

Excellence in Antibody and ELISA Development

BioGenes Berlin



Facts
Insights
Objectives



Immunization & Antibody Services

Custom Immunoassays

HCP Products & Services

Company Overview

BioGenes GmbH is an expert and a top-level service provider in the fields of challenging custom antibody and immunoassay development and offers complex analytical services.

Since 1992, we have been working with large and medium sized pharma and life-science companies as well as CMOs/CROs around the world. Our highly recognized services and products are used in the development, testing and production of biological therapeutics.

Choose BioGenes for unmatched quality and service in custom immunoassays and antibody development.

Your success is our priority.

Quality Assurance

BioGenes has been certified according to DIN EN ISO 9001 since 1999, demonstrating compliance with international requirements and regulations for quality assurance. In addition to this, we conduct assay pre-validation according to the International Conference on Harmonisation (ICH) guidelines.

Animal Welfare

BioGenes ensures compliance with German and EU animal welfare regulations, including guidelines for experimental animals and care standards set by FELASA. Our animal facilities are based in Germany and OLAW certified.



Highly specialized team in Berlin



Certified animal facility in Germany



Over 5,000 customers in 40 countries



10,000+ antibody and 400+ HCP projects



Inhouse antibody development & characterization

Immunization & Antibody Services

BioGenes has been providing routine and highly sophisticated custom antibody services for industry and research since 1992. We have undertaken numerous demanding projects for the most difficult targets. Our in-house animal facilities and laboratories are equipped to safety levels 1 and 2 and to risk levels 1-3**.

Monoclonal Antibodies (mAbs)

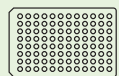
- Development and production of monoclonals in mice by enhanced hybridoma technology
- Cross-reactivity testing, pair search & antibody modification
- Hybridoma/Antibody sequencing



Phase 1
Consultation
with one of our experts prior and during the project



Phase 2
Immunization and titer determination
to select up to five mice



Phase 3
Cultivation of myelomas, cell fusion and hybridoma selection
via screening by ELISA



Phase 4
Cloning of relevant hybridomas
to obtain stable cell lines



Phase 5
QC and shipping of **cell culture supernatants** and **cryo cultures**

Approximate project duration:
5–8 months

Polyclonal Antibodies (pAbs)

- Species: rabbits, goats, sheep, rats or mice
- Adaptable immunization protocols (animal number and length)
- Specific or total IgG purification on demand
- Long-term experience in generation of polyclonal antibodies for in vitro diagnostics



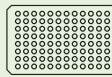
Phase 1
Consultation
with one of our experts prior and during the project



Phase 2
Preparation of the immunogen
(e.g., conjugation to carrier)



Phase 3
Immunization
according to the selected species and protocol



Phase 4
ELISA titer test
of pre-immune serum and antiserum



Phase 5
QC and shipping of **pre-immune sera** and **antisera**

Approximate project duration:
from 5 weeks, depending on the protocol

Anti-Idiotypic Antibodies

Anti-IDs are essential for monitoring and quantifying therapeutic antibodies and biosimilars in clinical samples, as well as for detecting antibody drugs that closely resemble circulating human immunoglobulins.

Development of monoclonal Anti-IDs

Monoclonal anti-IDs are routinely used as capture and detecting reagents in pharmacokinetic (PK) assays for the quantification of antibody drugs in patient serum.

- Tailored screening procedure to identify anti-IDs with specific properties, e.g. quantification, neutralization, blocking or identification of drug-to-target complexes
- Reproducible quality with lot-to-lot consistency in scalable amounts

Development of polyclonal Anti-IDs

Polyclonal anti-IDs are typically used as positive control in immunogenicity assays for the safety assessment of therapeutic antibodies.

- Tool for assay development to mimick human anti-drug antibodies
- Customized immunization schedules to obtain the required quantity of purified polyclonal anti-IDs
- Isolation of specific IgGs with subsequent anti-human-IgG antibody depletion by affinity purification

Non-Clinical Immunization Studies

The process of drug development involves non-clinical and clinical studies. Non-clinical studies are conducted using different protocols including animal studies. BioGenes offers non-clinical immunization studies in animals including mice (wildtype or transgenic), rats or rabbits for several applications (non-GLP) including:

- Testing of new vaccines and/or various adjuvants
- Challenging of vaccinated animals with the corresponding pathogen (up to biosafety level 2)
- Comparison of different routes of drug delivery
- Provision of blood, faecal and urine samples at various times after drug administration including final organ extraction

Custom Immunoassays

BioGenes has a wealth of experience in the development and production of robust and highly sensitive immunoassays for leading pharmaceutical and biotech companies worldwide. Our assays are suitable for various applications like quality control, drug discovery and diagnostics.

Development

- Inhouse development and production
- Polyclonal antibody generation in various species
- Monoclonal antibody development including pair search



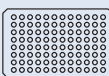
Phase 1
Consultation
with one of our experts prior and during the project



Phase 2
Preparation Immunogen
e.g. conjugation to carrier



Phase 3
In-house antibody development
characterization and modification



Phase 4
Assay development, qualification and pre-validation
acc. to regulatory guidelines



Phase 5
Assay kit production
or method transfer

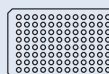
Approximate project duration:
6–18 months

Production

- Types of immunoassays: ELISA, CLIA and FIA
- Scalability according to your needs
- Production of assay components or complete kits, starting from 50 kits



Phase 1
Consultation
with one of our experts prior and during the project



Phase 2
Developing, Testing & Trial Production
to establish the parameter of the final product



Phase 3
Manufacturing
according to the agreed SOPs



Phase 4
QC & shipping
temperature-controlled, worldwide

Duration:
upon request

Special applications

Our custom immunoassays can be used for a variety of applications, including the assessment of drug efficacy and safety during the pre-clinical and clinical testing phases of biologics.

Immunogenicity Testing

Anti-drug antibodies (ADAs) may occur as an organism's response to a therapeutic protein drug during treatment, a reaction known as unwanted immunogenicity.

- Production of polyclonal antibodies (pAb) as positive control
- Labeling of the drug
- Selection of the pAb batch and assay design in bridging format
- Transfer of the antibodies or the assay method to FyoniBio or the customer's preferred CRO

Pharmacokinetic Assays

Pharmacokinetic assays investigate how the body reacts to the drug by monitoring distribution, metabolism and elimination.

- Production of monoclonal anti-drug antibodies
- Antibody pair search
- Characterization in matrices
- Transfer of the antibodies or the assay method to FyoniBio or the customer's preferred CRO for assay establishment
- At FyoniBio: Assay establishment and validation



Host Cell Protein Monitoring

At BioGenes, we understand the importance of reliable and effective Host Cell Protein (HCP) monitoring during biological drug manufacturing. The presence of Host cell derived impurities in the final drug substance can have adverse side effects when administered to human bodies or affect the drug product itself.

Ready-to-use ELISA Kits

Our enhanced generic 360-HCP ELISA approach provides multiple kits, each with a unique set of anti-HCP antibodies, resulting in superior HCP assays that detect a broad range of HCPs.

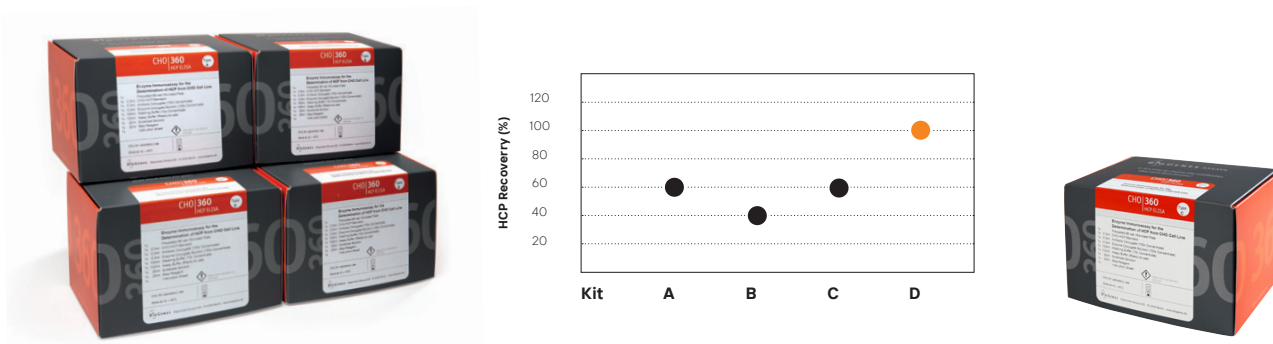
The ELISA kits are available for **CHO**, **E. coli** and **HEK293 cell lines** and suitable for early phases of drug and process development.

Features

- Method qualification according to applicable guidelines
- Different antibody set by various antigen preparations with distinct HCP pattern
- High specificity of antibodies approved by 2D analysis
- Detection of a broad range of HCPs with high sensitivity and specificity

How it works

Identify the best performing kit for your process with the starter set. The selected kit is then used for all subsequent tests.



BioGenes has more than 25 years of experience in developing highly sensitive host cell protein ELISAs for a variety of cell lines, e.g. mammalian, bacterial, yeast and even plant cell lines. During this time, we have successfully developed more than 400 process-specific or platform HCP ELISAs.

Custom HCP ELISA

Usually, process-specific or platform-specific ELISAs are required by regulatory bodies (FDA or EMA) for e.g. development and the commercial phase of biopharmaceuticals. The assay reagents have to fully demonstrate the feasibility of monitoring process-specific HCP.

Features

- Preparation of low molecular weight (LMW) fraction and total HCPs for immunization
- Flexible immunization protocols with different animal species
- Antibody purification tests of a representative antiserum pool
- Assay qualification/pre-validation is performed by established assay parameters according to ICH guidelines
- Reagent production for long-term availability



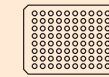
Phase 1
Consultation
with one of our experts prior and during the project



Phase 2
Antigen characterization
to evaluate whether antigen material represents HCP composition



Phase 3
Antibody generation
immunization, analysis, purification



Phase 4
Assay setup
qualification and reagent characterization



Phase 5
Pre-Validation
of the ELISA acc. to ICH guidelines



Phase 6
Method Transfer
to the customer or into kit production



Phase 7
Kit production / Deliverables

Approximate project duration:
12–18 months

Analytical Services for HCP Monitoring

BioGenes offers advanced technologies to characterize your Mock material, process samples, and to evaluate the anti-HCP antibody coverage by visual methods.

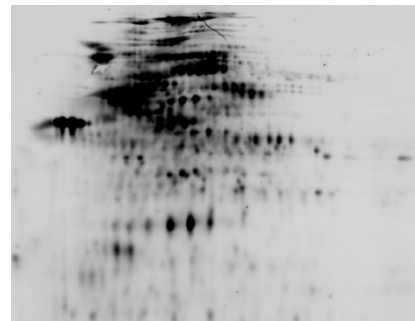
Sample characterization

Visualize, identify and compare proteins of several samples

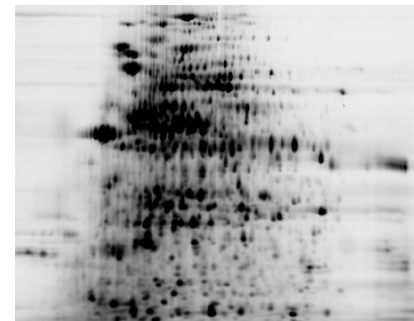
2D PAGE

- Higher resolution for improved protein visualization including low molecular weight proteins
- Various staining methods (Fluorescence, Silver, Coomassie)
- Spot picking for protein identification by mass spectrometry

Comparison of different 2D PAGE resolutions



Standard method

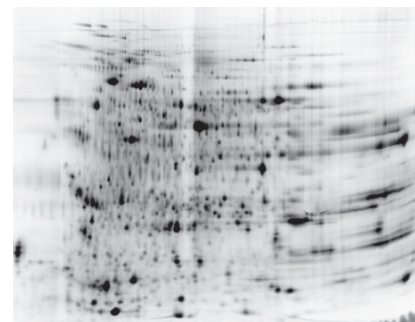


High resolution method

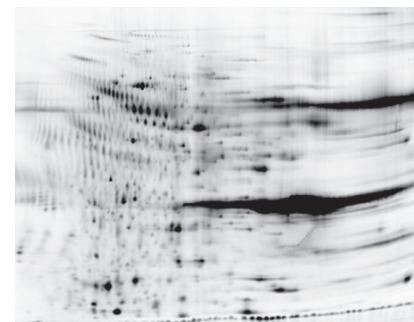
2D DIGE

- Comparative analysis of Mock and process samples
- Qualitative and quantitative evaluation

2D DIGE Analysis of Mock and process sample



Total protein spot pattern Mock



Total protein spot pattern process sample

In order to ensure successful HCP monitoring using an HCP ELISA, it is crucial to assess the suitability of the assay through analysis of the HCP antibody coverage. BioGenes recommends the use of orthogonal approaches to enhance the reliability of your HCP coverage determination and to overcome any limitations in the methodology.

Coverage of HCP antibodies

HCP coverage determination using Mock material and process sample by orthogonal methods

Immunoaffinity Chromatography & 2D DIGE or Mass Spectrometry

- Native assay conditions
- Broad dynamic range allows for detection of low abundant / low immunogenic proteins
- Improved suitability for product-containing samples
- Visual read-out with 2D DIGE
- Mass spectrometry services for protein identification & relative quantification in collaboration with partners upon request

High-Resolution 2D Western Blot

- Fluorescent multiplexing
- High sensitivity and accuracy



Choose BioGenes for unmatched quality and service in custom immunoassays and antibody development.

Your success is our priority.

1990
1991
1992
1993
1994

Experience from
various projects
since 1992



DIN ISO 9001: 2015
certified



All results &
reagents are
customer-owned



Full flexibility in
regard to single
services or full
packages



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