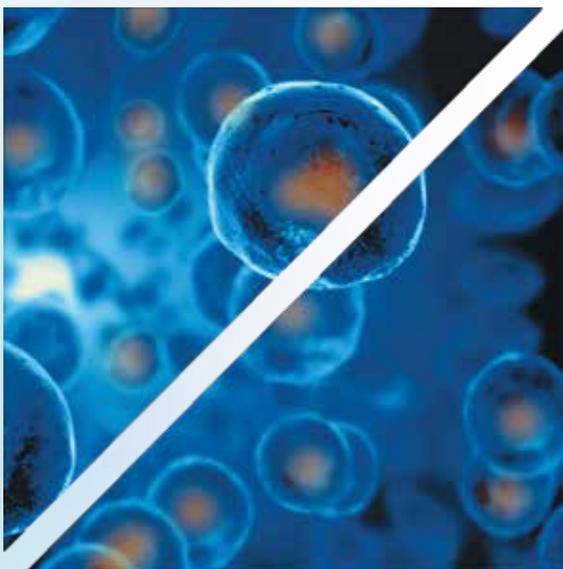


Immunogenicity

Immunogenicity assays are essential in cell and gene therapy as they assess the immune system's reaction to treatments. This evaluation is critical for vectors or transgene proteins, ensuring safety, efficacy, and compliance with regulatory standards. Pharmaron offers expertise in designing, developing, and validating assays to support these evaluations for your pre-clinical studies and clinical trials.



Services

in vivo

- Toxicology
- Biodistribution and Shedding
- Immunogenicity
- Small & Large Animal Models
- Regenerative/Stem Cell
- Testing
- Full Spectrum Ocular Services
- Custom Animal Models
- Immunocompetent Models
- Immunocompromise Models

Bioanalysis

- ADA and NAb Assay
- Cellular Response
- Cytokines Analysis
- Immunophenotyping
- Immunogenicity characterization
- Viral Clearance
- Vector Biodistribution
- Viral Shedding
- Biomarkers

Analytical Platforms

- LC-MS/MS
- ddPCR, qPCR, RT-PCR
- ELISA
- MSD
- Other Plate-based Assays (Absorbance, Fluorescence, Luminescence)
- Quantitative Western Blot
- Electrophoresis
- Chromatography
- Flow Cytometry

Add-on Services

- Generation & screening of antibodies (polyclonal, monoclonal)
- Quality PBMC isolation and/or sample treatment
- Peptide generation

Pharmaron conducts *in vivo* treatments on various animal models and gathers blood and other bodily fluids. Sample collection and processing are carried out using sterile methods to reduce the likelihood of contamination. Subsequently, the samples are examined for the detection of treatment-specific immunogenicity. Additionally, Pharmaron can utilize clinical samples for all these evaluations.

- Type of Treatment: AAV, LNP, Lentiviral, Plasmid, RNA, Oligonucleotide, Cell therapy
- Test System: Dog, minipig, rabbit, rat, sheep, guinea pig, humans
- Matrices: Blood, Serum, Plasma
- Analytes: Antibodies capsid, proteins, cytokines, surface/intracellular markers

Immunogenicity Assessment

Humoral Response	Cellular Response
<p>Choose Format & Platform</p> <ul style="list-style-type: none"> ■ ADA- Bridging or Direct binding ■ ADA- Platform: ELISA or MSD ■ NAb- Plate or Cell-Based ■ NAb- Reporter gene (plate-based or Flow) <p>Optimize Conditions</p> <ul style="list-style-type: none"> ■ Determine conc. of reagents ■ Acid Dissociation ■ Blocking and incubation conditions ■ Positive and negative controls ■ Minimal required dilution (MRD) <p>Validation Elements</p> <ul style="list-style-type: none"> ■ Assay Limits (LOB, LOD, LLOQ, ULOQ) ■ Cut point ■ Precision ■ Sensitivity ■ Selectivity ■ Specificity/Drug Tolerance 	<p>Choose Format & Platform</p> <ul style="list-style-type: none"> ■ ELISpot/FluoroSpot ■ ICS (Intracellular Cytokine Staining) ■ T Cell Proliferation Assay ■ Cytokine Release Assay (Luminex, ELISA, MSD) ■ Phenotyping and Cell Characterization Assay ■ Sequencing <p>Optimize Conditions</p> <ul style="list-style-type: none"> ■ Cytokine/chemokine/Growth Factor selection ■ Panel design and fluorophore selection ■ Antigen concentration and stimulation time ■ Antibody titration ■ Sample type and preparation ■ Controls <p>Validation Elements</p> <ul style="list-style-type: none"> ■ Assay Limits (LOB, LOD, LLOQ, ULOQ) ■ Precision ■ Sensitivity ■ Specificity



BioCGTFly0525v1



Laboratory Services



Chemistry, Manufacturing & Control



Clinical Development



Biologics & CGT