

Immunology & Large Molecule BioA Chemistry

The immunology and large molecule bioanalytical chemistry laboratories perform a range of tests evaluating PK, TK, ADA, biomarkers, immunogenicity, immunotoxicity. Additional capabilities include BSL-2/3 bacteriological and virus propagation, identification, morphological assessment, growth curves, and titration supporting in vivo efficacy and safety studies. Assessment of anti-viral antibody response is by TCID50, microneutralization (MN), plague, HA, and HAI assays depending upon virus and strain. Assessment of cell mediated immunity is performed by ELISpot and flow cytometry. The laboratory develops, qualifies, and validates assays according to SOPs supporting non-clinical GLP safety assessment as well as non-regulated exploratory studies. Lovelace Biomedical has the facility, equipment, and scientific expertise to meet your needs in large molecule studies from pharmacology to regulatory submission.

Capabilities

Our immunology and large molecule laboratories utilize state of the art equipment, a wide range of technology platforms, and have extensive experience in analytical assessment of biotherapeutics, vaccines, and gene/cell therapies to assist our clients from discovery through GLP safety assessment sample analysis. The laboratory is fully capable to provide de novo assay development, optimization, qualification, validation, including transfer validation in accordance with current regulatory requirements.

Highlights

- PK/TK/ADA
- ELISpot & Flow Cytometry
- Biomarker Methods
- Complement
- Immunotox Assays
- BacT & Virology Assays
- GLP Sample analysis

Instrumentation

- BD FACSymphony Flow Cytometer
- Molecular Diagnostics Plate readers
- Immunospot S6 & S5
- MSD QuickPlex sq120
- Spectramax i3X
- Spectramax M2