

# Custom antibody production services

## Overview of services

At Inotiv Bioproducts, we believe that when it comes to making antibodies, experience matters. For over 30 years, Inotiv Bioproducts has consistently provided the research community with high quality custom antibody production services. From the more traditional *in vivo* approach, to the leading-edge *in vitro* production method, to hybridoma development, Inotiv Bioproducts can tailor a program to meet your specific needs. Our technical staff will work with you to determine the best production approach for your research.

We understand the research process and how unexpected variability can negatively impact the quality and timeliness of results. Through our proven Quality Management System, our AAALAC/cGMP/OLAW compliant and USDA licensed facility, and our team of highly qualified and experienced professionals, we provide antibody products and services that you can depend on to support and enhance your research. By providing consistent high quality products and services in a timely manner, Inotiv Bioproducts helps you focus on your research, rather than on unwanted distractions.

### The Inotiv Bioproducts advantage

AAALAC accredited cGMP Compliant Facility

Expertise >30 years

Rapid turnaround time

Scientific Expertise

Superior Quality Management System





## IN VIVO (ASCITES) PRODUCTION

For an economical approach, Inotiv Bioproducts offers monoclonal antibody production as ascites in our AAALAC registered cGMP compliant facility. Our ready access to large numbers of high quality, genetically defined adventitious virus-free mice and rats ensures a rapid turnaround time at a competitive price. We can also help maximize your yield time through our innovative Optimization Program.

SERVICE	DESCRIPTION	CELL LINE	PRODUCTION TYPE	CAPACITY	ADVANTAGES
Optimization Program	<ul style="list-style-type: none"> <li>Different doses tested</li> <li>Ascites available can be evaluated before use</li> <li>Small to large run sizes</li> </ul>	Hybridomas, NSO and SP2/0	Balb/c, Nude, SCID, and other species	Small to large scale (10mg-100g)	<ul style="list-style-type: none"> <li>Determine optimal cell dose</li> <li>Allows maximal yield</li> <li>Verifies specifications</li> <li>Saves time</li> </ul>
Research Ascites Production (non-cGMP)	<ul style="list-style-type: none"> <li>When cGMP is not needed</li> <li>Unique service</li> <li>Same phases as cGM</li> </ul>	Hybridomas, NSO and SP2/0	Balb/c, Nude, SCID, and other species	Small to large scale (10mg-100g)	<ul style="list-style-type: none"> <li>No MAP Testing requirement</li> <li>Quicker turnaround time</li> <li>Custom protocols</li> <li>Reduced cost</li> </ul>
cGMP Production	<ul style="list-style-type: none"> <li>Diagnostic/Therapeutic use</li> <li>Extensive quality</li> <li>Program fully tested</li> </ul>	Hybridomas, NSO and SP2/0	Balb/c, Nude, SCID, and other species	Small to large scale (10mg-100g)	<ul style="list-style-type: none"> <li>AAALAC accredited cGMP compliant</li> <li>Optimized production</li> <li>Large animal inventory</li> <li>Complete documentation</li> </ul>

## IN VITRO MONOCLONAL ANTIBODY PRODUCTION

In addition to our ascites method of collection, Inotiv Bioproducts has the expertise to produce your monoclonal or secreted protein *in vitro*. We have the capacity to produce 10mg-300 grams of research or cGMP antibody, or other secreted proteins, in our innovative tissue culture bag and hollow fiber production units. We offer a variety of media options such as RPMI, DMEM, IMDM, serum free, protein free, or other custom media formulations.



SERVICE	DESCRIPTION	CELL LINE	PRODUCTION TYPE	CAPACITY	ADVANTAGES
Small Scale Production	<ul style="list-style-type: none"> <li>Cost effective for smaller research runs</li> <li>Good for early feasibility, clonal selection and media optimization</li> </ul>	Hybridomas (CHO's, 293's, PerC.6 and secreted proteins)	Tissue Culture Bag	Up to 1 gram per project	<ul style="list-style-type: none"> <li>Reduced cost</li> <li>Yield~20-150mg per 1 L bag</li> <li>Quick turnaround</li> <li>Excellent oxygen transport</li> </ul>
Large Scale Production	<ul style="list-style-type: none"> <li>Flexible and easy scale up</li> <li>Larger scale research and cGMP runs</li> </ul>	Hybridomas (CHO's, 293's, PerC.6 and secreted proteins)	Hollow Fiber Bioreactor	10mg-300g per project	<ul style="list-style-type: none"> <li>Max environmental control</li> <li>Reproducible manufacturing process</li> <li>Reduces extraneous proteins</li> <li>Highly concentrated product</li> </ul>



## HYBRIDOMA DEVELOPMENT

Inotiv Bioproducts' hybridoma development program is a flexible, interactive, and cost effective multi-phased service. We will work closely with you to design a program that will meet your requirements. Our custom development options include providing up to three, five, or ten clones, or as many as you require. As our customer, you retain all rights to any clones that are produced. Once the clones are developed, we can scale them up as ascites or tissue culture supernatant.

SERVICE	REQUIREMENTS	PROJECT OUTCOMES
<b>Stage I:</b> Immunization	<ul style="list-style-type: none"> <li>Immunize mice with antigen</li> <li>Boost/Test by ELISA or alternate method</li> <li>Additional boost(s) if needed</li> <li>Pre-fusion boost</li> </ul>	<ul style="list-style-type: none"> <li>Move mice with best titers as fusion candidates</li> <li>Immunizing multiple mice increases success</li> </ul>
<b>Stage II:</b> Fusion/Screen and Select	<ul style="list-style-type: none"> <li>Fusion with myeloma cell line</li> <li>Grow cells in HAT medium</li> <li>Initial screen/selection</li> <li>Screen</li> </ul>	<ul style="list-style-type: none"> <li>Screen all initial plates</li> <li>Expand positive wells and test by ELISA</li> <li>Set up to 30 positives for cloning</li> <li>Keep frozen back-up for future testing</li> </ul>
<b>Stage III:</b> Cloning/Frozen Stock	<ul style="list-style-type: none"> <li>First cloning</li> <li>Final cloning</li> <li>Selection for non-HT requirement</li> <li>Frozen stock and small antibody scale-up</li> </ul>	<ul style="list-style-type: none"> <li>Clone by limiting dilution method</li> <li>Test clones by ELISA</li> <li>Several cloning cycles</li> <li>Final clones expanded and small amount of antibody produced</li> </ul>

## POLYCLONAL ANTIBODY PRODUCTION

Our comprehensive Polyclonal Antibody Production service is offered in a variety of species. These include rabbit, goats, chickens, guinea pigs, rats, and mice. We can make your polyclonal using a wide range of antigens, bacteria, viruses, fungi, fusion proteins, synthetic peptides, plasmids, DNA, and other proteins. Peptide synthesis, carrier and labeling conjugations and purification can easily be added to your productions. Standard protocols are available for each species, or we can follow your specific protocol. All our procedures are fully documented, allowing complete traceability.

SERVICE	DESCRIPTION	PRODUCTION TYPE	PRODUCTION CAPACITY	AREA OF USE	ADVANTAGES
Polyclonal	<ul style="list-style-type: none"> <li>Proteins</li> <li>Peptides, variety of antigens</li> </ul>	Rabbits, Goats, Chickens, Mice, Rats, Guinea Pigs	Small to Large Scale (All size runs available)	Diagnostics, Research cGMP	<ul style="list-style-type: none"> <li>Variety of Species</li> <li>USDA Licensed</li> <li>Standard/Custom Protocols</li> </ul>

## IMMUNOGENICITY IMMUNIZATION

Inotiv Bioproducts provides a unique Immunogenicity Immunization service in a variety of species, such as rats, mice, guinea pigs, and rabbits. We provide serum samples from a wide range of antigens, bacteria, viruses, lipids, nucleic acids and other proteins. Non-immunogenic haptens require conjugation with an epitope such as a protein or polysaccharide before they can elicit an immunologic response. Standard protocols are available for each species, or we can follow your specific protocol. All our procedures and production records are fully documented, allowing complete traceability.



SERVICE	ANTIGEN	PRODUCTION TYPE	PRODUCTION CAPACITY	AREA OF USE	ADVANTAGES
Immunogenicity Immunization	Proteins, viruses, variety of antigen	Rabbits, Mice, Rats, Guinea Pigs	Small to Large Scale (All size runs available)	Vaccine, Research Discovery	<ul style="list-style-type: none"> <li>Variety of Species</li> <li>USDA Licensed</li> <li>Standard/Custom Protocols</li> </ul>

## ANTIBODY PURIFICATION

Inotiv Bioproducts can purify mg-to-gram quantities of your monoclonal or polyclonal antibodies utilizing a wide array of protein purification methods, for research or cGMP diagnostic use. We can also purify any raw antibodies that have been produced in your lab or from another supplier. Our scientific staff will work with you to discuss the best options available to meet your needs. Our goal is to develop a procedure which provides the best balance between yield, purity and cost.

SERVICE	ANTIGEN	PRODUCTION TYPE	PRODUCTION CAPACITY	AREA OF USE	ADVANTAGES
Antibody Purification IEF, SEC, MW Testing Fab & F(ab') <sub>2</sub> Fragmentation FITC, Biotin, Alk Phos, and HRP Conjugation	<ul style="list-style-type: none"><li>• Monoclonals</li><li>• Polyclonals</li><li>• Secreted Proteins</li><li>• IgM</li><li>• IgY</li></ul>	Protein A & G, Antigen affinity, Hydrophobic interaction, Size exclusion, Ammonium Sulfate, Ion exchange	Small to Large Scale (20mg-20g scale available)	Diagnostics, cGMP Diagnostic Research	<ul style="list-style-type: none"><li>• Variety of Methods</li><li>• Low endotoxin for <i>in vivo</i> use</li><li>• cGMP compliant for diagnostic use</li><li>• Purify customer's in-house antibody</li><li>• Standard/Custom Protocols</li></ul>

## MAP/RAP/HAP TESTING

(MOUSE, RAT AND HAMSTER ANTIBODY PRODUCTION TESTING)

If your Custom Antibody Production project must be free of mycoplasma or viral contamination, we recommend our MAP, RAP and HAP testing programs. These tests will screen your cell lines against the adventitious viruses associated with your cell line's origin. Testing is available by both PCR and serology.

## CELL LINE AND PROCESSING SERVICES

We have expanded our cell line and processing capabilities to offer a wider selection of services, thus helping you to complete your research more efficiently.

- Bioburden
- Endotoxin
- Sterility
- Subcloning
- Cell banking
- Cell line stability
- Mycoplasma cleanup
- Viability
- Cell weaning
- Cell recovery
- Cell line isotyping
- IgG testing

Our technical staff has extensive experience in microbiology, virology, cell biology, pathology, and lab animal medicine. This translates into knowing that your projects will be dealt with in a professional and timely manner.

### Your custom antibody production partner

Whether your needs call for ascites or *in vitro* production, we can supply a reliable stream of antibody to meet your research development and production needs. Our staff can perform an evaluation/optimization run to scale up, utilizing the proper regulatory documentation. We can also purify and further process your antibody to meet your desired specifications.