



BIOLOGICS TESTING SOLUTIONS

Bioassay Services

Assays Available

- *In vivo* potency
- *In vitro* bioassays
 - Assays for monoclonal antibodies
 - Cell proliferation
- Biosimilar support

With extensive experience in establishing, validating, and conducting routine bioassays to GMP standards, Charles River has the capability to perform a comprehensive array of both *in vitro* and *in vivo* bioassays for a variety of biologically active molecules.

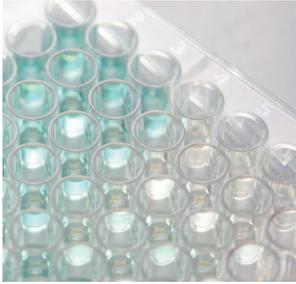
Our full range of services for bioassay development include method development, method transfer, method optimization, ICH-compliant method validation, lot release testing for drug substance and drug product, stability testing, accelerated stress condition testing, and comparability testing between innovator and biosimilar biological products.

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, PMSG, and hCG (performed to either EP or USP)
- Vaccines, including immunopotency, immunogenicity, antisera generation, and challenge studies (bacteria/viruses)
- Neurotoxins
- Allergens
- Antivenoms

EVERY STEP OF THE WAY



In vitro Bioassays

Charles River performs over 750 *in vitro* bioassays each year to cover a range of products. These include:

- Assays for monoclonal antibodies
 - Mode of action (e.g., ADCC, CDC, ADCP, and apoptosis)
 - Pathway-specific (e.g., for immune checkpoint mAbs and soluble targets)
 - Epitope binding/competitive binding
 - Fc gamma receptor binding
 - Bispecific mAbs, ADCs, and antiviral mAbs
- Cell proliferation assays
 - Cell-based potency for EPO, PTH, hGH, G-CSF, and GM-CSF
 - Antiviral cell-based for measuring the potency of interferons (IFN- α , IFN- β)

Assay Readouts

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

Statistical Evaluation

- Parallel line analysis
- Four- and five-parameter fit
- Equivalence test
- EC₅₀ determination

Biosimilar Support

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 the client's particular compound. These bioassays along with the complementary portfolio of services made available makes Charles River the optimal partner for biosimilar development.

