CUSTOM REAGENTS & CONTRACT SERVICES

bio-techne®

LEVERAGE BIO-TECHNE'S LEGACY OF SCIENTIFIC INNOVATION TO ADVANCE YOUR RESEARCH.

SERVICES

LEVERAGE OUR EXPERTISE TO SAVE TIME AND PROTECT YOUR BUDGET

When your work demands unique reagents or scientific support, turn to the decades of product development legacy behind Bio-Techne's trusted brands. 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.

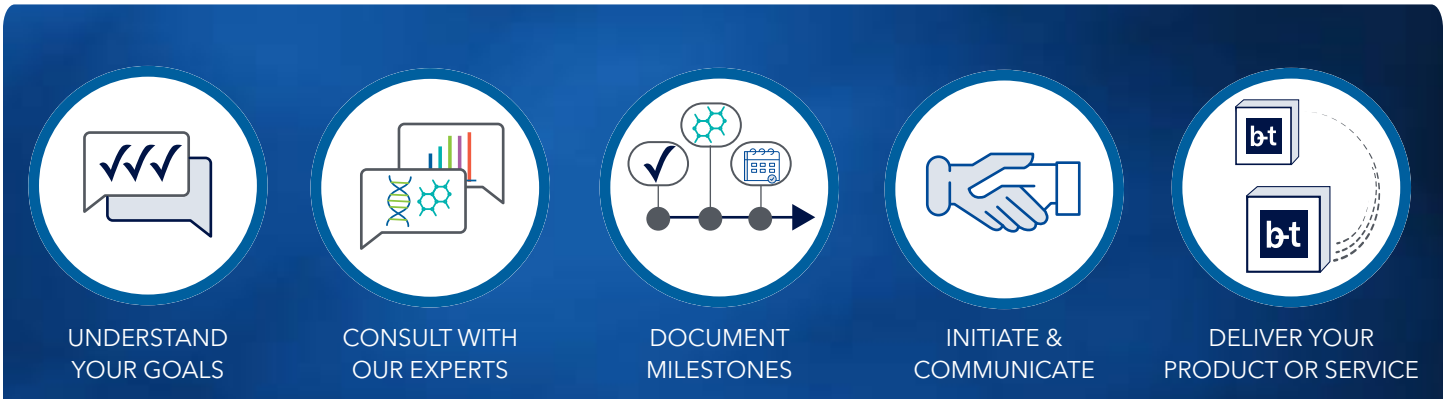
Bio-Techne is a global life science company providing innovative products and resources for the research and clinical diagnostic communities. Our expertise across three operating divisions spans laboratory research, preclinical and clinical studies, and reagents for manufacturing therapeutic and diagnostic tests, which makes us uniquely suited to ensure your custom solution is delivered successfully.

BENEFITS OF CUSTOM SERVICES FROM BIO-TECHNE

- ✓ Scientific expertise
- ✓ Consistency
- ✓ Supply
- ✓ Large-scale production
- ✓ Regulatory support
- ✓ Quality results
- ✓ Timeliness
- ✓ ISO-certified
- ✓ Quality Management System and FDA registered
- ✓ Cost savings
- ✓ Confidentiality
- ✓ Dedicated project managers

WHAT YOU CAN EXPECT

- ✓ Identify the need
- ✓ Consult with our experts
- ✓ Refine the project specifics, milestones, and deliverables
- ✓ Review a statement of work
- ✓ Receive regular project updates
- ✓ Accept delivery of custom product or service



As an established leader in the provision of custom services, Bio-Techne has developed a simple, efficient procedure to ensure we capture each customer's needs and maximize the probability of success in an efficient manner.

Learn more | rndsystems.com/services

WHAT SETS BIO-TECHNE APART FROM OTHER CUSTOM SERVICE PROVIDERS?

Bio-Techne is unlike other custom service providers in the biotech industry. As an established manufacturer of high-quality proteins, antibodies, immunoassays, 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?

BIO-TECHNE'S 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	BIO-TECHNE 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 Management 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 Diagnostics), to optimize reagents for manufacturing therapeutic and diagnostic tests.

CUSTOM SERVICES FROM THE BIO-TECHNE FAMILY

BIO-TECHNE BRAND	CORE SERVICES
R&D Systems	Protein, Antibody, ELISA development, Luminex assay development, Bioactivity testing, reagents for Ubiquitin-related products.
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.

APPLY THE EXPERIENCE OF THE SCIENTISTS BEHIND THE INDUSTRY'S BEST PROTEINS TO YOUR RESEARCH

PROTEIN SERVICES

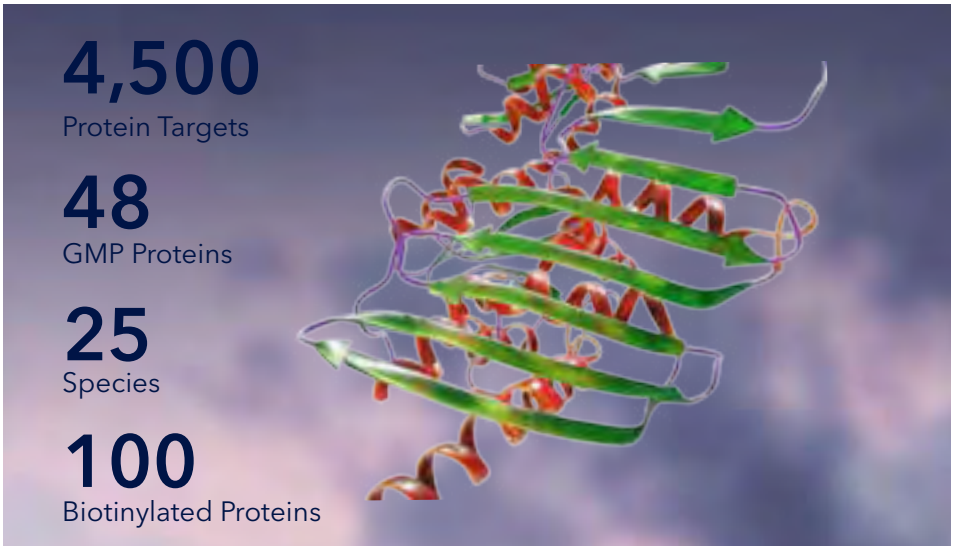
Recombinant protein technologies play a vital role in academic research and drug discovery. We believe that full length proteins are vital for activity, physiological relevancy, and structure. For over 30 years R&D Systems has produced gold-standard proteins. Ensure your critical reagents perform with R&D Systems™ custom protein production.

AVAILABLE SERVICES

- ✓ Recombinant protein expression and purification (with typical high purity, high bioactivity, and low endotoxin levels)
- ✓ *In vitro* protein modification and processing
- ✓ Point mutations
- ✓ Animal Component-Free Process, Animal-Free™, and GMP-grade
- ✓ Formulation to your requirements
- ✓ Thousands of non-catalog items available (unique proteins, tags and sources

UBIQUITIN/PROTEASOME CUSTOM SERVICES

Through our R&D Systems brand, we can provide flexible, high quality, and confidential protein biochemistry contract services for Ubiquitin-focused research. Learn more about these services at rndsystems.com/custom-ubiquitin.



Our existing protein catalog allows you to choose from 4,500 protein targets, 48 GMP proteins, 100 biotinylated proteins and 25 species. Protein products can be modified to meet your unique requirements or developed from scratch.

HISTORY	EXPERTISE	DELIVERY
Since 1985, R&D Systems has produced gold-standard proteins to meet the strictest development and purification standards.	Our scientists have developed methods to express and purify some of the most challenging proteins with the highest bioactivities on the market.	We will produce exactly what you need and provide a test sample. If it meets your requirements, we will scale up production to meet your research and development needs.

PROTEIN DEVELOPMENT – WHAT TO EXPECT

✓ **HIGH PURITY**. R&D Systems manufactures >95% of our proteins in house. With complete control over all quality testing, we are able to generate proteins to meet industry-leading purity specifications.

✓ **BIOLOGICAL ACTIVITY.** Proprietary methods for accurate protein folding ensure biologically relevant proteins and >900 validated bioassays, activity can be evaluated for most protein targets.

✓ **LOT-TO-LOT CONSISTENCY**. Multiple lots are created for R&D Systems proteins, all with matching specifications. Each new lot is tested side-by-side with previous lots to ensure unmatched consistency.

✓ **LOW ENDOTOXIN**. Each new production lot of protein is assessed for endotoxin using the Limulus Amoebocyte Lysates (LAL) assay. Our standard endotoxin specification is an industry-leading <0.1 EU/ug.

CUSTOM PROTEIN CONJUGATION & BIOTINYLATION

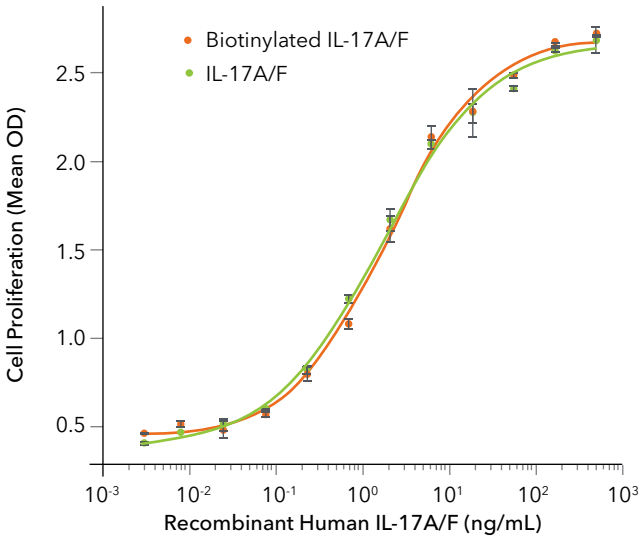
Conjugated proteins can be powerful tools to assess protein-protein interactions in a range of assay formats including immunoprecipitation, flow cytometry, immunoassays and surface plasmon resonance. To be successful, it is crucial that conjugation does not affect protein structure or activity. We offer protein conjugation services on most R&D Systems™ proteins. Available *in vitro* protein modifications include:

- Biotinylation
- Fluorescent probe labeling
- Non-standard chemical labels
- PEGylation
- AviTags™

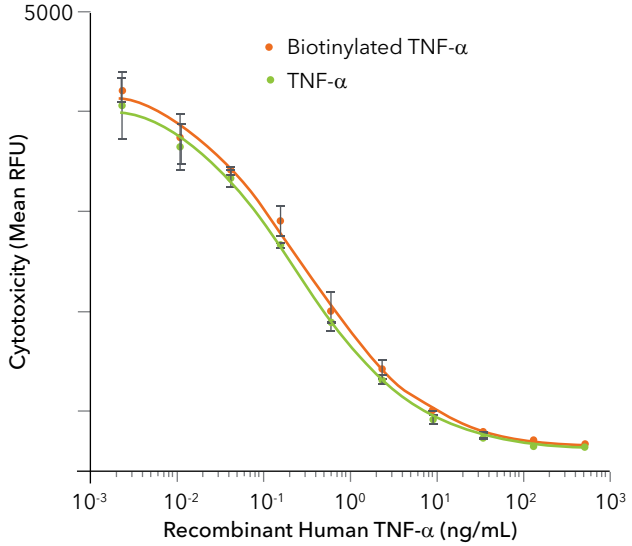
FEATURES AND BENEFITS

- Only source of labeled protein tested in the same bioassay as unlabeled proteins.
- Full Quality Control (QC) testing including Purity, Activity and Endotoxin.
- Removal of free conjugates and determination of conjugate to protein levels.
- Labeled via carbohydrates or amines to minimize interference of protein function.

BIOTINYLATED RECOMBINANT PROTEINS EXHIBIT THE SAME ACTIVITY AS OUR UNLABELED RECOMBINANT PROTEINS



Both Biotinylated Recombinant Human VEGF 165 (Catalog # BT293) and unlabeled Recombinant Human VEGF 165 (Catalog # 293-VE) stimulate HUVEC human umbilical vein endothelial cell proliferation. The ED_{50} for this effect is 1–6 ng/mL. The similarity in activity highlights that the biotinylated protein is fully functional.



Both Biotinylated Recombinant Human TNF-α (Catalog # BT210) and unlabeled Recombinant Human TNF-α (Catalog # 210-TA) promotes cytotoxicity in L-929 mouse fibroblast cells in the presence of the metabolic inhibitor actinomycin D. The ED_{50} for this effect is 25–100 pg/mL. The similarity in activity highlights that the biotinylated protein is fully functional.

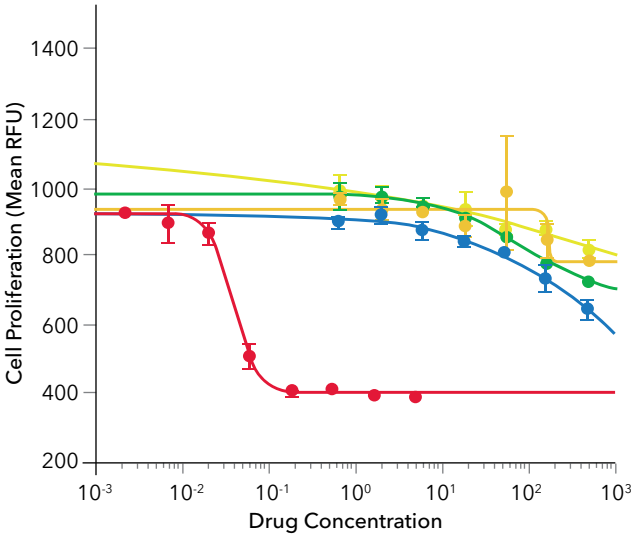
TAKE ADVANTAGE OF OVER 900 ESTABLISHED BIOASSAYS TO MEASURE BIOACTIVITY

BIOACTIVITY TESTING SERVICES

Run your molecule/compounds of interest against our bioactive protein in the established QC-driven bioassay

BIOASSAYS INCLUDE, BUT ARE NOT LIMITED TO

- ✓ Proliferation assays
- ✓ Cytotoxicity/Survival/Apoptosis
- ✓ Cellular differentiation
- ✓ Reporter assays
- ✓ Cytokine induction
- ✓ Chemotaxis
- ✓ Cell adhesion
- ✓ Signal transduction
- ✓ Neuronal assays
- ✓ Ligand/Receptor binding



Evaluation of drug candidates against a validated, biologically active positive control protein in a cell proliferation assay.

The same dedicated QC staff run our validated bioassays including your molecule of interest.

HISTORY	EXPERTISE	DELIVERY
With more than 4,000 bioactive proteins developed and tested, and over 3,000 small molecules available to modulate responses, no other company matches the bioassay experience of Bio-Techne.	We have more than 900 established bioassays available to test proteins, small molecules, and antibodies. Our scientists in Bioassay Services will consult with you to select and optimize an assay to deliver relevant results.	Raw data are provided, along with a professionally formatted report and a detailed summary of the bioassay protocol employed.

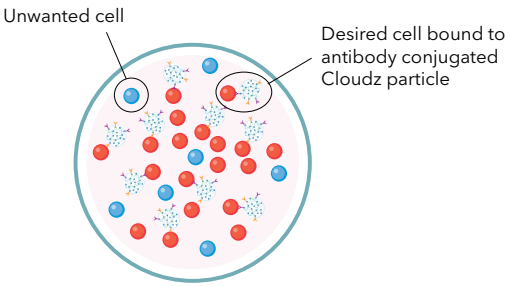
GENTLE, EFFICIENT, PIONEERING CUSTOM CLOUDZ™ PARTICLES FOR CELL SELECTION

CLOUDZ CELL SELECTION KITS

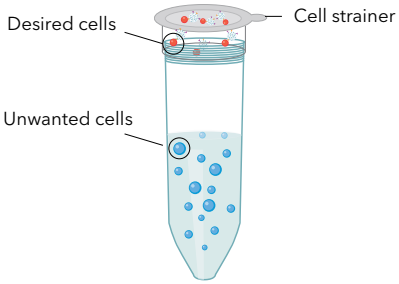
Bio-Techne is utilizing its pioneering Cloudz dissolvable hydrogel to design a cell selection system that enables the gentle capture and release of select cell populations. Using principles for cell selection, this technology is ideal for simplifying cell manufacturing protocols while reducing the risk of bead contamination during downstream cell culture processing. This technology is currently available as a custom service.

PRINCIPLE OF THE TECHNOLOGY

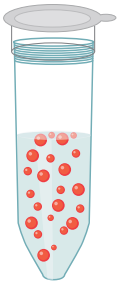
STEP 1
Cloudz Particles Bind Desired Cell Population



STEP 2
Desired Cells Retained



STEP 3
Dissolve Cloudz Particles and Collect Desired Cells



Customize Cloudz particles with up to three recombinant proteins or antibodies from R&D Systems, or your own proprietary molecules.

FEATURES

- ✓ Size exclusion-based cell selection
- ✓ Sequential cell selection available for improved target definition
- ✓ Compatible with multiple clinical expansion platforms
- ✓ Manufactured under Good Manufacturing Practice (GMP) controls
- ✓ Customizable for your desired cell population:
  - Modify hydrogel size
  - Define capture antibodies
  - Sequential selection formats

BENEFITS

- ✓ Ideal for cell therapy manufacturing
- ✓ Simplified recovery of cells
- ✓ Magnetic-bead free

HISTORY

The Cloudz technology arose out of the need for a scalable cell capture and release product that could streamline cell selection by eliminating the need for magnetic beads and the downstream "debeading" unit operation.

EXPERTISE

We have years of experience in bringing innovative technology to the market that helps the biopharma industry simplify their workflow at every step of the manufacturing process.

DELIVERY

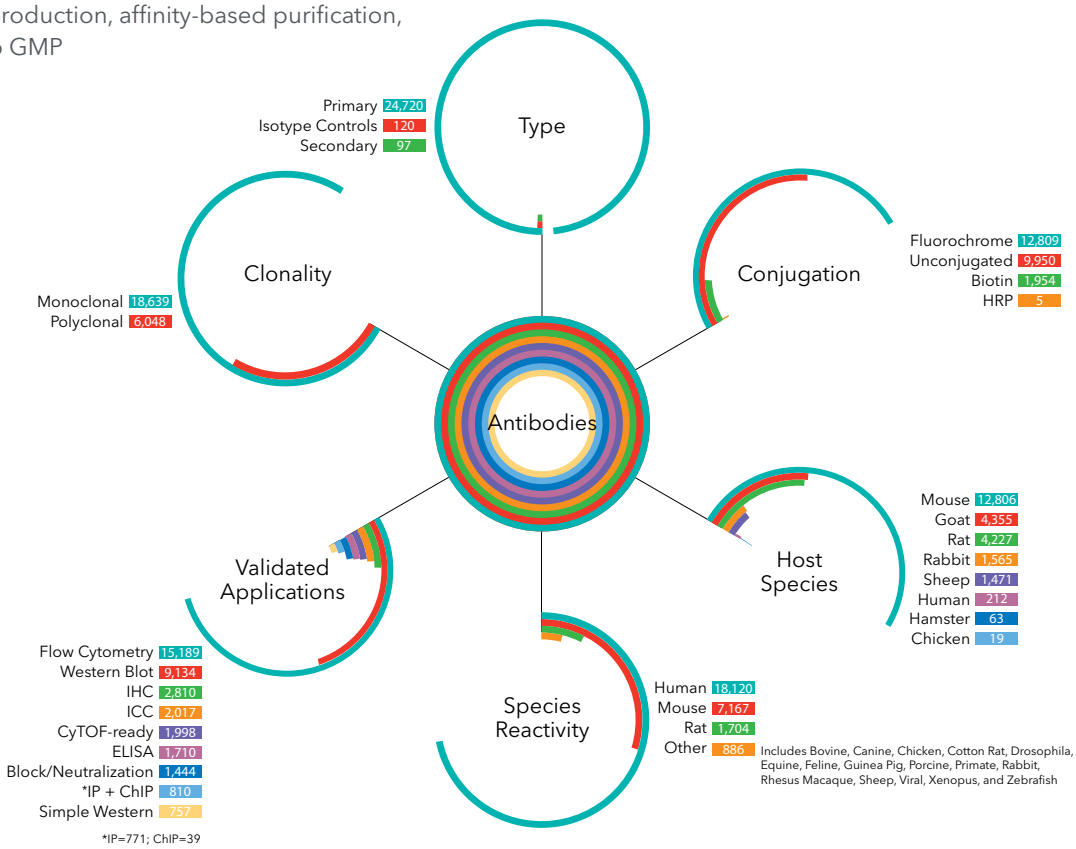
Our experienced scientists will work with you to ensure you obtain a pure and robust cell population for your *ex vivo* manufacturing workflow.

WHEN SPECIFICITY, LONG-TERM CONSISTENCY AND SUPPLY ARE CRITICAL, TRUST THE EXPERTS

ANTIBODY SERVICES

AVAILABLE SERVICES

- ✓ Polyclonal and monoclonal antibody development
- ✓ Llama and rabbit recombinant monoclonal antibody development
- ✓ Hybridoma to recombinant antibody conversion
- ✓ Polyclonal to recombinant antibody conversion
- ✓ Large-scale production, affinity-based purification, conversion to GMP
- ✓ Conjugation to fluorophores, HRP, and biotin
- ✓ Access to our hybridoma panels containing thousands of non-catalog sister clones
- ✓ Monoclonal production of client-supplied hybridomas



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.

HISTORY

R&D Systems manufactures more than 12,500 primary antibodies, against over 3,600 target analytes, across 19 different species.

EXPERTISE

Using in-house immunogens and proprietary technologies, R&D Systems generates the antibodies that define the industry leading Quantikine™ ELISA kits.

DELIVERY

We tailor immunogen and immunization protocols to generate antibodies with high specificity and outstanding performance in your desired application. If your provided test sample meets your requirements, we will scale up production to meet your research and development needs.

Learn more | rndsystems.com/custom-antibodies

RECOMBINANT CONVERSION AND ENGINEERING SERVICES

To ensure a critical antibody reagent for the lifetime of your research or product, R&D Systems™ hybridoma and B-cell to recombinant antibody conversion services produce a dependable supply of a 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.

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. 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 to a recombinant antibody with a high rate of success.

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 recombinant 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.

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.

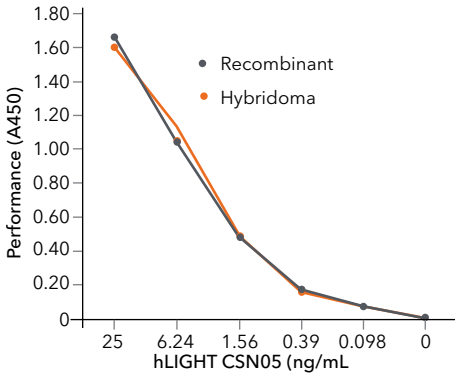
c. Comparison to the original hybridoma/ animal-derived antibody.

d. A data report.

e. A test recombinant antibody sample for the customer's evaluation.

3. 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.



An example of comparison data by direct ELISA showing equivalent performance between the original hybridoma-sourced antibody and the recombinantly expressed product.

TESTIMONIAL

"Conversion of our traditional monoclonal to recombinant antibody offered immortal supply of a very high quality product. We also liked the feature of the recombinant technology to be able to exchange the constant chain between different species and the ability to express the antibody as Fab fragments."

–Principal Scientist, Biotech Company

THOUSANDS OF NON-CATALOG MONOCLONAL ANTIBODIES AVAILABLE NOW!

For every monoclonal antibody in our catalog, we have multiple, additional non-catalog clones for the same target from the same and sometimes other hybridoma fusions. Available now, test these monoclonal antibody panels in your application to find the clone that produces optimal results. The exact antibody you are looking for could be hiding in our selection of non-catalog 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

Through our Novus Biologicals and R&D Systems brands, we can tailor our current retail antibodies to the specific requirements of your unique application. Our dedicated Conjugation Departments have optimized procedures for the addition of biotin, enzymes, and a myriad of fluorochromes, including:

Biotin	Fluorescein	Alexa Fluor® 350	Alexa Fluor 647
Alkaline Phosphatase	PerCP (Peridinin-chlorophyll Protein Complex)	Alexa Fluor 405	Alexa Fluor 700
Horseradish Peroxidase	NorthernLights™ 493	Alexa Fluor 488	Alexa Fluor 750
Phycoerythrin	NorthernLights 557	Alexa Fluor 532	Janelia Fluor® 549
Allophycocyanin	NorthernLights 637	Alexa Fluor 594	Janelia Fluor 646

In addition, we can adapt buffer formulations and endotoxin acceptance criteria to meet your needs. We also routinely supply purified cleavage fragments of our antibodies. For more information about generating F(ab)'2 and Fab fragments, please see the Recombinant Conversion and Engineering Services section.

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

CELL CULTURE MEDIA IS IMPORTANT
LET THE EXPERTS MAKE IT FOR YOU

CELL CULTURE MEDIA SERVICES

OVERVIEW OF CUSTOM CELL CULTURE CAPABILITIES

- ✓ Media or supplement production
- ✓ Supplied as liquid or powder
- ✓ GMP media production
- ✓ Media formula optimization
- ✓ Custom labeling
- ✓ Assays for testing media using stem cells, immune cells and other cell lines

CELL CULTURE MEDIA DEVELOPMENT EXPERIENCE:

CELL LINES AND PRIMARY CELLS

- ✓ HEK cells
- ✓ CHO cells
- ✓ Epithelial cells
- ✓ *Sf*21

IMMUNE CELL EXPANSION AND DIFFERENTIATION

NEURAL CELL CULTURE

TUMORSPHERES

STEM CELLS

- ✓ Mesenchymal Stem Cells
- ✓ Pluripotent Stem Cells
- ✓ Hematopoietic Stem Cells
- ✓ Cancer Stem Cells

CELL CULTURE MEDIA MANUFACTURING

The right cell culture media goes a long way. You've done the legwork to create the best media for your cells, now let us help you expedite and standardize production. Inquire about our custom cell culture media manufacturing services to start the conversation.

CELL CULTURE MEDIA FORMULATION AND OPTIMIZATION

Component optimization within cell culture media can be critical for performance. Using design-of-experiments (DOE) and our large portfolio of proteins and small molecules, we can generate media formulations that will help you find the best recipe.

SPECIALTY CELL CULTURE MEDIA TESTING

To provide consistent media to our customers we have developed and validated specialized assays, which are now available to you. We have a battery of established tests and assays in place to monitor growth, expansion, and differentiation for a variety of cell types. Inquire today to discuss custom assays based on your needs.

TESTIMONIAL

"Being a start-up, we were pleasantly surprised that Bio-Techne treated our development needs with as much attention as a larger company. As we scaled and made changes to our production model, Bio-Techne responded with flexibility to meet our increasing demand and schedule while still delivering consistent product to our specifications."

–Janet, StemoniX

PIONEERING CELL AND GENE THERAPY TOOLS TO SIMPLIFY YOUR WORKFLOW

CELL SEPARATION, CELL CULTURE, QUALITY CONTROL

Your vision is to create revolutionary cell and gene therapies to treat life threatening diseases. Bio-Techne is in this journey with you. As a full-solution ancillary reagent and services provider, we will stand by you, providing flexible and pioneering tools to simplify your workflow at every step of the manufacturing process. From CAR T cells to pluripotent stem cells, let us help you get your therapy to market!

SIMPLIFYING CELL AND GENE THERAPY THROUGH INNOVATION

Our goal is to provide innovative and flexible solutions that expedite the path of your cell therapy from the laboratory to the clinic. Our ancillary reagents, raw materials and automated analytic instrumentation provide the framework to confidently build out ex vivo manufacturing procedures. The following five attributes are at the core of our cell and gene therapy mission:

- ✓ **INNOVATIVE SOLUTIONS**. We are invested in creating reagents and tools that disrupt the status quo for manufacturing, validating and monitoring cell therapies. With a focus on efficiency and safety, our industry-leading technologies will enhance your cell therapy manufacturing process.
- ✓ **SCALABILITY**. Experienced manufacturing and quality systems at Bio-Techne will ensure that our GMP reagent supply meets your requirements for scale-up. With ISO 9001 and 13485 Certifications, USP and European Guidelines in place, you can be confident in the supply and quality of our raw materials for immune and stem cell therapy manufacturing.
- ✓ **FLEXIBILITY AND CUSTOMIZATION**. Our GMP-grade ancillary reagents are designed to plug into all existing closed system ex vivo cell manufacturing workflows. This flexibility lets you dictate the best culture vessel and manufacturing combination for scaling up your specific cell therapy. Our flexibility extends into GMP custom services for media, proteins, antibodies and cell selection. No cell therapy challenge is beyond our ability to help.
- ✓ **CONSISTENCY AND REPRODUCIBILITY**. We apply stringent quality standards to all of our cell therapy tools including GMP-grade reagents. We guarantee lot-to-lot consistency and proper documentation for every GMP reagent we produce, so you can be confident your process will be reproducible, compliant and traceable.
- ✓ **REDUCED RISK**. We are developing cell therapy manufacturing products to help you reduce the risk to patients. We follow GMP regulatory frameworks, and we are re-thinking the standard of reagent design with simplicity and safety in mind.

HISTORY	EXPERTISE	DELIVERY
In 2019, we began an initiative to unite our industry-leading reagents to provide the cell therapy community with a rich and user-friendly resource for reagents, instrumentation and scientific expertise across the cell therapy workflow.	The products that form our cell and gene therapy solutions portfolio come from our 35+ year history of making gold-standard reagents.	Our scientists will guide you through your manufacturing process during the development, scale up, and manufacturing of your cell or gene therapy. We will work with you to produce exactly what you need.

GOOD MANUFACTURING PRACTICES

PROTEINS, ANTIBODIES, SMALL MOLECULES, MEDIA

As proteins and antibodies are produced in biological systems, changes in the manufacturing environment or processes can make them susceptible to batch-to-batch variability. Extra-ordinary attention to detail at all levels of the manufacturing process is necessary to ensure consistency. R&D Systems™ and Tocris™ GMP products are designed to specifically meet the stringent requirements necessary for their use as cell therapy reagents or as ancillary proteins used in manufacturing. Develop a GMP protein or antibody from scratch or take an existing product to the GMP level.

GMP SERVICES

ANIMAL-FREE

Dedicated controlled-access animal-free laboratories ensure that at no point in production are these products exposed to potential contamination by animal components or byproducts. Some animal-free proteins are also GMP.

GMP

Proteins and antibodies are manufactured under guidelines that allow for their use as ancillary materials in cell therapy or for further manufacturing processes. They may or may not be manufactured using animal-free processes depending on the characteristics of the given protein.

ANIMAL COMPONENT-FREE PROCESS (ACFP)

ACFP recombinant proteins are expressed in an animal-free certified insect cell line using dedicated animal-free raw materials and labware. Production and purification procedures use equipment and media that are confirmed animal-free but performed outside of our dedicated animal-free laboratory. Some ACFP proteins are also GMP.

THE BIO-TECHNE GMP ADVANTAGE

Often our GMP proteins originate from the same clone, sequence, and expression system as our traditional research grade materials. This makes the conversion to GMP as seamless as possible. We can convert an existing protein to GMP, or we can completely develop a protein of interest from scratch. GMP antibodies are produced exclusively using the HEK293 cell line following conversion to recombinant antibody.

- Full QA review
- Traceability
- N-terminal sequence
- Viral testing
- Mycoplasma testing
- Additional bioactivity/bioburden
- Lot specific C of A
- On site audits
- Individual specification sheets
- Batch-to-batch consistency

HISTORY	EXPERTISE	DELIVERY
Our family of world-class brands offer an unbeatable portfolio of pioneering GMP reagents including nearly 50 GMP-grade proteins, GMP cell culture media, and the first GMP small molecules for stem cell therapy.	As a pioneer in cell and gene therapy solutions, our quality management systems stay up-to-date on guidance within this rapidly evolving field in order to provide the safest and most compliant GMP reagents for *ex vivo* manufacturing.	Our goal is to provide cell therapy manufacturers with a consistent, safe and continuous supply of GMP-grade raw materials.

HARNESS THE UNIQUE EXPERIENCE AND EXPERTISE OF THE R&D SYSTEMS™ QUANTIKINE™ ELISA TEAM

ELISA DEVELOPMENT

AVAILABLE SERVICES

- ✓ Antibody matched pair screening
- ✓ Assay development and optimization
- ✓ Complete ELISA kit manufacturing
- ✓ Precision automated microplate coating
- ✓ Translation to automated platforms
- ✓ Facilitate the transition from RUO to IVD

For additional platform options please see the Luminex and ProteinSimple Sections

Trust the experts behind Quantikine ELISAs to help develop your immunoassay of interest.

TESTIMONIAL

"Mellitus was looking for a development partner to assist the Company in converting its research assay to a commercially viable in vitro diagnostic. We had firsthand knowledge of the exquisite technical expertise residing within R&D Systems. With its focus on assisting clients to optimize assay reagent formulations and achieve target product performance criteria, we knew we had found the right partner. The group we are working with is very diligent in effectively completing jointly designed experiments and optimizing assay component configurations to meet design requirements. The team is timely, dedicated and responsive. We remain confident that the Mellitus Assay will complete product development within our timelines, thanks to our Development Partner, R&D Systems."

–Bruce H. Phelps, Technology Consultant

HISTORY	EXPERTISE	DELIVERY
Our unrivaled reputation for quality has made Quantikine ELISA Kits the gold standard and most referenced, ready-to-use ELISAs in the industry.	Our scientists have developed hundreds of unique diluents and have decades of experience optimizing conditions to detect a range of analytes.	Throughout the iterative immunoassay development process, our expert scientists and project management team will provide data reports and recommendations for assay improvements. As projects evolve, we have quality management systems and regulatory affairs in place to support every need, from basic discovery research, preclinical and clinical research through companion diagnostic applications.

ACCELERATE BIOMARKER DISCOVERY, VALIDATION, AND DETECTION WITH UNIQUE ANALYTE PANELS

LUMINEX® ASSAY DEVELOPMENT

R&D Systems offers Luminex Assays for simultaneously detecting and quantifying multiple target analytes in qualified complex sample types. They require small sample volumes, are cost-effective and allow researchers to collect more data in less time than other assays. If we don't have Luminex assays available for some of your analytes of interest, we can custom develop from panels of existing protein and antibody reagents.

AVAILABLE SERVICES

- ✓ BEAD REGION CONFLICT RESOLUTION: Is a bead region conflict preventing you from getting all your analytes on the same panel? We can reassign bead regions so you can get all your results with one assay. Bead region change services offered at no extra charge!*
- ✓ BULK PACKAGING When ordering multiple kits, we can package kit materials in bulk to reduce packaging waste and storage space at no extra charge.*
- ✓ LOT SEQUESTRATION To reduce potential lot qualifications in a long-term study, we can save you time by reserving your Luminex materials, so everything is built from the same batch.*
- ✓ Unique analyte development
- ✓ Optimized panel configurations
- ✓ Sample type validation
- ✓ Evaluation of externally sourced antibodies
- ✓ Panel assembly to minimize required sample volume

TESTIMONIAL

"Partnering with the Luminex® team at R&D Systems for missing analyte development was invaluable to our project. Their Quality Assurance expertise and open communication ensured transparent study progression."

–Director, Biotech Company

Custom Luminex assay development leverages the vast array of existing antigens and antibody panels.

HISTORY

With the largest immediately available retail analyte selection and an active development pipeline of new targets, R&D Systems has developed a reputation for delivering high quality and customized content for Luminex assays.

EXPERTISE

Building on the legacy of immunoassay development, our scientists can often translate Quantikine ELISA reagents to the Luminex platform and can optimize assay performance using decades of immunoassay experience.

DELIVERY

Utilizing our massive in-house collection of antibodies and proteins reduces development time, saves you money, and puts custom multiplex panels that detect your specific analytes of interest in your hands faster.

*Terms and conditions apply

Learn more | rndsystems.com/custom-luminex

ANALYTICAL TESTING SERVICES

Bio-Techne offers a wide range of analytical testing methods for evaluation of customer supplied material or our gold-standard R&D Systems™ proteins and antibodies.

We offer flexibility in our services to be sure that your specific requirements are fully addressed. In addition, our services are governed by established, rigorous quality assurance measures or follow good laboratory practices, so you can be confident in the accuracy of the data.

SERVICE	DESCRIPTION	ESTIMATED TIMELINE
Size Exclusion Chromatography (SEC)	Quantitative method for separation based on size. Typically used for purity and aggregation determinization.	1 week
High Performance Liquid Chromatography (HPLC)	Rapid method for assessment of purity and quantitation of small molecule or biomolecular analytes.	1 week
Dynamic Light Scattering (DLS)	Rapid method for size determination of proteins, antibodies, or other particles. Measures hydrodynamic radius. Commonly used to assess aggregation.	1 week
Static Light Scattering (SLS)	Assesses aggregation and provides accurate solution state mass of proteins or antibodies.	1 week
Mass Spectrometry • Intact mass • Protein ID • PTM analysis • PTM analysis with glycan mapping	Triple Quadrupole and Orbitrap technologies for mass determination, trace component quantitation, and in-depth characterization of protein molecular form.	2–4 weeks
Dynamic Scanning Fluorimetry (DSF) – Thermostability	Used to predict formulary stability and refolding effectiveness. Generally used with multiple sample conditions to determine optimal conditions.	1 week
cIEF (Maurice)	Isoelectric point determination. Benchmark function for measuring lot consistency, formulating buffers, and observing biosimilarity.	1–2 weeks
N-glycan Fingerprint (Gly-Q)	Rapid method to identify N-glycan footprint trace in proteins and antibodies.	1–2 weeks
N-terminal Sequencing (5 aa)	Qualitative, semi-quantitative method for identification of up to 15 amino acids at the N-terminus of a protein.	1–2 weeks
MFI (USP <788>)	USP <788> compliant. Determination of particle concentration and identity by morphology.	1–2 weeks
Surface Plasmon Resonance Affinity (SPR)	Measures changes in the thickness of a surface to determine rate of ligand association or dissociation.	2–4 weeks

HISTORY

We have over 30 years of experience in producing life science research reagents. Through our custom services, you have access to the technologies and instrumentation we use to analyze the gold-standard products we manufacture.

EXPERTISE

We specialize in a broad range of testing techniques to support analysis of your samples.

DELIVERY

Entrusting our expert personnel with your samples ensures accurate results that are returned in a timely, efficient and customized manner under our proven quality management systems.

SIMPLE SOLUTIONS FOR COMPLEX GENE EDITING PROBLEMS: CUSTOM GENOME ENGINEERING SERVICES

GENE EDITING SERVICES

R&D Systems is different. Our expertise and experience using novel strategies and tools allow us to provide industry-leading services that address highly complex gene delivery and gene editing challenges. We take pride in fully understanding the needs of our customers to develop a quote personalized for your unique project.

WHAT WE OFFER

- ✓ Custom engineered cell lines
- ✓ Primary cell editing services
- ✓ Pluripotent stem cell editing
- ✓ Non-viral genetic modifications for cell and gene therapy manufacturing
- ✓ Expertise in a diverse array of biological assays and culture systems

WHY CHOOSE R&D SYSTEMS GENOME ENGINEERING SERVICES?

- ✓ R&D Systems expertise and proprietary tools provide two distinct advantages
  1. We deliver projects faster than anyone in the industry
  2. We take on the most difficult and challenging projects so you can focus on your research
- ✓ You receive regular status updates on your project
- ✓ We vigilantly monitor promised delivery dates to meet your deadline
- ✓ We have delivered hundreds of engineered cell lines for the world's leading pharmaceutical companies

TESTIMONIAL

"We have been utilizing the Genome Engineering Services (GES) team for the last two years to take on our most challenging gene engineering projects. They provide the most up-to-date engineering tools, strategies, and techniques to ensure the quickest turn-around of the final cells. The GES team really has some of the brightest and most tenacious scientists that treat our project as if it was their own research."

–Senior Scientist, Fortune 25 Pharmaceutical Company, West Coast

HISTORY	EXPERTISE	DELIVERY
Our Genome Engineering Service was founded with the explosion of interest in non-viral genome editing techniques to provide cutting-edge innovation for research, discovery and cell therapy manufacturing.	Our scientists have developed novel methods for complex genome engineering projects that enable faster, more cost-effective research.	Using our expertise, we deliver your custom engineered cell line in industry-leading timelines, depending on the nature and complexity of your project.

ANALYTICAL SOLUTIONS DIVISION: PROTEINSIMPLE PLATFORM CUSTOM SERVICES

CUSTOM SERVICES ON BIO-TECHNE PLATFORMS

SERVICES INCLUDE, BUT ARE NOT LIMITED TO:

- ✓ Antibody screening, optimization
- ✓ Assay/method development
- ✓ Assay transfer
- ✓ scWest chip scanning
- ✓ Sample analysis (Research Use Only)

KEY PRODUCT FEATURES AND SERVICES

SIMPLE WESTERN

GEL-FREE, BLOT-FREE, HANDS-FREE CAPILLARY-BASED IMMUNOASSAY PLATFORMS

- ✓ Antibody screening
- ✓ Assay feasibility and assay development
- ✓ Run samples for an established assay*

MAURICE

REPRODUCIBLE, QUANTITATIVE ANALYSIS OF IDENTITY, PURITY AND HETEROGENEITY PROFILES FOR YOUR THERAPEUTIC PROTEINS

- ✓ Method development
- ✓ Method transfers from other platforms
- ✓ Run samples for an established assay*

SINGLE-CELL WESTERN

SINGLE-CELL PROTEIN EXPRESSION ANALYSIS

- ✓ Antibody screening
- ✓ Assay development
- ✓ scWest chip scanning
- ✓ Run samples for an established assay*

MICRO FLOW IMAGING (MFI)

SUBVISIBLE PARTICLE ANALYSIS FOR BIOPHARMACEUTICALS

- ✓ Method development
- ✓ Run samples for an established assay*

SIMPLE PLEX

HANDS-FREE, SENSITIVE AND REPRODUCIBLE IMMUNOASSAYS

- ✓ Assay development
- ✓ Assay component development (for 48-Dig cartridge)
- ✓ Run samples for an established assay*

TESTIMONIAL

"The ProteinSimple Custom team did a great job of delivering assay feasibility data in a timely manner that helped drive decision making."

–Simple Western custom services customer

HISTORY	EXPERTISE	DELIVERY
Since 2011, ProteinSimple has produced cutting-edge analytical instrumentation to simplify and advance protein analysis.	Our scientists are world experts in our platforms and have deep domain knowledge to efficiently develop methods that suit our customer's requirements.	We will deliver the assay and results you need to support your research and development needs.

*Limited samples numbers, for Research Use Only

TRUST OUR WORLD-CLASS CHEMISTRY TEAM TO DELIVER UNIQUE COMPOUNDS AND SCREENING PANELS

CHEMISTRY SERVICES

CUSTOM SYNTHESIS SERVICES

We specialize in mg to kg scale synthesis of complex organic molecules including active pharmaceutical ingredients (APIs), amino acids, peptides, scaffolds, building blocks, rare organics, and specialty fine chemicals.

- ✓ Compounds requiring complex multistep chemistry
- ✓ Chiral synthesis and resolution/separation of enantiomers
- ✓ Stable labeling (both ^{13}C and ^{2}H are routine)
- ✓ Route development
- ✓ Conjugation chemistry
- ✓ Synthesis and extraction of natural products

CHEMICAL ANALYSIS SERVICES

We can provide complete analytical support, with comprehensive QC data packages or individual analytical techniques including NMR, HPLC, MS, LC-MS, IR, optical rotation and micro-analysis.

- ✓ 400 MHz Bruker multi-nuclear NMR spectroscopy (^{1}H, ^{13}C, ^{31}P, ^{19}F)
- ✓ HPLC (normal phase, reverse phase and chiral) and UHPLC (reverse phase only)
- ✓ Gas Chromatography with ECD and FID
- ✓ Optical rotation, microanalysis, FTIR spectroscopy
- ✓ Preparative HPLC (1-10s gram capability, UV/Vis or MS detection)
- ✓ Preparative SFC (1-10s gram capability, chiral separations)

CHEMICAL SOURCING SERVICES

Our global supply network is second to none. We can provide access to a reliable and sustainable source of high-quality products including carbohydrates, prostaglandins, natural products, APIs, and peptides.

- ✓ Extraction and supply of natural products from specialist phytochemical companies
- ✓ APIs sourced from a global network of suppliers
- ✓ Specialized fine chemicals such as carbohydrates, nucleotides, prostaglandins,and fermentation products
- ✓ Technologies such as peptide synthesis, kilo scale production and GMP manufacturing
- ✓ Raw materials and chemical synthesis services from established providers

HISTORY	EXPERTISE	DELIVERY
Since the early 1980s, Tocris has been a leading global supplier of innovative high-performance life science research reagents. The Tocris™ range contains over 4,500 products including established research standards and the latest tools to enable scientists to drive their research forwards.	Based in a state-of-the-art chemistry facility in the UK, we synthesize the majority of our products in-house. Our chemistry and analytical teams are highly experienced in preparing biologically active molecules that are both structurally and synthetically diverse.	We begin by listening. We understand that the needs of our customers are unique, and we will take the time to establish your requirements, whether it be for individual products or longer-term collaborations. By adhering to good practice and listening to our customers, Tocris fulfils its mission to drive life science research forward and make new discoveries possible.

CUSTOM COMPOUND LIBRARIES FROM TOCRIS

In addition to our off-the-shelf range of Tocriscreen™ compound libraries, we offer a custom library service allowing you to cherry-pick compounds for your research. Our customer service team and scientifically trained personnel will be pleased to help you create a unique compound library, designed to meet your exact screening requirements. Libraries are available in both wet (DMSO) and dry formats, with supplied compounds being the same high-quality found throughout the Tocris catalog. Compounds are supplied with full pharmacological activity data and have proven solubility, purity and stability.

PRE-DISSOLVED COMPOUND LIBRARIES

- ✓ Compounds supplied at 10 mM in DMSO
- ✓ Minimum order of 70 compounds, 100 µL volume per compound
- ✓ Various formats available (includes 96-well racks with 2D barcoded Matrix™ storage tubes and SepraSeal caps, 96-well microplates or 384-well Labcyte Echo qualified plates)
- ✓ Restricted to Tocriscreen Plus Libraries compound list (1280 compounds)

DRY COMPOUND LIBRARIES

- ✓ Minimum amount of 2 mg per compound
- ✓ Compounds supplied in barcoded vials (customer own or supplied by Tocris)
- ✓ Majority of compounds in Tocris catalog offered (full list available on request)

CUSTOM DEGRADER SERVICES

Targeted Protein Degradation (TPD) refers to the use of heterobifunctional small molecule Degraders (e.g. PROTACs™) to achieve knockdown of a protein of interest. These small molecules are composed of an E3 ligase ligand and a target protein ligand, joined by a linker. Binding of both ligands results in the formation of a ternary complex between E3 ligase and target protein, resulting in polyubiquitination of the protein and its subsequent degradation by the proteasome.

Tocris provides a selection of commercially available building blocks to support Degrader research and development including functionalized E3 ligase ligands and E3 ligase ligands conjugated to common linker groups. Tocris also offers a custom service for the design and synthesis of Degrader building blocks for your targeted protein degradation research. Additionally, we can partner with your discovery project for the custom design and synthesis of active Degraders.

ACCESS THE WORLD'S FIRST COMMERCIAL EXOSOME ANALYSIS PLATFORM

EXOSOME SERVICES

We uniquely offer multiple platforms that allow the exploration and validation of exosomal RNA (exoRNA), cell-free DNA (cfDNA), and/or proteins to identify biomarkers using biofluid samples instead of an invasive tissue biopsy.

WHY CHOOSE OUR EXOSOME SERVICES?

- ✓ We have over 10 years of experience developing liquid biopsies and have partnered with the world's leading Bio-Pharmaceutical companies to complete large, multi-center, international clinical trials.
- ✓ We have the only platform that allows the co-isolation of exoRNA + cfDNA in a single step to achieve high sensitivity for rare, low frequency mutations.
- ✓ We have a Certified CLIA laboratory and infrastructure to support clinical trial sample processing.
- ✓ Our technology can help pharma and research organizations use biofluids to discover, detect and validate biomarkers including:
  - Facilitating safer and more effective drug dosing and selection
  - Identifying and reducing the risk of adverse effects
  - Supporting faster clinical validations
- ✓ We have in-house expertise in regulatory, bioinformatics and companion diagnostic assay development.

WHAT WE OFFER

- ✓ cGMP clinical grade exosome isolation and exoRNA, exoRNA + cfDNA, and/or exoProtein extraction
- ✓ Exosome depletion of non-relevant exosomes
- ✓ Exosome enrichment of tissue-specific exosomes
- ✓ RNA-Seq of whole transcriptome including coding and non-coding regions
- ✓ NGS panels including all mRNAs, 1400 gene pan-cancer, 170 gene medical oncology
- ✓ A portfolio of assays to detect *EGFR T790M, ALK, ARv7, IDH* and more
- ✓ Custom assay development including qPCR, dPCR, mutant enrichment PCR, NGS and protein
- ✓ Tailored bioinformatics/AI tools for biomarker discovery and variant detection

HISTORY

For over a decade, Exosome Diagnostics, Inc. has been a pioneer in the commercialization of exosome analysis, launching the world's first exosome-based diagnostics. The company's CSO, Johan Skog, Ph.D., is a lead author on the first published study that reported the detection of tumor-derived mutations in exosomal RNA isolated from serum and other biofluids. In the last five years, we have partnered with leading pharma companies to enable their programs using our exosome-based custom services.

EXPERTISE

Exosomes are a rich source of information from the cell and enables complete RNA transcriptome profiling, mutational profiling or protein analysis. At ExosomeDx, we have the leading experts in exosome isolation and molecular biology on our team to advance your programs from biomarker discovery, to translational development, to clinical trials with real-time patient testing in our CLIA lab. We have also developed a platform that isolates tissue-specific exosomes whenever further enrichment is required.

DELIVERY

Our proprietary technologies allow quick and efficient analysis of biofluid samples (e.g. plasma, serum, urine, cerebrospinal fluid, etc.) to deliver high-quality results in 4-12 weeks depending on the assay needs.

Learn more | exosomedx.com/partnerships

GENE EXPRESSION LIKE YOU'VE NEVER SEEN BEFORE: SPATIAL GENOMICS USING RNAscope™ ISH

ACD'S PHARMA ASSAY SERVICES

Advanced Cell Diagnostics (ACD)'s Pharma Assay Services provides RNAscope and BaseScope services to support pre-clinical and clinical studies for pharma and biotech partners globally, with years of experience in every step of the drug development process.

WHY CHOOSE OUR PHARMA ASSAY SERVICES TEAM?

- ✓ We have a collection of RNAscope and BaseScope pre-qualified tissues that are guaranteed for RNA quality, along with a list of vendors from which we can source your tissues of interest.
- ✓ Tissue sectioning, RNAscope and BaseScope staining, brightfield and fluorescent whole slide scanning, scoring, and image analysis are all performed in-house under a streamlined workflow.
- ✓ Our PhD and MD level scientists and pathologists are experts in using image analysis software to perform data analysis to provide quantitative measures of gene expression at the cellular level.

TESTIMONIAL

"We've had a great experience working with ACD. Using their service team, we were able to move faster through our testing for Phase I trial. We are very happy with the quality of data, thoroughness in the reports we received and would highly recommend them for ISH assay development and implementation."

–Dr. Omar Kabbarah, Principle Scientist at major biopharmaceutical company

WHAT WE OFFER

- ✓ **TARGET VALIDATION.** Screen and validate candidate targets by assessing target expression levels in drug-treated versus naïve samples or disease vs normal tissues
- ✓ **BIOMARKER ASSAY DEVELOPMENT.** Evaluate candidate biomarker expression and establish assay performance and dynamic range using bioanalytical method validation guidelines
- ✓ **AAV BIODISTRIBUTION.** Profile the biodistribution of AAV vector together with genetically modified transgenes within the tissue context
- ✓ **CAR/TCR BIODISTRIBUTION AND FUNCTION**. Visualize the biodistribution of CAR T or TCR T cells within the tumor microenvironment and assess functionality with co-detection of immune cell markers or markers of activation
- ✓ **SAFETY/TOXICOLOGY TISSUE SCREENING**. Single-molecule detection for high sensitivity screening of normal tissues for pre-clinical ADME and safety assessment including on-target/off-tumor expression
- ✓ **CDX ASSAY DEVELOPMENT.** Partner with ACD to support the assay feasibility, proof of concept and validation steps of your RNAscope CDx development efforts

HISTORY

Advanced Cell Diagnostics (ACD) is a leader in the emerging field of spatial genomics with its proprietary RNAscope and BaseScope™ *in situ* hybridization (ISH) platforms, which are capable of detecting and quantifying RNA biomarkers in the tissue context at single molecule sensitivity. Since its launch in 2011, the technology boasts 2000+ peer-reviewed publications, now at a rate of approximately two publications per day.

EXPERTISE

Our team of specialists, scientists and pathologists provide unparalleled expertise for ACD ISH platforms and ensures that you will have confidence in the science, data and research conclusions.

DELIVERY

With universal hybridization conditions across all probes in the ACD catalog, there is minimal assay development required and actionable results can be obtained in weeks rather than months.

Learn more | acdbio.com/services

OEM MANUFACTURING FOR THE CLINICAL DIAGNOSTIC INDUSTRY

Today's IVD market is extremely competitive, posing new challenges to manufacturers. Occasionally on-site capabilities of manufacturers are insufficient to meet customer needs and they are needing to supplement with external support. Bio-Techne collaborates with companies at all stages of development and processes. We utilize FDA-compliant, phase-based design control processes for product development. As a dynamic, flexible and regulatory compliant partner, Bio-Techne complements in-house expertise with a full breadth of services to successfully bring projects to completion. Our state-of-the-art facilities, highly experienced personnel, formulation expertise and regulatory compliance (maintaining the following certifications: cGMP, ISO 13485:2016, EN ISO 13485:2016, ISO 9001:2015, CE Mark, CMDR) help ensure we meet customer requirements.

DIAGNOSTIC AREAS WE SUPPORT

- ✓ Tumor (Cancer) markers
- ✓ Cardiac markers
- ✓ Coagulation
- ✓ Diabetes
- ✓ Drugs of abuse
- ✓ Flow cytometry
- ✓ General chemistry/immunochemistry
- ✓ Hematology
- ✓ Lipids
- ✓ Specific proteins
- ✓ Therapeutic drug monitoring
- ✓ Blood gas/glucose
- ✓ Urine chemistry/urinalysis

SERVICE CAPABILITIES

- ✓ Assay development
- ✓ Technology transfer
- ✓ Packaging development
- ✓ Regulatory support
- ✓ Technical support
- ✓ Stability programs

MANUFACTURING CAPABILITIES

- ✓ Liquid formulation/filling
- ✓ Powder formulation
- ✓ Powder blending and filling
- ✓ Reagent tablets
- ✓ Lyophilization
- ✓ Off-line/In-line labeling
- ✓ Kit assembly/packaging
- ✓ Final product testing

HISTORY

For more than 40 years, Bio-Techne has provided numerous manufactured products to the IVD industry. With recent advances in Point-of-Care testing, Bio-Techne is able to service this rapidly expanding market need.

EXPERTISE

As a dynamic, flexible and regulatory compliant partner, Bio-Techne complements in-house expertise with a full breadth of services to successfully bring projects to completion.

DELIVERY

Our experienced process and assay development experts will customize products to meet your specific application requirements. We leverage our resources to manufacture the highest quality standards at competitive costs.

VETERINARY DIAGNOSTICS AND RAPID TEST DEVELOPMENT PROGRAM

Since launching Paratest for veterinary fecal parasite diagnostics in early 2017, we have expanded our veterinary portfolio with new product development and soon-to-launch lateral flow based rapid tests. We now offer easy-to-use timely diagnostics for infectious disease, kidney disease, diabetes, heart disease and more.

AVAILABLE SERVICES

- ✓ Custom rapid test development
- ✓ Lateral flow assay development
- ✓ Rapid test manufacturing
- ✓ Technical consultation

WE CAN HELP BRING YOUR RAPID TEST IDEAS TO THE WORLD

STEP 1: FEASIBILITY

- Project plan and specification
- Initial concept evaluation on lateral flow device including preliminary sensitivity
- A prototype device you can hold in your hand

STEP 2: DEVELOPMENT

- Assay reagent optimization
- Sample collection and matrix compatibility testing
- Cassette suitability and reader evaluation if desired
- Preliminary stability
- Assay performance studies including limit of detection, reproducibility and specificity
- Design for transfer to manufacturing

STEP 3: MANUFACTURING

- Three or more lots manufactured for your specific validation studies
- Released GMP documentation
- Final stability testing
- USDA/CVB regulatory support if required

HISTORY

Bio-Techne entered into the veterinary diagnostic market in 2017 when it partnered with Brazil-based DK Diagnostics to release the PARATEST® system in U.S.

EXPERTISE

We have over 20 years of experience designing, testing and optimizing immunoassays to measure analytes from samples taken from over 15 different species.

DELIVERY

Our customers can benefit from our laboratory capabilities, which range from one-time analytical test requirement studies for development or investigation, to full support of the product life cycle. Our wide range of analytical and stability testing services are designed to ensure timely processing and precise results.

bio-techne®

bio-techne.com

R&D SYSTEMS | NOVUS BIOLOGICALS | TOCRIS | protein simple | ACD | exosomedx

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