

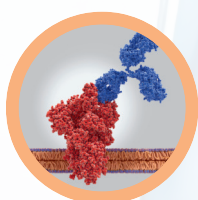
BIOLOGICS & ATMPs TESTING PLATFORMS

Adgyl Lifesciences delivers end-to-end testing solutions for biologics, ensuring precision and compliance at every stage.

Our expertise span bioassays, and immunogenicity assessments, tailored to meet the highest global quality standards.

From early drug development through to commercial release, our services are designed to support critical milestones and guarantee adherence to international regulatory guidelines — helping you bring safe, effective biologics to market with confidence.

BIOASSAYS



Cell based

- Reporter gene proliferation and neutralisation assay



Non-cell based

- Immunogenicity assay
- Cytokine assay
- Ligand binding assay
- Biomarker assay



IIRMI

(Innate Immune Response Modulating Impurities)

- Human Peripheral Blood Mononuclear Cells (PBMC's)
- Cell lines (TLR specific)

GENOMICS SOLUTIONS



Pharmacogenomics -

Screening using microarray (GDA PGx)



Toxicogenomics

Effect of drugs on different pathways | RNASeq and qPCR for Gene expression



Biomarkers

Exome sequencing | Whole genome sequencing | Single gene mutation detected by Sanger sequencing



Microbiome

Microbiome & metagenome characterisation | 16S for bacteria | ITS for Fungus | Shotgun Metagenomics

ADVANCED TESTING CAPABILITIES

- **Potency & Functional Assays**
 - Transgene expression
 - Cytotoxicity assays
 - Cytokine release
 - Reporter gene assays
- **Receptor Binding & Cell-based Assays**
 - Receptor-ligand binding
 - Cell-based reporter assays
- **Formulation / test item analysis**
- **PK Biodistribution**
- **Immunogenicity (ADA, Nab)**
- **Identity and Phenotypic Assays** - Biomarker (target engagement or modulation), Immune profiling
- **Impurities and Immunogenicity Testing**
 - Empty capsids and residual proteins
 - Immunogenicity for antibody and cellular responses
- **Biodistribution** - Biodistribution & shedding assessments and replication-competent virus testing

Supported Modalities (at a glance) - mAbs | Bispecifics | Fusion proteins | Enzymes | Peptides | Proteins | Cell Therapy (CAR-T) | Gene Therapy | Nucleic Acids (mRNA, DNA) | Vaccines and more

WORKFLOW



REGULATED BIOANALYSIS AND IMMUNOGENICITY

- Development, transfer, validation of PK/TK, ADA and NAb methods to support various stages of biologics/biosimilar development
- Use of sensitive assay platforms like LC-MS/MS, ELISA and MSD
- Complimentary capabilities to generate assay specific polyclonal antibodies and labelled reagents

Active Compounds -

Dulaglutide | Liraglutide | Plecanatide | Linaclotide | Teriparatide | Retatrutide | Semaglutide | Tirzepatide | Insulin Glargine

Type of Agonist -

Single agonist | Dual agonist | Tri-agonist

Parameters assessed in the validation assay -

Relative potency | Relative bias | Accuracy | Precision | Linearity | Range | Specificity

GENOMICS SOLUTIONS FOR ONCOLOGY

- Whole genome sequencing
- Exome sequencing
- Somatic and germline variant identification
- RNA sequencing
- Single cell sequencing
- Epigenetics using NGS/array
- SNP validation using Sanger and Hotpot variant identification

INSTRUMENTATION

- Meso Scale Discovery QuickPlex SQ 120
- Molecular Devices SpectraMax M2e multimode reader
- Tecan M200 multimode reader
- Perkin Elmer EnVision multimode reader
- Biotek 405 TS Plate Washer
- Biotek 405 LS Plate Washer



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