

Safety and Activity Testing Services



BIOASSAYS

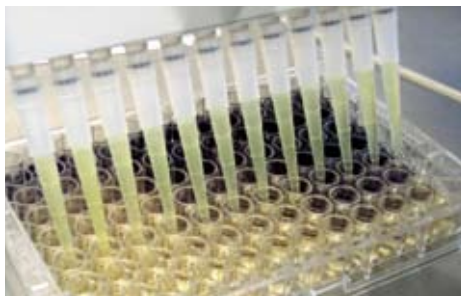
BSL BIOSERVICE performs the testing of about 350 batches of client material per year using a diverse range of bioassay types. Batch release testing is performed for both EU and US market.



For more than 25 years BSL BIOSERVICE has provided the scientific and experimental know-how to design and execute tailor-made bioassays in close collaboration with our clients from all over the world.

Our expertise in establishing cellular in vitro bioassays and our experience in the performance of non cell-based and in vivo bioassays are at your disposal in this sophisticated service.

In addition to various Sponsor specific assays the pharmacopeial methods for Erythropoietin (EPO), (PEG)-Filgrastim/Filgrastim (G-CSF), Urofollitropin (FSH), and Insulin are presently established.



Our development, validation and performance of bioassays/potency assays is US FDA approved and can be performed according to GLP and GMP regulations. Validation strategies are based on sponsors' requirements as well as international guidelines and recommendations (e.g. ICH, US-FDA, ISO, EMEA, USP/EP).

The team of bioassay scientists is aware of the newest trends and discussions in the field due to regular participation at international Bioassay conferences and workshops.

We offer you individual advice concerning your specific project with regard to scientific and regulatory requirements.



Development Validation Routine Testing

**GLP and GMP
US FDA approved**

In Vitro Bioassays

Assay Types

- Cell proliferation
- Cell survival
- Reporter Gene
- ELISA
- PACE, KIRA etc.
- Binding Assays
- CTL, ADCC, CDC

Assay Readouts

- Absorbance
- Luminescence
- Fluorescence
- Radioactivity (HTS)
- Flow cytometry (FACS)
(HTS, Six color)

In Vivo Bioassays

- Hormones, vaccines
(immunopotency, immunogenicity)
- Established pharmacopeial methods for Erythropoietin, FSH, Insulin etc.