diagnostics
with passion

sifin



Contract Manufacturing Monoclonal Antibodies, Native & Recombinant Proteins

Certified processes for maximum quality and safety in diagnostics

FDA audited
DIN EN ISO 9001
CERTIFIED QUALITY MANAGEMENT SYSTEM
DIN EN ISO 13485

Our specialist know-how lies in the FDA-approved contract manufacturing of monoclonal antibody concentrates for blood grouping serology.

Evaluation | Mycoplasma decontamination | Master and working cell banks | Express manufacturing

Company Profile

DIAGNOSTICS WITH PASSION



Your Trusted Partner in Diagnostics

The roots of sifin diagnostics gmbh, although established in 1991, can be traced back to the early 19th century. The "Impfinstitut" – the Vaccination Institute – founded in 1802 later became the Berlin Vaccination Institution, which was part of the Institute of Epidemic Control, later re-baptised as the State Institute for Immunopreparations and Culture Media in 1966 in former East Germany. This institute was what would eventually become sifin diagnostics gmbh.

Thanks to investments by a German family of entrepreneurs in 1992, the diagnostics division (microbiology and blood grouping serology) continued after the German reunification.

Since then, sifin diagnostics gmbh has recorded constant growth. Today the company, which is still in family ownership, has an established position in the diagnostics industry. In the past few years, especially the export activities have been strengthened and could be intensively developed in the key markets of Europe and Asia.

sifin diagnostics gmbh offers more than 600 standard products in the area of microbiology and immunology. Beside this we are proud of our flexibility in special requests. We thus provide culture media according to your formulation, or we take care of your cell line. Our monoclonal antibodies may be supplied in your required format as ready-to-use or concentrate in bulk volumes.

The company has an excellent reputation thanks to its great flexibility and reliability in the fulfilment of specific customer requests. sifin diagnostics gmbh is a trusted partner and competent contact for many companies all over the world.

Contents

Contract Manufacturing
Monoclonal Antibodies,
Native & Recombinant Proteins

Our expertise, your benefits 4
- ✓ Excellent quality management
- ✓ Tailored antibodies
- ✓ Satisfied partners since 1994

Process flow 5
- ✓ Contract manufacturing of mammalian cell-based products
- ✓ Optional service

Consultation, immunisation and hybridoma generation 6
- ✓ Overview
- ✓ Additional services

Cell line evaluation 7
- ✓ Status evaluation

Mycoplasma decontamination 8
- ✓ Reliable elimination of mycoplasma

Creation of a master and working cell bank 9
- ✓ For use in manufacturing of production cell cultures

Cell banking 10
- ✓ Consistent product quality over years
- ✓ Excellent maintenance of working cell banks

sifin 6-week special 11
- ✓ Express manufacturing

Broad range of chromatography and immunochemical techniques 12
- ✓ Techniques
- ✓ Labelled antibodies

Monoclonal antibodies à la carte 13
- ✓ Monoclonal antibodies available as concentrates or in bulk volumes
- ✓ Blood grouping serology & immunochemistry
- ✓ Anti-Shigatoxin (Verotoxin)
- ✓ Monoclonal Anti-Rabies, FITC-labelled
- ✓ Anti-Salmonella or Anti-Shigella

Your key to success 14
- ✓ Executive summary
- ✓ From laboratory scale to large-scale production

TAILORED PRODUCTS

Optimised management of your cell line and reliable production of antibodies in high concentrations

Date of revision: 16/10/2023



Our Expertise, Your Benefits
Your Benefits at a Glance

Excellent quality management

- DIN EN ISO 13485
- DIN EN ISO 9001
- FDA audited

TAILORED PRODUCTS

„sifin diagnostics gmbh addresses all IVD-regulated markets in contract manufacturing and is among the few FDA-audited contract manufacturing companies producing monoclonal antibodies for blood grouping diagnostics."

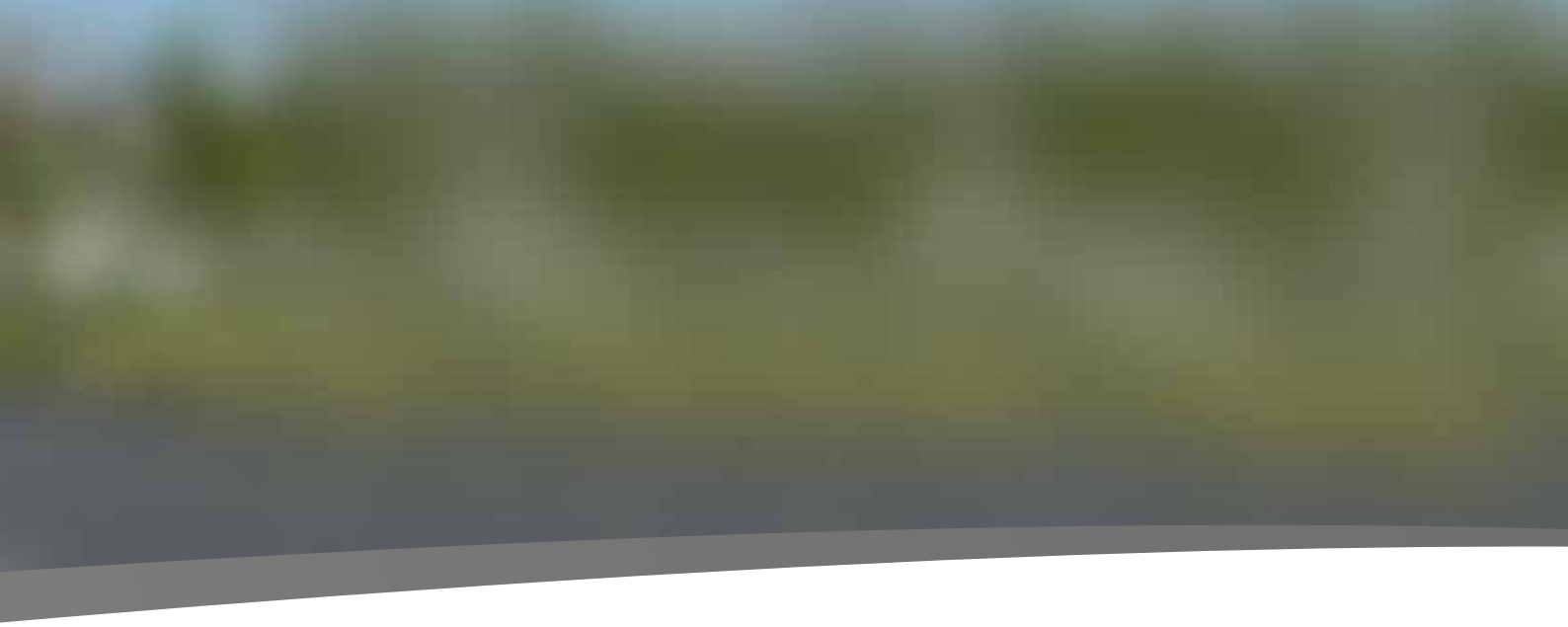
Tailored antibodies

- Monoclonal antibodies in cell culture supernatant
- Purified monoclonal antibodies
- Labelled monoclonal antibodies

Satisfied partners since 1994

- Long-term partnerships with national and international IVD companies
- High concentration of monoclonal antibodies
- High-cell-density batch processes
- Contract manufacturing of mammalian cell-based products





Process Flow
Tailored Products

Contract manufacturing of mammalian cell-based products

Advice, immunisation and hybridoma generation

Cell line evaluation (mammalian cells)

Mycoplasma testing, mycoplasma elimination where necessary

Production at laboratory scale, evaluation of results by customer

Production or recommendation for further action

Delivery
mAb, native or recombinant glycoproteins, conditioned cell culture supernatants, biomass

Optional service

- Recloning
- Creation of a working cell bank
- Cryogenic storage
- Immunochemistry



Consultation, Immunisation and Hybridoma Generation

Example project

Development of murine hybridoma clones for production of monoclonal antibodies follows a step by step protocol with the possibility of project termination at any step of the development

Step 1	**Immunisation of 3 mice and bleed for control of antibody titer by solid phase ELISA, selection of one mouse for cell fusion**	12-14 weeks
Step 2	**PEG mediated cell fusion of mouse splenocytes with mouse myeloma cells (SP2/0-Ag14), screening for hybridoma growth and antibody production**	2-4 weeks
Step 3	**Hybridoma selection of up to 8 clones, subcloning of 3 selected clones by limiting dilution (3x per clone), propagation and cryoconservation (5 ampoules per clone)**	8-10 weeks

Customer decision for:

Transfer of selected clones to customer

Cultivation and evaluation of antibody production

Upscaling

Additional services

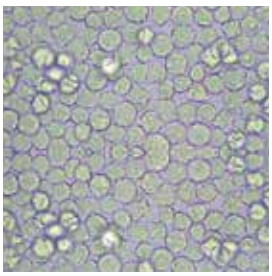
- Determination of antibody isotype and IgG subclasses by ELISA

Seramun

Cell Line Evaluation
Status Evaluation

We check whether your cell line is free of mycoplasma, how effectively your cell line is growing and how well the target product is being secreted

- Initial check of hybridoma cell line (test of cell density and vitality)
- Growth of cell line until development of inoculum for a suitable culture system for suspension culture (spinner/roller cultures)
- Culture management and monitoring
- Accumulation of culture supernatant containing product
- Affinity cleanup
- Dialysis/buffering against PBS
- Aseptic filling
- Creation of a reference sample
- Protein quantification using OD_{280}
- Delivery as agreed
- Batch certificate



Do you have a specific request?

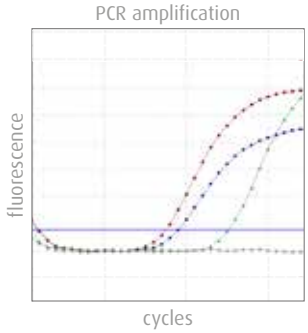
We develop and produce according to your demand.

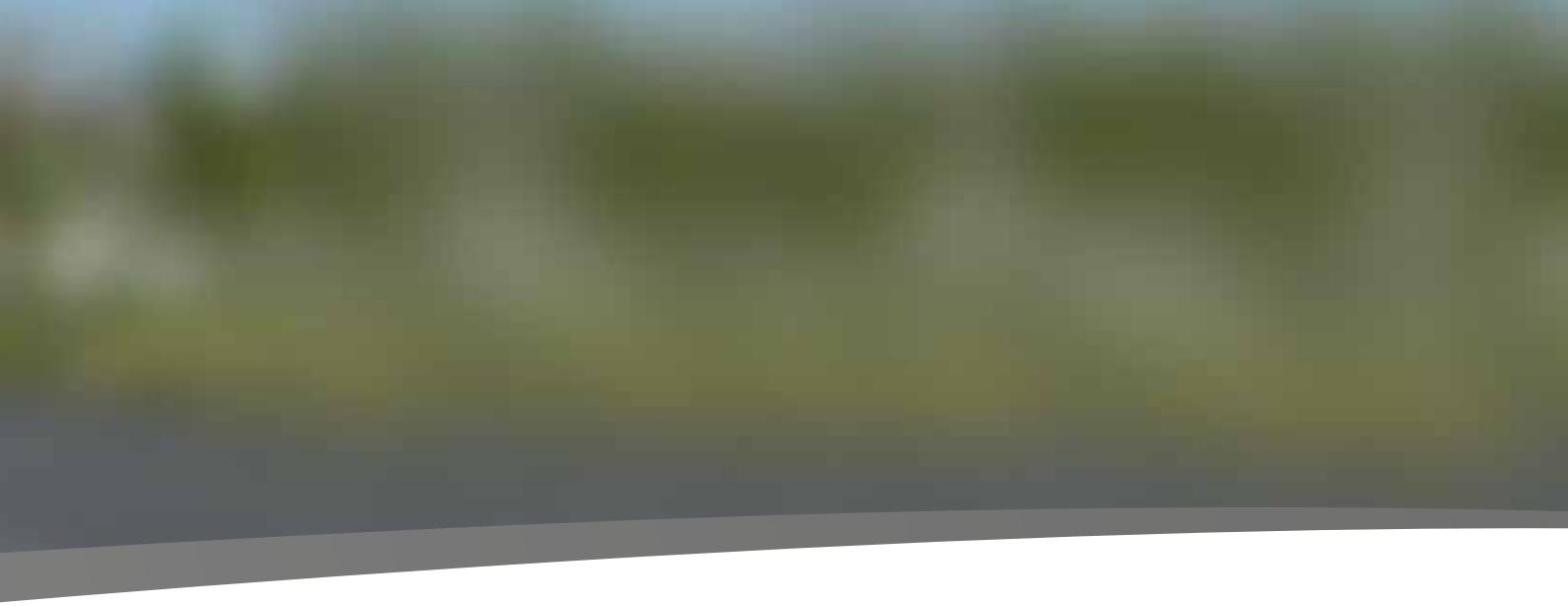


Mycoplasma Decontamination
Reliable Elimination of Mycoplasma

Our team of experts takes care of...

- Growth of cell line in quarantine area
- Splitting and seeding in cell culture plates
- Use of suitable antibiotics
- Optical evaluation and culture management over a 3-week period
- Discontinuation of antibiotics
- Control analysis as agreed
- Optical evaluation and culture management over a 2-to-3-week period
- Creation of three frozen back-up vials
- Internal control of mycoplasma status using PCR
- Continuation based on result and discussion





Creation of a Master & Working Cell Bank For Use in the Manufacturing of Production Cell Cultures

You want to protect your products with the best quality possible – so do we!

- Revitalisation of the cell line
- Growth and transfer to the production area
- Inoculum of a suitable culture system
- Culture transfer to the log growth phase
- Harvest of biomass
- Cell count and vitality quantification (dye exclusion)
- Adjustment of live cell count for each cryo vial to at least 2 x 10^6 cells
- Cell vitality ≥ 70 %
- Creation of 10 cryo vials plus one vial for quality control
- Revitalisation of the cell line for quality control purposes
- Internal control of mycoplasma status using PCR
- Routine production of more than 10 mg



Cell Banking
We take Care of Your Treasures

Consistent product quality over years!

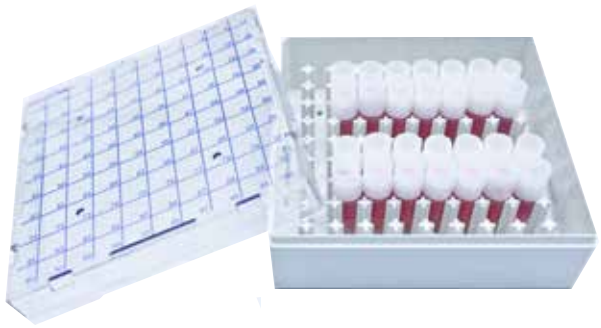
Production services help to secure your supply of raw materials:
Thanks to well-maintained working cell banks, we as your production partner guarantee consistent product quality over years!

Excellent maintenance of working cell banks

For the target markets sifin offers all production scales, from laboratory to pilot batches to “large-scale” production to continuous delivery to our partners.

For monoclonal antibodies this can range from a few milligrams to several hundred grams in varying purity levels, from concentrate to biomass to purified monoclonal antibodies or proteins.

- Generation of master and working cell banks
- Long-term storage of cell banks in liquid nitrogen



sifin 6-Week Special
Express Manufacturing

For urgent cases we offer you our express service

- Revitalisation of the available and established hybridoma cell line
- Adaptation of the hybridoma cell line
- Growth of the cell line until generation of inoculum of a suitable culture system
- Culture management and monitoring
- Accumulation of culture supernatants containing product
- Affinity purification
- Dialysis/ buffering against PBS
- Aseptic filling
- Creation of a reference sample
- Protein quantification using OD_{280}
- Delivery
- Certificate of quality control



sifin 6-Week Special

You will receive your delivery within 6 weeks of the receipt of your order.



TAILORED PRODUCTS

Our range of techniques enables almost all quality grades for in-vitro diagnostic applications or research projects.

Broad Range of Chromatography and Immunochemical Techniques

We offer a wide range of chromatography techniques related to the cleanup of proteins and monoclonal antibodies

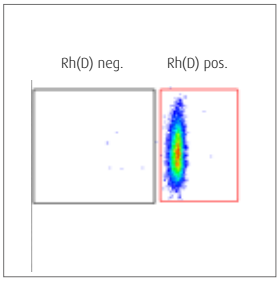
- Precipitation
- Immunoaffinity cleanup (AC)
- Hydroxyapatite (HA)
- Size exclusion chromatography (SEC)
- Other techniques on request

Labelled antibodies

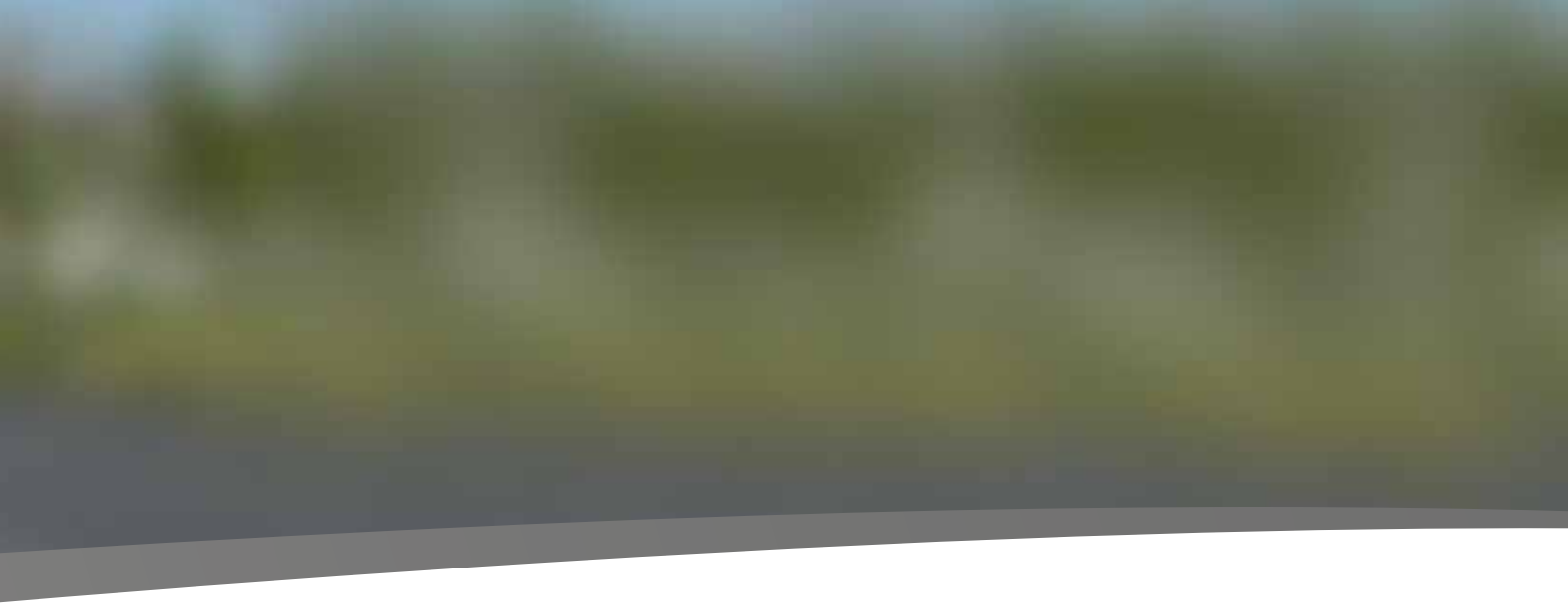
Labelling of 10 mg of protein or more

- Biotin conjugation
- POD conjugation
- FITC conjugation
- Other labelled antibodies on request

Flow cytometry: LOR mAb (sifin mAb, conjugated with FITC)



Rh-positive blood



Monoclonal Antibodies à la Carte
Blood Grouping Serology & Immunology

Monoclonal antibodies available as concentrates or in bulk volumes

Product	Description	Clone
Anti-A	murine monoclonal antibody	A-11H5
Anti-A	murine monoclonal antibody	A-5E10
Anti-B	murine monoclonal antibody	B-6F9
Anti-B	murine monoclonal antibody	B-2D7
Anti-D	human monoclonal antibody	BS225
Anti-D	human monoclonal antibody	NaTH119
Anti-D	human monoclonal antibody	LOR-15C9
Anti-H	murine monoclonal antibody	A-46/B/B-10
Anti-M	murine monoclonal antibody	M-11H2
Anti-N	murine monoclonal antibody	N-20H12
Anti-Human-IgM	capture antibody	
Anti-Mistellektin (A chain) 5F5	5F5 binds preferentially to native epitopes of mistletoe lectins I-III	
Anti-Mistellektin (A chain) 5H8, POD-labelled	5H8 binds preferentially to native epitopes of mistletoe lectins I-III	
Anti-Shigatoxin 1	reacts with subunit B of Shigatoxin 1	VT 109/4-E9b
Anti-Shigatoxin 2	reacts with subunit A of Shigatoxin 2	VT 135/6-B9
Anti-Shigatoxin 2	reacts with subunit B of Shigatoxin 2	VT 136/8-H4
Monoclonal Anti-Rabies, FITC-labelled	sensitive detection of the classical rabies virus or bat associated lyssaviruses	
Anti-Salmonella or Anti-Shigella	antibodies on request	



Your Key to Success

Executive summary

The basis of and key to your success is your production cell line. Based on many years of expertise, numerous cell culture techniques have been established to secure the long-term supply of raw materials for contract manufacturing, even if very little information is available at the start of the project.

- Mycoplasma checks protect the production area
- Quarantine area enables clean transfers and, if necessary, the sanitation of cell lines infected with mycoplasma
- Evaluation processes show the status quo and provide preliminary smaller product batches for quality control by the customer
- Subcloning techniques stabilise growth and secretion properties
- The generation of master and working cell banks form the basis of routine production
- Our long-term storage of production cell lines are the final touch to this range
- Satisfied business partners since 1994

This means that our production-to-order services offer a broad range of different production techniques to provide the best possible solution for achieving an objective in our customer's interest.

From laboratory scale to large-scale production

With 15 independent fermentation units all needs can be met, because batch cultures, fed-batch cultures, perfusion cultures and high-cell-density processes are routine for us!

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