
- NGSP Level 1 certification for 12 consecutive years.

• Qualification certificates

CAP certificate

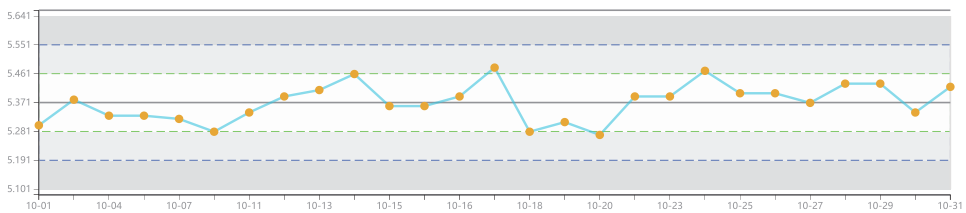
ISO15189

Level 1 lab certificate by NGSP

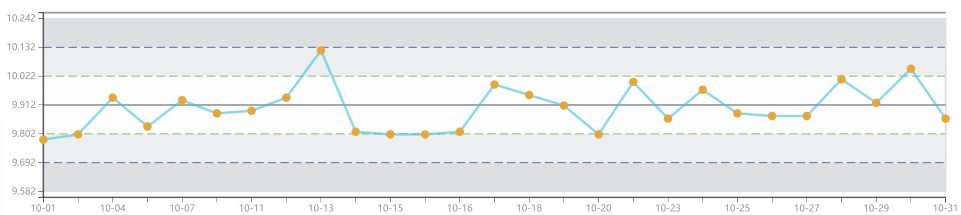
Primary efficacy endpoint-Quality control measurements for HbA1c testing

Daily quality monitoring is performed using two concentration levels. Monthly trend analysis is conducted to review QC data and ensure long-term stability and compliance with international standards.

A1C quality control level 1



A1C quality control level 2



Extensive experience in diabetes mellitus projects-Test results approved by authorities

Since 2010, KingMylab has supported the implementation of over 100 clinical study projects on diabetes mellitus, and more than 100,000 samples have been tested, accumulating extensive experience in clinical study projects of diabetes mellitus. In recent years, the research and development of new target hypoglycemic drugs has been greatly demanded, especially the new hypoglycemic drugs SGLT2i and GLP-1RA, which have characteristics of reducing blood sugar, blood pressure and weight levels, as well as preventing adverse cardiovascular event while protecting renal blood flow, etc.. These clinical advantages supported by the multidimensional indicators such as efficacy and safety of the central lab are significant.

More than 100 clinical trial projects of diabetes mellitus

More than 100,000 samples tested

Multiple years of continuous involvement in national CDC chronic disease monitoring projects, with cumulative sample size in the hundreds of thousands

100% compliance in NMPA inspections: By the end of 2024, diabetes mellitus-related projects have passed nearly 50 audits and NMPA inspections

Providing end to end project management

Experienced project management team

Project managers have been strictly trained and assessed, possessing excellent professional qualities and excellent organizational and coordination abilities. The team has successfully managed over 4,000 projects.

30%	35%	65%	50%
Master degree or above	More than 5 years of experience	Experience in managing over 50 projects	Experience in NMPA inspection

Digital empowerment

Lab-CTMS——Project operation management system

Project management:

Project operation protocol, visit plan and follow-up tracking, inspection item trigger rules, blind management rules, historical data comparison criteria, etc.

Data management:

Collaborating with the data management team to customize lab data process real-time logical audits based on clinical trial objectives, enabling remote data access and real-time data QC.

Sample management:

Sample life cycle management, backup sample classification management, etc.

Self-service:

Consumable kits application, logistics appointment, result reporting (alert value/critical value prompt, result trend), project data dashboards, etc.

KMCS——Central lab information system

The lab testing process is managed electronically from sample receipt to report issuance, ensuring full process traceability and reducing manual recording errors.

The system includes comprehensive operation logs, ensuring the entire process is authentic and traceable.

Based on risk management system

KPI management of central lab projects

- RFP confirmation
- Sample tracking
- Assay development
- Document traceability
- Project design
- Kit supply
- CTMS system configuration
- Deviation/Variation control
- Quality control of first batch testing
- Report/Data delivery

KingMYlab

Scientific, compliant, one-stop laboratory and
data service platform for clinical trial

Accelerating drug development, advancing human health

www.kingmylab.com

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