

LARGE MOLECULE BIOANALYTICAL SERVICES

TRACK RECORD OF EXPERIENCE:

	SAMPLES ANALYZED
PK	>46000
PD	>11500
ADA	>600
Vaccines	18575
Total	>75000

BIO ANALYTICAL LABORATORY

- State-of-the-art equipments
- Prerequisite for light sensitive molecule handling
- Restricted entry
- Refrigerators & freezers for reagent storage

EXPERTISE AND STAFF:

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

• PK ASSAYS

- Levothyroxine
- Adalimumab
- Follicle Stimulating hormone
- Bevacizumab
- Erythropoietin
- Trastuzumab
- Etanercept
- Rituximab and others

• IMMUNOGENICITY ASSAY

- Erythropoietin
- Adalimumab
- Trastuzumab
- Bevacizumab and others

IMMUNOGENICITY TESTING:

THREE TIRED EVALUATION APPROACH INCLUDES

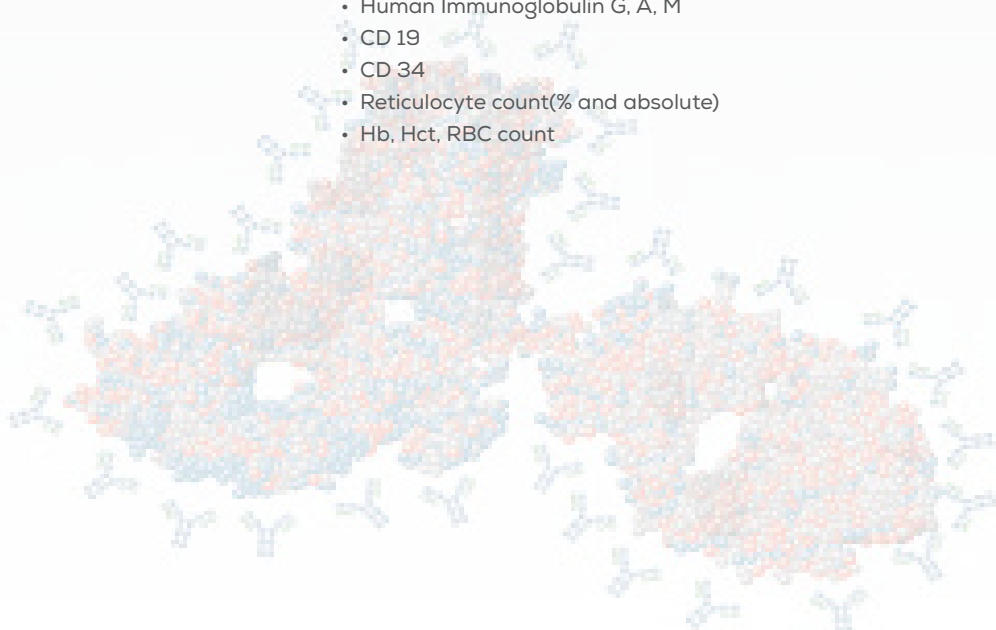
- Anti drug antibody screening test
- Positive ADA confirmation test
- Titration

METHODS AVAILABLE

- Anti drug antibody testing for Erythropoietin
- Anti drug antibody testing for Bevacizumab
- Anti drug antibody testing for Rituximab

METHODS FOR PHARMACO-DYNAMIC ASSESSMENTS INCLUDE

- Low molecular weight heparin (anti factor IIa and anti factor Xa , TFPI)
- 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 full 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

INSTRUMENTS:

- Microplate reader with absorbance, luminescence and fluorescence features (Spectramax iD3)
- Bio-safety cabinet (ESCO, 6Ft)
- 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

VACCINE STUDIES:

OUR VACCINE EXPERIENCE INCLUDES METHOD VALIDATION AND SAMPLE ANALYSIS FOR

- Measles virus IgG
- Mumps virus IgG
- Rubella virus IgG
- Diphtheria toxoid IgG
- Bordetella Pertusis IgG
- Tetanus toxoid IgG
- Varicella zoster 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 haemagglutination inhibition method.

TECHNOLOGY PLATFORMS FOR VACCINE ANALYSIS,

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

TESTING OF BIOMARKERS FOR PHC, NEUTRACEUTICALS AND OTHER RELATED CLINICAL TRIAL STUDIES:

The lab provides comprehensive support in validation and analysis of wide range of biomarkers for PHC, neutraceuticals 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
- Three -70°C freezer, one -20°C freezer
- Regulated temperature monitoring system