



Agilex GLP Bioanalytical Services

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Agilex at a Glance

We are Australia's leading bioanalytical laboratory, with over 20 years' experience delivering market leading service

+350

Cumulative projects

+85%

Repeat customers

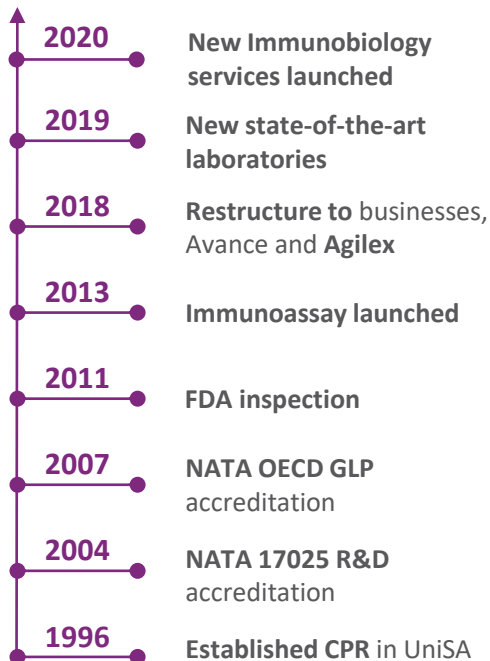


Across +10 countries

+75

Experienced staff

Our history



Our service lines



LC-MS/MS bioanalysis



Immunoassay/ Immunobiology analysis



Biomarkers

Why Agilex?



Customer focused

+20 years of experience, we pride ourselves on customer service



Data integrity and quality assurance

Our FDA-inspected facilities have OECD GLP recognition and ISO 17025 Accreditation with NATA



Timeliness and speed

Your project will be delivered on time and with the highest quality results

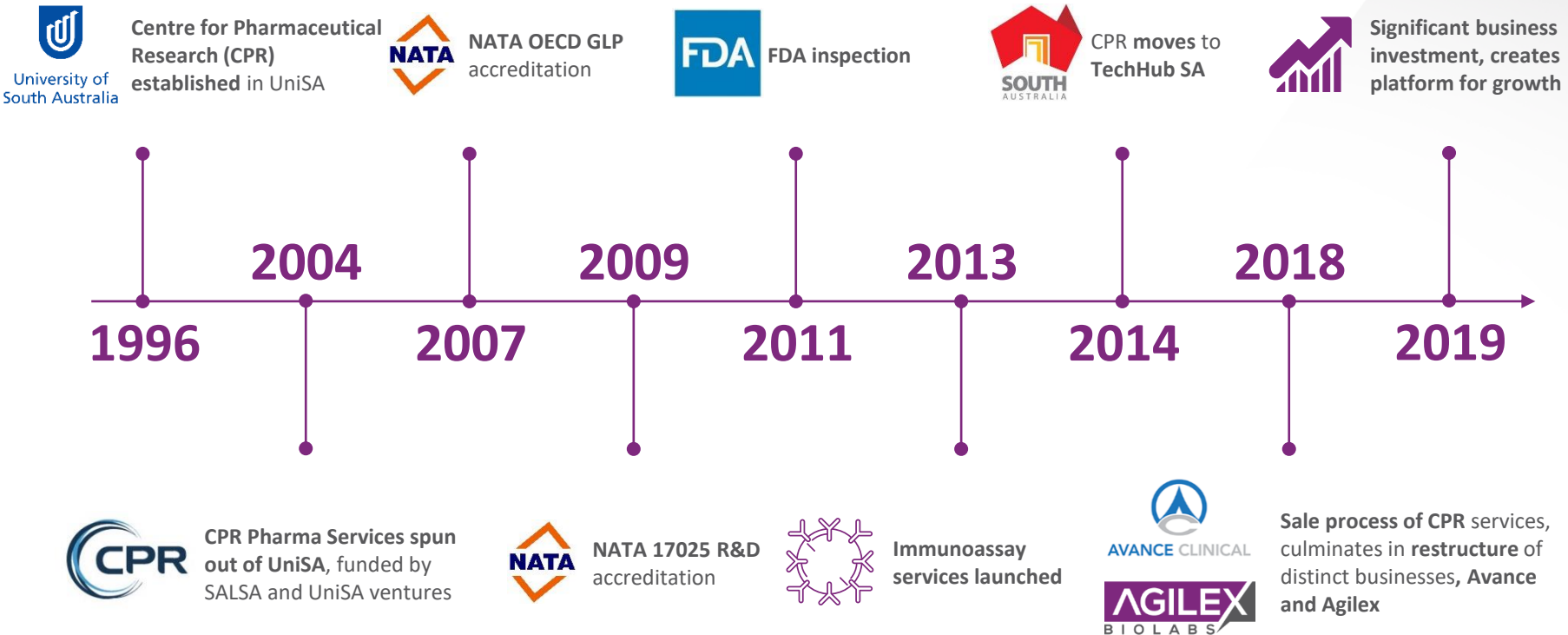


R&D tax incentive

You may be eligible for the Australian R&D refundable tax offset of 41%

Our History

With over 20 years' experience, we have a deep history as the leading Australian bioanalytical laboratory



Our Laboratory

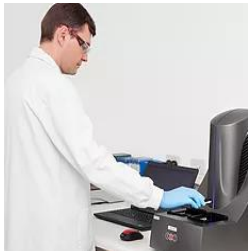
With over 75 staff brought in from around the world, we have created the Australian centre of bioanalytical excellence in LC-MS/MS, immunoassay, immunobiology and biomarker services



LC-MS/MS Bioanalysis

Our LC-MS/MS team of experts **averages over 15 years of experience**

With **six Sciex API 4000 LC-MS/MS** and our **Sciex API QTRAP 5500 LC-MS/MS** system, we have the **capability to deliver any sized project**



Immunoassay / Immunobiology Analysis

Our scientists have **over 10 years experience** in developing and validating compliant PK, PD and Immunogenicity assays

With the recent installation of Gyrolab™ Platform, and the upcoming addition of Luminex MAGPIX xPONENT™ and BD FACSymphony™ A3 20 colour flow cytometry analysers **we have everything you need for your next project**



Biomarkers

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 lifecycle of a clinical programme

+75
staff brought in from
around the world

7
LCMS-MS systems

+300
validated
bioanalytical assays

Our Track Record

With over 350 projects under our belt we are the Australian partner of choice for Pharmaceutical and Biotechnology companies worldwide

+350

Cumulative projects

+50

Projects a year

+85%

Repeat customers



Across +10 countries

Our Offering

We pride ourselves on delivering quality service, on-time across each of our core service lines



Customer focused

With 20 years of experience and a business built on repeat customers, we pride ourselves on customer service



Data integrity and quality assurance

Our FDA-inspected facilities have OECD GLP recognition with NATA and ISO 17025 Accreditation with NATA



Timeliness and speed

You can be confident that your project will be delivered by the experts on time and with the highest quality results



R&D tax incentive

Customers may be eligible for the Australian R&D refundable tax offset of 43.5% for research and development conducted Australia



Experience and Expertise

Team of + 55 Senior Chemists / Analytical Scientists

- > 15 years average experience across senior scientists
- Conduct complex method development for NCE / NBE
- Lead GLP projects
- Combined team expertise for:
 - Troubleshooting
 - Delivery of assay development under tight deadlines

Agilex Biolabs Authorship

- Our experience is enhanced by annual attendance of 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 regulatory guidance.

White Paper
10th Anniversary Issue of Bioanalysis

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Bioanalysis

Recommendations for classification of commercial LBA kits for biomarkers in drug development from the GCC for bioanalysis

Over the last decade, the use of biomarker data has become integral to drug development. Biomarkers are not only utilized for internal decision-making by sponsors; they are increasingly utilized to make critical decisions for drug safety and efficacy. As the regulatory agencies are routinely making decisions based on biomarker data, there has been significant scrutiny on the validation of biomarker methods. Contract research organizations regularly use commercially available immunoassay kits to val-



Rafiq Islam¹, Sumit Kar¹,
Hanna Ritzén² et al.

Conference Report

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11th GCC Closed Forum: cumulative stability; matrix stability; immunogenicity assays; laboratory manuals; biosimilars; chiral methods; hybrid LBA/LCMS assays; fit-for-purpose validation; China Food and Drug Administration bioanalytical method validation



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Bioanalysis

12th GCC Closed Forum: critical reagents; oligonucleotides; CoA; method transfer; HRMS; flow cytometry; regulatory findings; stability and immunogenicity

The 12th GCC Closed Forum was held in Philadelphia, PA, USA, on 9 April 2018. Representatives from international bioanalytical Contract Research Organizations were in attendance in order to discuss scientific and regulatory issues specific to bioanalysis. The issues discussed at the meeting included: critical reagents; oligonucleotides; certificates of analysis; method transfer; high resolution mass spectrometry; flow cytometry; recent regulatory findings and case studies involving stability and nonclinical immunogenicity. Conclusions and consensus from discussions of these topics are included in this article.

Chad Briscoe¹, Nicola Hughes²,
Roger Hayes³ et al.

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Bioanalysis

GCC Consolidated Feedback to ICH on the 2019 ICH M10 Bioanalytical Method Validation Draft Guideline

Corey Nehls¹, Michael Buonarati², Stephanie Cape³, Rafiq Islam⁴, Christina Satterwhite⁵, Chad Briscoe⁶, Roger Hayes⁷, Andrew Dinan⁸, Kurt Sales⁹, Shelby Anderson⁹, Jennifer Vance⁹, John Lindsay¹⁰, Jennifer Zimmer¹¹, Philippe Couerbe¹², Ardeshir Khadangi¹³, Sarah Maasjo¹³, Orlando Bravo¹⁴, Kathie Lindley¹⁵, Liam Moran¹⁶, Timothy Sangster¹⁷, Jenifer



LC-MS/MS Services

Method Development

- Blood, plasma, serum, saliva, urine, skin strips, tissue etc
- Mice, rat, dog, human etc
- NCEs & generics

GLP Method Validation

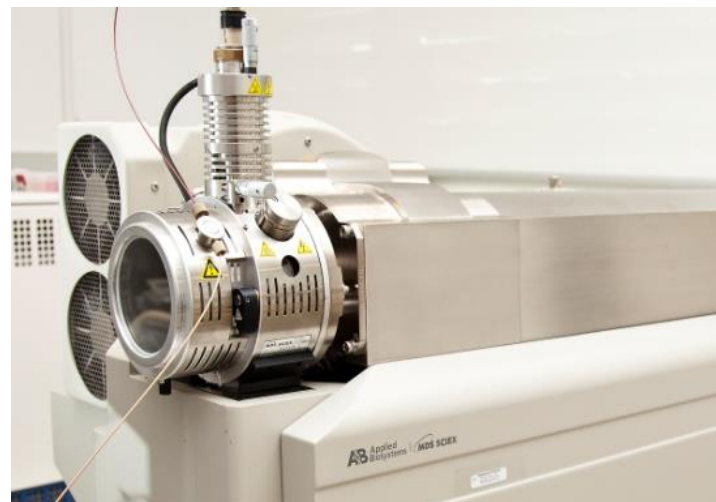
- Full validation to FDA/EMA Bioanalytical Guidance
- Partial validation
- Method transfer

GLP Sample Analysis

- GLP clinical
- GLP pre-clinical sample analysis
- Non-GLP discovery sample analysis

Dose formulation & TK analysis

- GLP preclinical studies



LC-MS/MS Analytical Capability

Liquid Chromatography - Mass Spectrometry (LC-MS/MS)

- AB Sciex - 5500Q, 6*4000s, most common in large pharma & CROs
- AB Sciex Triple Quad 5500Q system
 - More sensitive than 4000 series
- All LC-MS/MS fully qualified and under change control
- Full service contracts and local engineer



LC-MS/MS Experience

Chemistry – PK/PD

- Sugars, nucleotides, enantiomers, steroids, prodrugs, immunosuppressants, nanoparticles, neurotransmitters, peptides
- Biologics – proteins, Mabs
- Specialty multiplex assays – 5 analyte cannabinoid assay

Biomarkers

Addressing research unmet needs

Addressing immunoassay low level deficiencies

- Peptide hormones
- Steroids
- Neurotransmitters

Alzheimer's assays

- Triplex Abeta 1-38, Abeta 1-40 and Abeta 1-42

No assay available - de novo development

- 3-O-methyl glucose (3-OMG)



Immunoassay Services

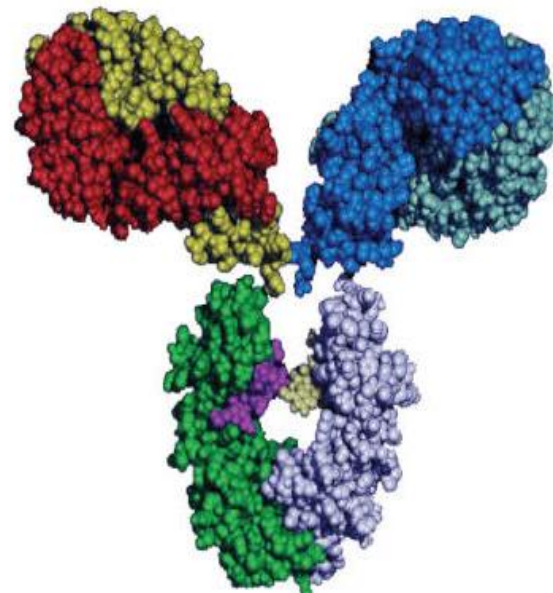
Immunoassay/Ligand Binding

- Quantitative PK analysis of macromolecules, incl. monoclonal antibodies
- Immunogenicity (anti-drug assays)
- Neutralising antibody assays (LBA)

Types of Molecules Measured and Supported

- Recombinant proteins
- Monoclonal antibodies
- Bispecific antibodies
- Fusion proteins
- Oligonucleotides
- Vaccines
- Small molecule-conjugates
- Biosimilars/Biobetters
 - Lucentis®/Ranibizumab
 - Forsteo®/Forsteo®/Teriparatide
 - Avastin®/Bevacizumab
 - Actemra®/Tocilizumab
 - Xolair®/Omalizumab
 - Herceptin®/Trastuzumab
 - Soliris®/Eculizumab

Antibody:
150,000 Daltons



Aspirin:
180 Daltons



Method Development and Validation

Method Development

- Bespoke methods developed from sponsor-provided or commercial available reagents
- Blood, plasma, serum, saliva, urine, tissue etc
- Mice, rat, dog, human etc
- *De novo* raise antibodies (outsourced to BioGenes, BioRad)
- Synthesis of oligonucleotide probes (commercial suppliers)

GLP Method Validation

- Full validation to FDA/EMA Bioanalytical Guidance
- Partial validation
- Method transfer

GLP Sample Analysis

- GLP clinical
- GLP preclinical sample analysis
- Non-GLP discovery sample analysis

TK Analysis

- GLP preclinical studies

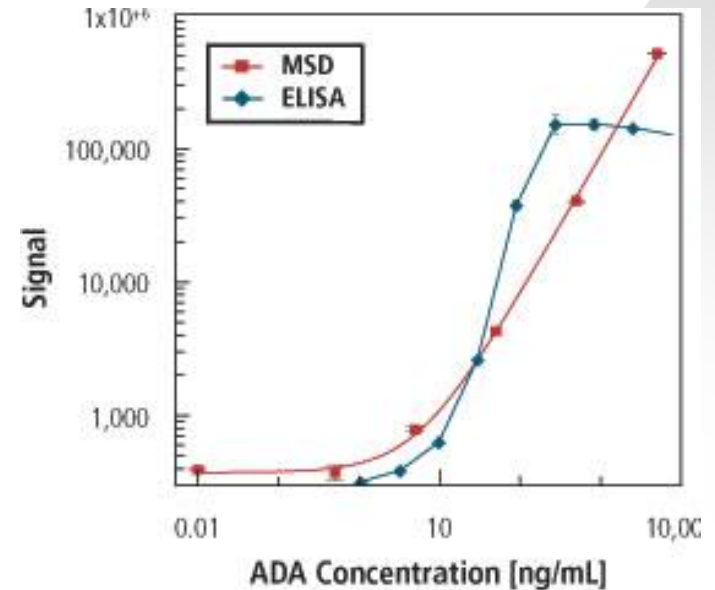
Immunoassay Services

Pharmacokinetic Analysis

- Analysis of test article in biological fluid
- Macromolecules
- Immunoassays/ligand binding assays

Immunogenicity Assessment

- Assessment of anti-drug antibodies
- Screening/confirmatory/titre
- Neutralising activity
- Equipment platform: Mesoscale Quickplex SQ120
 - State-of-art multiplexing instrument
 - Excellent sensitivity
 - High dynamic range vs ELISA (graph)



Immunoassay Instrumentation



MSD Quickplex SQ120

- PK
- Immunogenicity



Gyrolab xPlore™

- PK
- Immunogenicity



Spectramax Paradigm™

- PK
- Immunogenicity



Biotek 405 LS

- Automated plate washer



Molecular devices AquaMax

- Automated plate washer



Nanodrop

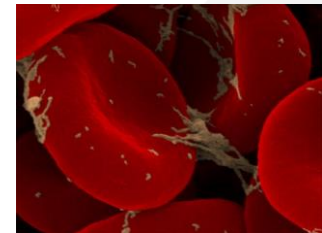
- Microvolume spectrophotometer

Immunobiology Services

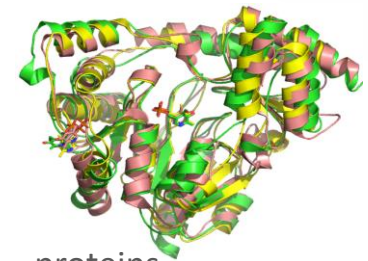
Immunobiology is broad area of science that intersects multiple therapeutic areas of emerging importance, including Immunology and cellular and molecular biology. Commencing in Q2 of 2020, Agilex Biolabs will be offering a new immunobiology service to assist clients better understand the mechanisms behind their drugs and fully evaluate the effects of test compounds

Services will include:

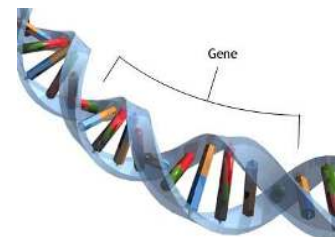
- Flow cytometry
 - Immunophenotyping in blood
 - Extracellular markers of cell activation, indicators of cell injury and death
 - Receptor occupancy and test article binding
- Cell-based models and primary culture assays
 - Cell-based assays for mode of action
 - Cell-based neutralising antibody assays
 - PBMC and whole blood analysis
 - PBMC and whole blood stimulation and cytokine release
- Biomarker assessments
 - Single and multiplex analysis with Luminex and Mesoscale (MSD)
 - Single analyte analysis using commercially available assays or bespoke



cells



proteins



genes

Immunobiology Instrumentation



MSD Quickplex SQ120

- Multiplex Biomarkers/cytokines/chemokines
- Up to 50 analytes per sample
- Broad dynamic range



Gyrolab xPlore™

- Single analyte PD/Biomarker assays



Spectramax Paradigm™

- Single analyte ELISA



Luminex MAGPIX xPONENT

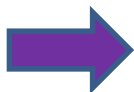
- Multiplex Biomarkers/cytokines/chemokines
- Up to 50 analytes per sample
- Broad dynamic range



BD FACSymphony A3 20 colour flow cytometer

- 22 parameters
- Broad range of dyes for multi-analyte analysis on single cells

Typical Workflow at Agilex



RFP Phase

Typical information required: Type of drug (NCE/NBE)/chemical structure/existing methods/preclinical data



Procurement Phase

Requirements: List of materials and critical reagents from sponsor.

Timeframe: Typically 4 weeks depending on suppliers and stock



R&D Phase – Method Development/Transfer

Requirements: Methods to be transferred/discussion around assay requirements and sensitivity/drug tolerance

Timeframe: Typically 4 weeks LC-MS/MS and 8 weeks Immunoassay/immunobiology



GLP Validation phase

Requirements: which regulatory agency (EMA/FDA/both)

Length of long term stability required (LTS)

Timeframe: Typically 4 weeks + additional 2 weeks QA

Quality Assurance

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

GLP Consulting Services

- Our highly experienced QA team regularly consult to external parties who require training and advice on GLP or other quality systems requirements

Any Questions?



Contact us

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Get in touch to learn more about how we can help you deliver your next project