

LARGE MOLECULE BIOANALYTICAL SERVICES

EXPERTISE:

We have a team of highly qualified and dynamic staff with a blend of young and experienced scientists in the field of large molecule bio analysis. The team holds proven expertise and experience in

- Pharmacokinetics(PK) bioanalytical services
- Immunogenicity (ADA) bioanalytical services
 - Screening Assays
 - Confirmatory Assays
 - Titering Assays
 - neutralizing Ab

Assays

- Bio marker bioanalytical services
- Vaccine Immunogenicity testing services

BIO ANALYTICAL LABORATORY

- State-of-the-art equipments
- Prerequisite for light sensitive molecule handling
- Restricted entry
- Dedicated storage and sample accession area

A) PHARMACOKINETICS TESTING

• PK ASSAYS

- Adalimumab
- Trastuzumab
- Rituximab
- Bevacizumab
- Pertuzumab
- Etanercept
- Erythropoietin
- G-CSF
- Peg-GCSF
- Vitamin-B12 by CMIA
- FSH by CMIA
- Levothyroxine

B) IMMUNOGENICITY TESTING

• THREE TIRED EVALUTION APPROACH INCLUDES

- Anti drug antibody screening assay
- Positive ADA confirmation assay
- Titration
- Immunogenicity assay
 1. Anti drug antibody testing for Erythropoietin
 2. Anti drug antibody testing for Bevacizumab
 3. Anti drug antibody testing for Rituxumab
 4. Anti drug antibody testing for Adalimumab
- Neutralizing assay
 1. Neutralizing antibody testing for Bevacizumab
 2. Neutralizing antibody testing for Adalimumab
 3. Neutralizing antibody testing for Rituximab

C) PHARMACODYNAMIC ASSESSMENTS

- Low molecular weight heparin
 - Anti factor Xa (Chromogenic)
 - Anti factor Iia (Chromogenic)
 - HEP test (Clotting)
 - APTT (Clotting)
 - TFPI by ELISA
- IGF-1
- hGH
- Human Immunoglobulin G, A, M
- CD 19
- CD 34
- Reticulocyte count (% and absolute)
- Hb, Hct, RBC count

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CELL CULTURE LABORATORY

The large molecule bio-analytical lab also includes a well equipped state-of-the-art cell culture laboratory to provide support for large molecule bio-analysis. This cell culture lab set up enables thorough evaluation of neutralizing anti drug antibodies using cell based assays, The cell culture lab also supports various other cell based assays key to new product development. Such assays include cell cytotoxicity assay, cell viability assay, cell proliferation assay etc. Potency assay or functional bioassay for drug is one of major requirements for new drug development.

- State-of-the-art equipments
- UV light provision for lab sterilization
- Separate area for autoclave and hot-air oven
- Pass-box facility for transfer of materials to the lab

CELL BASED METHOD TESTING

1. Adalimumab Neutralizing antibody cell based assay
2. Rituximab Neutralizing antibody cell based assay
3. Cytokine release In-Vitro assay

IN-VITRO METHOD

1. In-Vitro Protein Flocculation
2. In-Vitro Hemolytic Index
3. In-Vitro drug Interference Study
4. In-Vitro Platelet Activation
5. In-Vitro Hemolytic potential of drug

VACCINE STUDIES:

OUR VACCINE EXPERIENCE INCLUDES METHODS VALIDATION AND SAMPLE ANALYSIS FOR

- Measles virus IgG
- Mumps virus IgG
- Rubella virus IgG
- Diphtheria toxoid IgG
- Bordetella Pertusis IgG
- Tetanus toxoid IgG
- Haemophilus influenzae type B IgG
- Anti hepatitis B surface antigen (Hbs) IgG
- Anti-S Typhi Vi IgG
- Influenza virus H1N1, H3N2 and Type B-10 Brisbane, Type B-12 Massachusetts IgG detection done by haemagglutination and aemagglutination inhibition method.

TECHNOLOGY PLATFORMS FOR VACCINE ANALYSIS

- ELISA
Chemiluminescent microparticle immune assay (CMIA)
- Cell culture

TESTING OF BIOMARKERS CONSUMER RESEARCH, NUTRACEUTICALS AND OTHER RELATED CLINICAL TRIAL STUDIES:

The lab provides comprehensive support in validation and analysis of wide range of biomarkers for PHC, nutraceuticals and other related clinical trials. The lab has a wide range of validated biomarker methods to support aforementioned studies.

- Ghrelin
- Adiponectin
- Leptin
- Acetylcholine
- Epinephrine
- Nor Epinephrine
- Malondialdehyde
- Dopamine
- Isoprostane
- Melatonin
- Super oxide dismutase
- Oxidized LDL
- Nitrotyrosine
- Serotonin
- MCP-1
- Klotho protein
- Catalase

SAMPLE MANAGEMENT:

- Dedicated and trained sample custodian
- -70°C freezers
- -20°C Freezers
- Regulated temperature monitoring system

INSTRUMENTS:

- Microplate reader with absorbance, luminescence and fluorescence features (Spectramax iD3)
- Bio-safety cabinet (ESCO, 6 Ft)
- Co2 incubators (Thermo Scientific Steri-cycle i160)
- Inverted microscope with LED-fluorescent attachment and camera (Zeiss Axio Vert, A1 FL-LED)
- Liquid nitrogen biocanister (Thermo Scientific, 20L)
- Ultra-low freezer (Eppendorf, -70°C)
- Refrigerator (Celfrost)
- Refrigerating Centrifuge (Thermo Scientific)
- Semi-micro weigh balance
- Constant temperature water-bath
- Autoclave
- Hot-air oven