Australia's Largest and Most Technologically Advanced Biolab with Global Reach

AGILEX BIOLABS

Our mission is to deliver bioanalytical excellence

# PK, PD Immunogenicity Biomarkers

## Why Agilex Biolabs?

**Unparalleled Experience**
>150 years of combined experience in early phase research.

**Data Integrity and Quality Assurance**
Our FDA-inspected facilities have OECD GLP recognition and ISO 17025 Accreditation with NATA. Highest quality data acceptable to all regulatory agencies.

**Timeliness and Speed**
Fast turnaround for Single Ascending Dose (SAD) and Multiple Ascending Dose (MAD) studies.

**43.5% R&D Tax Incentive**
Eligible biotechs can receive a 43.5% cash refund of Australian R&D expenses.

## AGILEX Biolabs is the only FDA inspected bioanalytical laboratory in Australia, supporting preclinical and clinical trials with a global client base for over 25 years.

Agilex Biolabs specialises in bioanalysis of small molecules and biologics for PK, immunogenicity, biomarkers and immunological pharmacodynamics assessments utilising LC-MS/MS, immunoassay (Mesoscale, GyrolabxPloreTM, Luminex) and flow cytometry (BD FACSymphony A3 20 colour cell analyser).

Our operational scale ensures:
- Fast turnaround times, delivered as standard for FIH studies e.g. SAD cohort results delivered within 3 working days
- Analytical results; processed with Watson LIMS, the global industry standard for Bioanalytical CROs, providing data output in multiple formats

### Bioanalysis

Agilex Biolabs has over 25 years' experience in supporting pre-clinical and clinical programs. Our scientists have expertise in development of robust compliant PK, PD and immunogenicity assays de novo or by method transfer from a client's laboratory.

Our growing biomarker menu includes bioanalytical assays for compounds from small molecules to high molecular weight peptides. Our scientists take a tiered approach to creating either exploratory, qualified or validated assays to support the entire life cycle of a clinical program.

Our expertise includes:

### Peptides/Proteins by LC-MS/MS / Small Molecules

NCEs, sugars, nucleotides, enantiomers, steroids, prodrugs, peptides, immunosuppressants, nanoparticles, neurotransmitters, polymeric mixtures:
- Capability to assay peptides/ proteins using Immunocapture techniques and/or
- Protein MS
- PK Analysis
- PD Analysis
- Biomarkers

# PK, PD Immunogenicity Biomarkers

## Biologics by Immunoassay

**Pharmacokinetics (PK)**
PK analysis using colorimetric, fluorescence, chemiluminescence or electrochemiluminescence (MSD) detection for recombinant or fusion proteins, monoclonal antibodies, bispecific antibodies, ADCs, biosimilars.

**Immunogenicity**
Anti-drug antibody (ADA) and neutralising antibody (Nab) assays:

- Screening and confirmatory testing using a state-of-the-art MesoScale Discovery instrument to achieve the highest sensitivity
- Neutralising antibody detection using cell based or competitive ligand binding assay

**Biomarkers**
Biomarker analysis either by de novo setup of assays or commercially available kits. Tiered approach according to study design: exploratory > qualified > validated assays.

Sensitive multi-platform analysis for either single analyte or multi-plex panels:

- Meso Scale Discovery (MSD) – single or multiplex assays
- GyrolabxPloreTM – automated nanolitre-scale immunoassays
- Luminex MAGPIX xPONENT Analyser – multiplex assays

**Pharmacodynamics (PD)**
PD analysis to determine the effect of drugs and their mechanism of action. Our laboratories use the latest state-of-the-art technology to support immunology, cell biology and mode of action assays, including:

- Immunophenotyping
- Receptor occupancy
- Cytokine release assays (whole blood or PBMC-stimulation assays) and cytokine/biomarker profiling
- PBMC assays and cellular mechanism of action assays

## Quality Assured

AGILEX Biolabs operates a fully quality assured, FDA inspected laboratory, to ensure that within the principles of Good Laboratory Practice (GLP), assays are validated to the latest FDA/EMA bioanalytical guidance and study samples are assayed and reported to the Sponsor's desired format.

**Certification:**

- OECD Principles of Good Laboratory Practice (GLP) Certification from the Australian Government's OECD GLP compliance monitoring authority (NATA)
- ISO 17025 R&D Accreditation (NATA) for the analysis of drugs and metabolites in biological fluids by LC-MS/MS, HPLC and Immunoassay
- ICH Good Clinical Practice (GCP) Guidelines compliant

**Get in touch with our expert scientists to learn more about how we can help you deliver your next project.**