# Antibody Custom Services

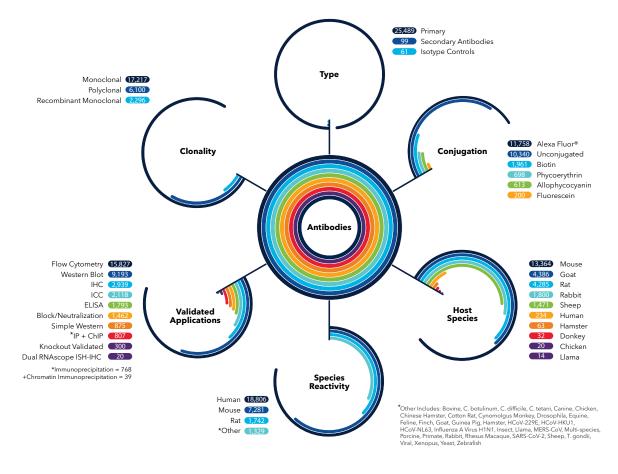
bietechne<sup>®</sup> RD SYSTEMS

## A History of Antibody Expertise

Since 1976, R&D Systems, a Bio-Techne brand, has developed and manufactured high-quality reagents for the bio-scientific industry. As the world leader in research immunoassay development, our gold-standard Quantikine® ELISA kits are built using recombinant proteins and panels of antibodies that are also developed and manufactured in-house. Our products are produced in the USA, under a stringent Quality Management System in our ISO-certified, FDA-regulated facility. Our expert scientists have optimized methodologies to maximize the probability of success when developing traditional monoclonal and polyclonal antibodies In addition, our cutting-edge molecular biology team leads the industry in their ability to generate recombinant, engineerable antibodies to support the unique demands of the research and diagnostic communities. As a Custom Service client, all of our antibody generation expertise, experience, and optimized processes are applied to your project.

## When Specificity, Long-Term Consistency, and Supply Are Critical, Trust The Experts.

R&D Systems manufactures more than 25,000 primary antibodies, against over 4,000 target analytes, across 19 different species. Using in-house immunogens and proprietary technologies, R&D Systems generates the antibodies that define the industry-leading Quantikine ELISA kits. In addition, we manufacture high-performance antibodies that are specifically validated for IHC, ICC, Western blot, flow cytometry, neutralization activity, and many other applications.



\*A graphic illustration to depict the breadth of experience and expertise in the field of antibody development. Data are based on R&D Systems current retail offering

## *More Clones Equals Greater Success*

For every monoclonal antibody in our catalog, we have additional non-catalog clones for the same target generated during the development process. These monoclonal antibody panels are available now to test in your application to find the clone that produces optimal results. The ideal antibody you are looking for could be hiding in our selection of noncatalog monoclonal antibodies.

#### What You Can Expect

- Avoid the delay and cost of from-scratch development of new antibodies
- Increase the probability of success in your application with additional pair combinations
- All clones are positive for the analyte in direct ELISA
- Discover an extensive panel of non-catalog antibodies
- Available immediately

## Modify Our Existing Antibodies to Meet Your Needs

We can tailor our current retail antibodies to the specific requirements of your unique application. Our dedicated Conjugation Department has optimized procedures for the addition of biotin, enzymes, and a myriad of fluorchromes. In addition, we can adapt buffer formulations and endotoxin acceptance criteria to meet your needs.

We routinely supply purified cleavage fragments of our antibodies. For more information about the generation of F(ab)'2 and Fab fragments, please see the Recombinant Conversion Engineering Services section.



Antibody Conjugation Options			
Biotin	Allophycocyanin (APC)	NorthernLights 557	Alexa Fluor 594
Alkaline Phosphatase (AP)	Fluorescein (FITC)	NorthernLights 637	Alexa Fluor 647
Horseradish Peroxidase (HRP)	PerCP	Alexa Fluor® 405	Alexa Fluor 700
Phycoerythrin (PE)	NorthernLights™ 493	Alexa Fluor 488	Alexa Fluor 750

Alexa Fluor® is a registered trademark of Molecular Probes, Inc., Eugene OR.



R&D Systems headquarters is located in Minneapolis, Minnesota.

# *Partner with The Experts for Custom Antibody Solutions*

When your work demands unique reagents or scientific support, turn to the decades of antibody development and application optimization behind the trusted products from R&D Systems. Together with a dedicated project manager, our expert scientists, quality assurance team, and world-class technical support, we will deliver solutions exactly tailored to **bring you success faster and more economically.** 

#### A Defined Process to Deliver Custom Solutions

Saving you time and resources are the foundation of our custom antibody services. A successful project is dependent on expediting your research by leveraging our expertise.

As an established leader in the provision of custom services, R&D Systems has developed a simple, efficient procedure to ensure we capture each customer's needs and maximize the probability of success. Importantly, we listen to your scientific needs to understand your immediate and long-term goals. A dedicated custom service project manager will then align the appropriate expert scientists from both parties. To ensure mutual success, all performance specifications, milestones, timelines, and deliverables are agreed upon and formally documented in a Statement of Work. Following project initiation, the project manager provides frequent updates to keep the customer fully informed regarding project progression.

#### Benefits of Custom Services From R&D Systems:

- Save time
- Economical
- Scientific expertise
- Confidentiality
- Consistency
- Regulatory support
- Supply
- Outsourcing QA burden
- Large-scale production
- Dedicated project managers



## *Custom Antibody Generation*

By partnering with our expert development team, generate custom monoclonal or polyclonal antibodies, from immunogen design through to purified antibody specificity screening.

We design immunogens (full-length proteins, peptides, or transfectants) and immunization protocols to generate antibodies with high specificity and outstanding performance for your desired application. To manage risk, our typical project structure includes a pre-agreed mass of purified antibody for you to assess in your hands. If the provided test sample meets your requirements, we will scale up production to meet your research, development, and manufacturing needs.

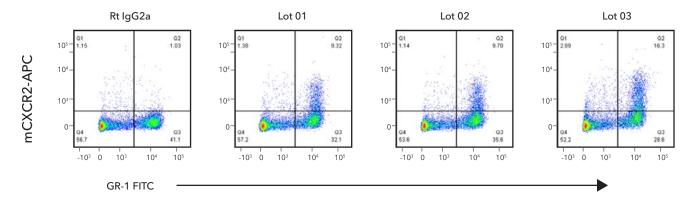
#### **Traditional Antibody Development Services**

- Polyclonal (goat, rabbit, llama or sheep\*)
- Monoclonal (mouse and rat hybridoma)
- Large-scale production
- Antigen affinity-based purification
- Monoclonal production from client-supplied hybridoma
- Access to our hybridoma panels containing thousands of non-catalog clones

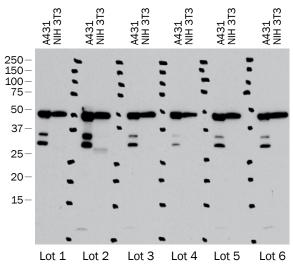
\*additional species are available on demand.

#### Lot-to-Lot Consistency

Importantly, if multiple lots are required, our stringent Quality Assurance and Quality Control departments ensure each lot of antibody meets the agreed performance specifications.



Lot-to-lot comparison of Rat Anti-Mouse CXCR2 Monoclonal Antibody on mouse bone marrow cells. Cells were stained with either Rat Anti-Mouse CXCR2 Monoclonal Antibody or Rat Anti-Mouse IgG2a Isotype Control and Anti-GR-1 FITC Conjugated Antibody. CXCR2 was detected with Anti-Mouse APC Secondary Antibody.



Lot-to-lot comparison of Mouse Anti-Human Caspase 1 Antibody. There is high consistency across lots produced over 6 years.

## Recombinant Antibody Engineering Services

To ensure a critical antibody reagent for the lifetime of your research or product, develop a new custom recombinant antibody or convert your existing clone. R&D Systems<sup>™</sup> **hybridoma and B cell to recombinant antibody conversion** services produce a dependable supply of custom engineered monoclonal antibody. The proprietary processes at R&D Systems guarantee yields that provide the gram quantities required for the development of diagnostic and therapeutic reagents.

#### Novel Custom Recombinant Antibody Development

Choose from rabbit or llama as the host animal for your custom recombinant antibody project. Rabbit recombinant antibodies are useful for projects requiring shorter timelines as they have a quicker turnaround from immunization to B cell cloning than larger host animals. LlaMABody<sup>™</sup> or heavy chain antibodies (HCABS), are recombinant antibodies generated in llamas that offer many unique benefits and engineering options (see table below). We offer multiple forms of camelid antibodies including native llama heavy chain IgG antibodies, VHH antibody domains and VHH domains on a human IgG scaffold.

Conventional Antibodies	Camelid VHH Antibodies (HCABs)
2HC/2LC	2HC
Large: 150 kDa	Small: 90 and 15 kDa
6 CDRs form Antigen Concave Binding Site	Compact 3CDR form Convex Antigen Binding Site
Limited to Surface Epitopes	Access to Privileged Epitopes, Cavities, Active Sites
Denature at High Temperature/pH	High Thermal and Conformational Stability
May Lose Avidity in Engineered State	Modular and Amenable to Engineering
Applications Limited due to Size/ Stability	Many Applications due to Size/ Stability/Low Immunogenicity/ Ease of Production

#### Advantages of Recombinant Antibody Conversion

Traditional hybridoma-secreted monoclonal antibodies can drift or even crash. Polyclonal antibody supply is normally limited and dependent on a source animal. Conversion to a recombinant monoclonal effectively renders the antibody immortal and future supply of your critical reagent is guaranteed. In addition to ensured supply and absolute consistency in performance, the antibody sequence is now defined and the opportunity to further engineer is available.

Limitation of your current antibody	Solutions provided by recombinant conversion/ engineering
Inconsistency/drift	No longer a concern.
Supply risk	The antibody is immortal.
Production time	Larger lots of forecasted mass held in inventory.
Production expense	Cost-effective.
QA burden	Outsourced to R&D Systems.
Large-scale production	Multiple grams.
Low yield	Increase yield with specific expression vectors.
Can't engineer	Fully capable. We can specifically modify the species, isotype, hinge region, and Fc regions.
Need truncated form(s)	Generate highly pure recombi- nant F(ab)'2 and Fab fragments that are superior to enzymatically cleaved species.
Tagging	His, GFP, V5, and many more.
Undefined clonality	Is your critical reagent a true monoclonal? We have extensive experience with biclonal antibodies.

Benefits of Custom Services from R&D Systems: Whether your antibody was raised in mouse, rat, llama, rabbit or goat, or if it is a monoclonal or polyclonal, we can convert it to a recombinant antibody with an extremely high rate of success.

#### The Process

#### 1. The customer provides:

- a. Cell line expressing antibody, (monoclonal), blood sample (polyclonal), or full-length antibody sequence.
- b. A small amount of antigen and original, traditionally expressed antibody for comparison testing.

#### 2. Our service includes:

- a. Conversion to recombinant antibody.
- b. Small scale expression of recombinant antibody.
- c. Comparison to the original hybridoma/ animal-derived antibody.
- d. A data report.
- e. A test recombinant antibody sample for the customer's evaluation.

#### f. The deliverables:

If the recombinant antibody meets the customer's needs, R&D Systems scales up production to generate the forecasted mass. Purified antibody and required QC documentation (e.g. Certificate of Analysis) are exclusively supplied to the customer on demand.

## *Custom GMP Antibodies*

Choose Bio-Techne to manufacture your GMP compliant custom antibodies for drug discovery, diagnostic, and cell ex vivo use. Develop a recombinant GMP antibody from scratch or convert an existing research-grade antibody into a recombinant GMP antibody. Employ our antibody engineering expertise, to humanize or increase the antibody yield. Ensure a consistent, high-quality supply of your raw materials, by utilizing our stable or transient expression options and our established scale-up and scale-out.

## What Sets R&D Systems Apart from Other Antibody Service Providers

R&D Systems is unlike other custom service providers in the biotech industry. As an established manufacturer of highquality proteins, antibodies, ELISAs, and other products for the life science industry we are uniquely positioned to facilitate our customers' short, medium, and long-term goals. A critical factor when outsourcing is to determine if the provider can address secondary goals. What happens if the initial project is successful? Can the vendor scale-up? Does the provider meet your company's Quality Assurance requirements for the next stage of development or manufacturing?

#### **R&D Systems Quality Philosophy**

All of our custom products and contract services are **governed by rigorous quality assurance measures**, so you can be confident in the accuracy of the data and the performance of our custom products. Importantly, our manufacturing facilities ensure that, following the success of your initial research, we can provide large-scale masses of critical, specialized reagents to assure your continued success. Work performed within our FDA-regulated facility means that you can move seamlessly into regulatory agency submissions with our regulatory affairs team as a partner.

Our policies conform with the requirements of the Code of Federal Regulations (21 CFR 820); Quality System Regulations for Medical Devices, ISO 13485:2003 Standard and ISO 9001:2008 Standard, the In Vitro Diagnostic Directive 98/79/EC and the Canadian Medical Device Regulations.

## Partnering for Long-term Success

Customer Product Phase	R&D Systems Differentiating Factors
Immediate development needs	Take advantage of our product development expertise to save time and meet deadlines.
Medium-term supply of critical reagents	The stringent Quality Manage- ment Systems that govern our ISO-certified, FDA-regulated facility will ensure large-scale production of consistent product that meets all agreed QC specifications.
Long-term product development (or translation across platforms)	Leverage the family of Bio-Techne brands, which span three operating divisions (Biotech, Protein Platforms, and Diagnos- tics), to optimize reagents for manufacturing therapeutic and diagnostic tests.

#### Additional Custom Services from The Bio-Techne Family

Once you have experienced custom antibody development from R&D Systems, you may also be interested in related services from additional development teams and brands.

Bio-Techne Brand	Core Services
R&D Systems™	Proteins, Antibodies, Ubiquitin-re- lated products, ELISA develop- ment, Luminex assay develop- ment, Bioactivity testing.
Tocris™	Custom chemistry to provide unique compounds and screening panels.
ProteinSimple™	Simple Western™ and Simple Plex™ assay development.
Novus Biologicals™	Modification of existing antibodies in the expansive Novus portfolio.
Clinical Diagnostics Division	Clinical diagnostic kits and reagents. Development and packaging of clinical controls
Advanced Cell Diagnostics	In situ gene expression services
Exosome Diagnostics	Exploration and validation of exosomeal RNA, cell-free DNA and proteins in biofluid samples.

## Where Science Intersects Innovation<sup>™</sup>

Bio-Techne® | R&D Systems<sup>™</sup> Novus Biologicals<sup>™</sup> Tocris Bioscience<sup>™</sup> ProteinSimple<sup>™</sup> ACD<sup>™</sup> ExosomeDx<sup>™</sup> Asuragen<sup>®</sup>

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