

Non-Clinical Services: Bioanalysis

Our bioanalysis platform supports non-clinical studies across both small- and large-molecule drugs, with proven reliability demonstrated by successful proficiency testing in both domains. Analytical laboratories are equipped with fully networked chromatography workstations, designed to meet international standards for computational system management and regulatory compliance. These capabilities ensure accurate, reproducible, and high-quality bioanalytical data to support pharmacokinetic (PK), toxicokinetic (TK), and exposure studies for diverse drug modalities.



Bioanalytical Method Development and Validation

- UPLC MS / MS method for quantitative analysis of small molecules, peptides, oligonucleotides
- UPCC MS / MS method for quantitative analysis of chiral drugs
- Q-Tof metabolite analysis and protein characterization
- GC MS method for in vivo and in vitro analysis of drugs
- ELISA or MSD method for quantitative analysis and immunogenicity of protein drugs
- PCR, live imaging, flow cytometry, and immunofluorescence for cellular and gene level analysis



Molecular Biological Testing

We provide comprehensive molecular biological analyses, including vaccine and neutralizing antibody assessment, detection of anti-drug antibodies (ADAs), and quality control testing of cell products. Our assays cover exogenous factors, sterility, mycoplasma, tumorigenicity, and oncogenicity,

supported by both in vitro and in vivo experiments across multiple species, including rats, mice, guinea pigs, rabbits, dogs, monkeys, and pigs. Some applications are as below:

- Cellular immunophenotyping, such as lymphocyte subtype detection (CD3+ CD4+ CD8+), B-lymphocyte (CD45+ CD20+), macrophages (M1 and M2 types), NK cells (CD16+ CD56+)
- Multi-cytokine assays: flow cytometry CBA, MSD, ELISPOT
- Humoral immunoassay: immunoglobulins (IgA / IgE / IgG / IgM), complement C3 / C4 / C5 / C5a, specific antibody detection and method development
- Antibody drug receptor occupancy: ELISA, flow cytometry
- ADA and neutralizing antibody analysis: cytometric, MSD, ELISA
- Tissue distribution of cellular and gene therapy drugs: QPCR, live imaging, immune-fluorescence, flow cytometry
- Cell product quality control testing: FDA, EMA, Pharmacopoeia



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