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

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

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.


PARTNERING FOR LONG-TERM SUCCESS

CUSTOM 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

UNDERSTAND YOUR GOALS
CONSULT WITH OUR EXPERTS
DOCUMENT MILESTONES
INITIATE & COMMUNICATE
DELIVER YOUR 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
HISTORY
Since 1985, R&D Systems has produced gold-standard proteins to meet the strictest development and purification standards.

EXPERTISE
Our scientists have developed methods to express and purify some of the most challenging proteins with the highest bioactivities on the market.

DELIVERY
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 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 relevance, 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.

4,500 Protein Targets
48 GMP Proteins
25 Species
100 Biotinylated Proteins

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.

CUSTOM PROTEIN CONJUGATION & BIOTINYLLATION
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
• PEGylation
• AviTags™
• Non-standard chemical labels

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 ED50 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 cytoxicity in L-929 mouse fibroblast cells in the presence of the metabolic inhibitor actinomycin D. The ED50 for this effect is 25–100 pg/mL. The similarity in activity highlights that the biotinylated protein is fully functional.

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

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.
**HISTORY**
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.

**EXPERTISE**
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.

**DELIVERY**
Raw data are provided, along with a professionally formatted report and a detailed summary of the bioassay protocol employed.

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**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

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**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

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**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.

---

**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**
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**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.
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

Unstable/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.

Production time
Larger lots of forecasted mass held in inventory.

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.

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. I

–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:

- Alkaline Phosphatase
- Peroxidase
- Fluorescein
- Alexa Fluor
- PerCP (Peridinin-Chlorophyll Protein Complex)
- NorthernLights™
- Alexa Fluor 488
- Alexa Fluor 750
- Alexa Fluor 700
- NorthernLights™
- Alexa Fluor 405
- Alexa Fluor 677
- Alexa Fluor 594
- NorthernLights™
- Alexa Fluor 532
- Alexa Fluor 549
- Alexa Fluor 646
- Alexa Fluor 664
- Alexa Fluor 549
- Alexa Fluor 594
- Janelia Fluor®
- Alexa Fluor 750
- Janelia Fluor 637
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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

CELL CULTURE MEDIA DEVELOPMENT EXPERIENCE:
CELL LINES AND PRIMARY CELLS
✓ HEK cells
✓ CHO cells
✓ Epithelial cells
✓ 293

IMMUNE CELL EXPANSION AND DIFFERENTIATION
✓ Stem Cells
✓ Mesenchymal Stem Cells
✓ Pluripotent Stem Cells
✓ Hematopoietic Stem Cells
✓ Cancer Stem Cells

NEURAL CELL CULTURE

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.
✓ 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.
✓ 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, LSP 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.

HISTORY
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.

EXPERTISE
The products that form our cell and gene therapy solutions portfolio come from our 35+ year history of making gold-standard reagents.

DELIVERY
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.

Learn more | rndsystems.com/custom-media
Learn more | rndsystems.com/custom-cell-gene-therapy
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 product to GMP, or we can completely develop a product of interest from scratch or take an existing product to the GMP level.

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.

GOOD MANUFACTURING PRACTICES

PROTEINS, ANTIBODIES, SMALL MOLECULES, MEDIA

• Full QA review
• Mycoplasma testing
• Individual specification sheets

• Traceability
• Additional bioactivity/bioburden
• Batch-to-batch consistency

• N-terminal sequence
• Lot specific C of A
• Individual specification sheets

• Viral testing
• On site audits

HISTORICAL PERSPECTIVES

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.

EXPERTISE

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.

DELIVERY

Our goal is to provide cell therapy manufacturers with a consistent, safe and continuous supply of GMP-grade raw materials.

HISTORY

Our unrivaled reputation for quality has made Quantikine ELISA Kits the gold standard and most referenced, ready-to-use ELISAs in the industry.

EXPERTISE

Our scientists have developed hundreds of unique diluents and have decades of experience optimizing conditions to detect a range of analytes.

DELIVERY

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.
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 realign 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 SEQUSTRATION: 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

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.

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.

<table>
<thead>
<tr>
<th>SERVICE</th>
<th>DESCRIPTION</th>
<th>ESTIMATED TIMELINE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size Exclusion Chromatography (SEC)</td>
<td>Quantitative method for separation based on size. Typically used for purity and aggregation determination.</td>
<td>1 week</td>
</tr>
<tr>
<td>High Performance Liquid Chromatography (HPLC)</td>
<td>Rapid method for assessment of purity and quantitation of small molecule or biomolecular analytes.</td>
<td>1 week</td>
</tr>
<tr>
<td>Dynamic Light Scattering (DLS)</td>
<td>Rapid method for size determination of proteins, antibodies, or other particles. Measures hydrodynamic radius. Commonly used to assess aggregation.</td>
<td>1 week</td>
</tr>
<tr>
<td>Static Light Scattering (SLS)</td>
<td>Assesses aggregation and provides accurate solution state mass of proteins or antibodies.</td>
<td>1 week</td>
</tr>
<tr>
<td>Mass Spectrometry</td>
<td>Triple Quadrupole and Orbitrap technologies for mass determination, trace component quantitation, and in-depth characterization of protein molecular form.</td>
<td>2–4 weeks</td>
</tr>
<tr>
<td>Dynamic Scanning Fluorimetry (DSF) - Thermostability</td>
<td>Used to predict formulary stability and refolding effectiveness. Generally used with multiple sample conditions to determine optimal conditions.</td>
<td>1 week</td>
</tr>
<tr>
<td>iEF (Maurice)</td>
<td>Isoelectric point determination. Benchmark function for measuring lot consistency, formulating buffers, and observing biocompatibility.</td>
<td>1–2 weeks</td>
</tr>
<tr>
<td>N-glycan Fingerprint (Gly-42)</td>
<td>Rapid method to identify N-glycan footprint trace in proteins and antibodies.</td>
<td>1–2 weeks</td>
</tr>
<tr>
<td>N-terminal Sequencing (5 aa)</td>
<td>Qualitative, semi-quantitative method for identification of up to 15 amino acids at the N-terminus of a protein.</td>
<td>1–2 weeks</td>
</tr>
<tr>
<td>MPS (USP &lt;788&gt;)</td>
<td>USP &lt;788&gt;-compliant. Determination of particle concentration and identity by morphology.</td>
<td>1–2 weeks</td>
</tr>
<tr>
<td>Surface Plasmon Resonance Affinity (SPR)</td>
<td>Measures changes in the thickness of a surface to determine rate of ligand association or dissociation.</td>
<td>2–4 weeks</td>
</tr>
</tbody>
</table>

Learn more | rndsystems.com/services

*Terms and conditions apply
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

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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

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.

EXPERTISE

Our scientists have developed novel methods for complex genome engineering projects that enable faster, more cost-effective research.

DELIVERY

Using our expertise, we deliver your custom engineered cell line in industry-leading timelines, depending on the nature and complexity of your project.

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*

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 13C and 1H 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 (1H, 13C, 31P, 19F)
✓ 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/Visible 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
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.

DELIVERY
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.

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
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.

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.

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 SeparaSeal 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)

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.
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.

WHAT WE OFFER

✓ TARGET VALIDATION: Screen and validate candidate targets by assessing target expression levels in drug-treated versus naive 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

✓ CART/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 ADMC 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

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

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

Learn more | rndsystems.com/services
Since launching Paratext 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.