AGILEX BIOLABS

Our mission is to deliver bioanalytical excellence

PK, PD Immunogenicity Biomarkers

Key Competitive Advantages

Scale

- >55 dedicated laboratory staff
- SCIEX LC-MS/MS systems
- Meso Scale Discovery (MSD) – immunogenicity platform
- GyrolabxPlore™ – automated nanolitre-scale immunoassays
- Luminex MAGPIX xPONENT Analyser - biomarker multiplexing
- BD FACSymphony A3 20 colour flow cytometer - immunology/PD/receptor occupancy
- Watson LIMSTM – laboratory information management system
- Approx. 60,000 samples assayed in 2018

Depth of Experience

- 20 year track record
- > 15 years average experience across senior scientists
- de novo assay development capability for small and large molecule Bioanalysis

FDA Inspected

Australian R&D Tax Rebate

- Companies may be eligible to apply for the 43.5% refundable tax offset

AGILEX Biolabs is the leading bioanalytical CRO in the Asia-Pacific, supporting preclinical and clinical trials with a global client base for over 20 years

We conduct bioanalysis of both small molecule and biologics using the established platforms of LC-MS/MS and Immunoassay to support diverse studies from a global client base.

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 55 dedicated laboratory staff and over 20 years experience in supporting preclinical 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 experience is enhanced by annual attendance at global bioanalytical workshops (WRIB, EBF), participation in industry discussion with regulatory agencies and co-authorship of influential white papers in bioanalysis to keep abreast of the latest science and regulatory interpretation of the appropriate guidances

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Our expertise includes:

Small Molecule / Peptides / Proteins by LC-MS/MS

NCEs, sugars, nucleotides, enantiomers, steroids, prodrugs, peptides, immunosuppressants, nanoparticles, neurotransmitters, oligonucleotides, polymeric mixtures:

- Capability to assay peptides/ proteins using Immunocapture techniques and/or
- Protein MS i.e. unique signature peptide fragments
- PK Analysis
- PD Analysis
- 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 newly refurbished laboratories now include immunobiology services using 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 (eg: ADCC)

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