IMMUNOBIOLOGY SERVICES

• PK • Immunogenicity • PD (Immunology and Flow Cytometry)
• Cell-based assays • Biomarkers

AGILEX BIOLABS

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.

What is Immunobiology?

Immunobiology is a functional branch of immunology, which deals with the biological effects of the immune system.

In higher organisms, the immune system is responsible for surveillance, detection and eradication of foreign cells and pathogens.

The immune system is comprised of a complex network of cells, which start out as bone-marrow-derived hematopoietic progenitor/stem cells and differentiate into lymphocytes (T cells, B cells, natural killer (NK) cells and monocytes) in the bone marrow, lymphoid tissue, and organs (highlighted in the adjacent flow diagram).

These cells are commonly called white blood cells and are detectable in whole blood or can be isolated from whole blood and stored long term as peripheral blood mononuclear cells (PBMC).

Agilex Biolabs' immunobiology service can assist clients to better understand the mechanisms behind their drugs and fully evaluate the effects of test compounds.

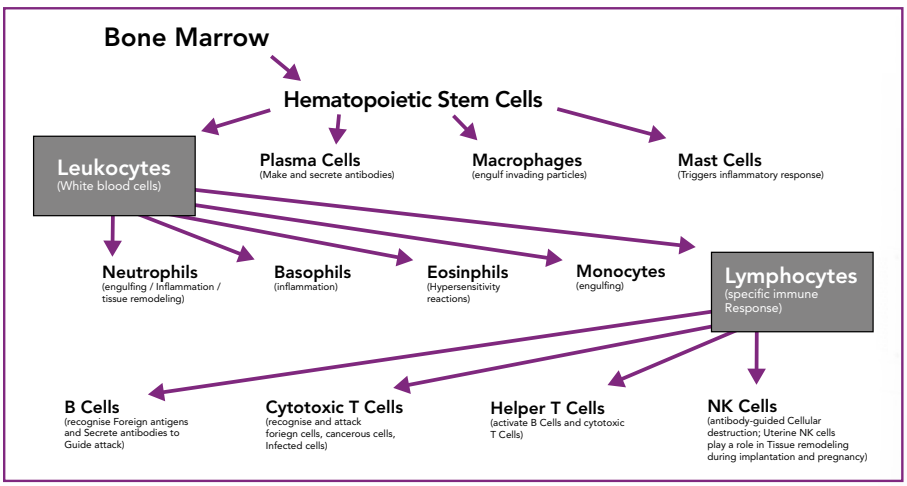
Our Services
Our experienced team can develop and validate a wide array of assays to the latest FDA/EMA bioanalytical guidance, utilising the very latest technology and equipment. Examples include:

Pharmacokinetics (PK)
Immunoassay ligand-binding (ELISA, MSD, Gyrolab) and LC-MS-MS bioanalytical services

Immunogenicity
Anti-drug antibody assays (homogenous with acid dissociation, SPEAD, PandA) and neutralising antibody assays (nAb)

Pharmacodynamics
Mode of action (Cell-based assays)
Cytokine release assays (PBMC or whole blood) Cell-based assays (nAb)
Tissue extraction and analysis of intracellular signaling

Biomarkers
MSD or Luminex single or multiplex



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Immunology Services

Our expanded immunobiology service includes immunological marker evaluation using the latest BD Biosciences FACSymphony™ A3 cell analyser equipped with 20 colour capability (configuration shown below).

Emission Band	370-400	420-450	480-540	570-590	610-630	650-680	700-750	780-810
355 UV	BUV395		BUV496	BUV563			BUV737	BUV805
405 Violet		BV421	BV480/BV510		BV605	BV650	BV711	BV786
488 Blue			BB515 / FITC				BB700	
561 YG				PE	PE-CF594	PE-Cy5		PE-Cy7
640 Red						APC	APC-R700	APC-H7

Immunology and Flow Cytometry

Immunological marker evaluation using the BD FACSymphony™ A3, 20 colour flow cytometer, for:
Immunophenotyping - Receptor Occupancy - Functional Immunological assays

Standard flow cytometry panels

WHOLE BLOOD			PBMC			General Cancer - PBMC		
Marker	Emission band	Target	Marker	Emission band	Target	Marker	Emission band	Target
CD3	BUV395	T cell	CD3	BUV395	T cell	CD3	BUV395	T cell
CD20	BV421	B cell	CD20	BV421	B cell	CD8	BV510	T Cytotoxic
CD193 (CCR3)	BV510	basophil / eosinophil	CD8	BV510	T Cytotoxic	CD4	FITC	T Helper
CD63	FITC	basophil activation marker	CD4	FITC	T Helper	CD134/OX40	BV786	Activated T cells
CD15	PE	neutrophil	CD45RA	BUV737	naïve T cells	CD45RA	BUV737	naïve T cells
CD45RA	BUV737	naïve T cells	CD14	PE-CF594	classic monocyte	CD154	PE	T cell activation
CD14	PE-CF594	monocyte	CD56*	PE Cy7	NK cells	CD80	APC H7	T cell activation
CD56*	PE Cy7	NK cells	CD16	APC	NK / intermediate & non-classical monocyte	FVS	R700	live / dead
CD16	APC	NK / neutrophil / granulocyte	FVS	R700	live /dead	CD279 (PD-1)	BV650	Immune checkpoint
FVS	R700	live/dead				CD274 (PDL1)	BV421	Immune checkpoint