charles river

Bioassays

With extensive experience in establishing, validating and conducting routine bioassays to Good Manufacturing Practice (GMP) standards, Charles River Biologics Testing Solutions has the capability to perform a comprehensive array of both in vitro and in vivo bioassays for a variety of biologically active molecules.

Bioassay Services

Charles River is able to provide a full range of services for bioassay development from inception to validation and testing. These services include:

- Method development
- Method transfer
- Method optimization
- ICH-compliant method validation
- Lot release testing for drug substance and drug product
- Stability testing
- Biocomparability testing for follow-on biologics

Assays Available

- Cell proliferation assays
  - Cell-based potency assays for EPO, PTH, G-CSF and GM-CSF
  - Antiviral cell-based assays for measuring the potency of interferons (IFN-α, IFN-β)
- Assays for monoclonal antibodies
  - Mode of action (MOA) assays: ADCC, CDC, apoptosis, pathway-specific reporter-based setups
  - Binding assays
  - Proliferation assays
  - Competitive assays
  - Neutralization assays

Assays Available

- Cell proliferation assays
- Assays for monoclonal antibodies
- Immunogenicity testing
- *In vivo* potency assays

Assay Readouts

- Fluorescence
- Time-resolved fluorescence
- Absorbance
- Luminescence
- Analysis by flow cytometry

Statistical Evaluation

- Parallel line analysis
- Four-parameter fit
- Five-parameter fit
- EC_{50} determination

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Assays Available (continued)

- Immunogenicity testing
  - Anti-drug antibody (ADA) assays: binding and neutralizing antibodies
  - Dendritic cell maturation assays
  - T-cell proliferation assays
  - Multiplex cytokine analysis by flow cytometry
- *In vivo* potency assays

Biosimilars

With extensive experience developing bioassays for monoclonal antibodies, Charles River is able to provide expert opinions and support for the analysis of biosimilars. Assays for many biosimilars have already been developed and optimized by our team of scientists and, after discussions, can be adapted to your particular compound. These bioassays along with the complementary portfolio of services available from Charles River make us the optimal partner for your biosimilar development needs.

In Vivo Potency Assays

Charles River can aid in the development of an *in vivo* potency assay through range-finding studies by investigating parameters such as dose level and route of administration, followed by validation and implementation. We have experience conducting *in vivo* bioassays for the purposes of showing efficacy and safety. These assays include adjuvant assessment, lot release potency, bacterial and viral challenge studies, and stability testing for a diverse range of products, including:

- Hormone potency assays, such as FSH, FSH-LH and hCG (performed to either EP or USP)
- Vaccines (performed to EP or USP, or new assays can be established)
- Neurotoxins
- Allergens
- Antivenoms
- Bacteria
- Blood products