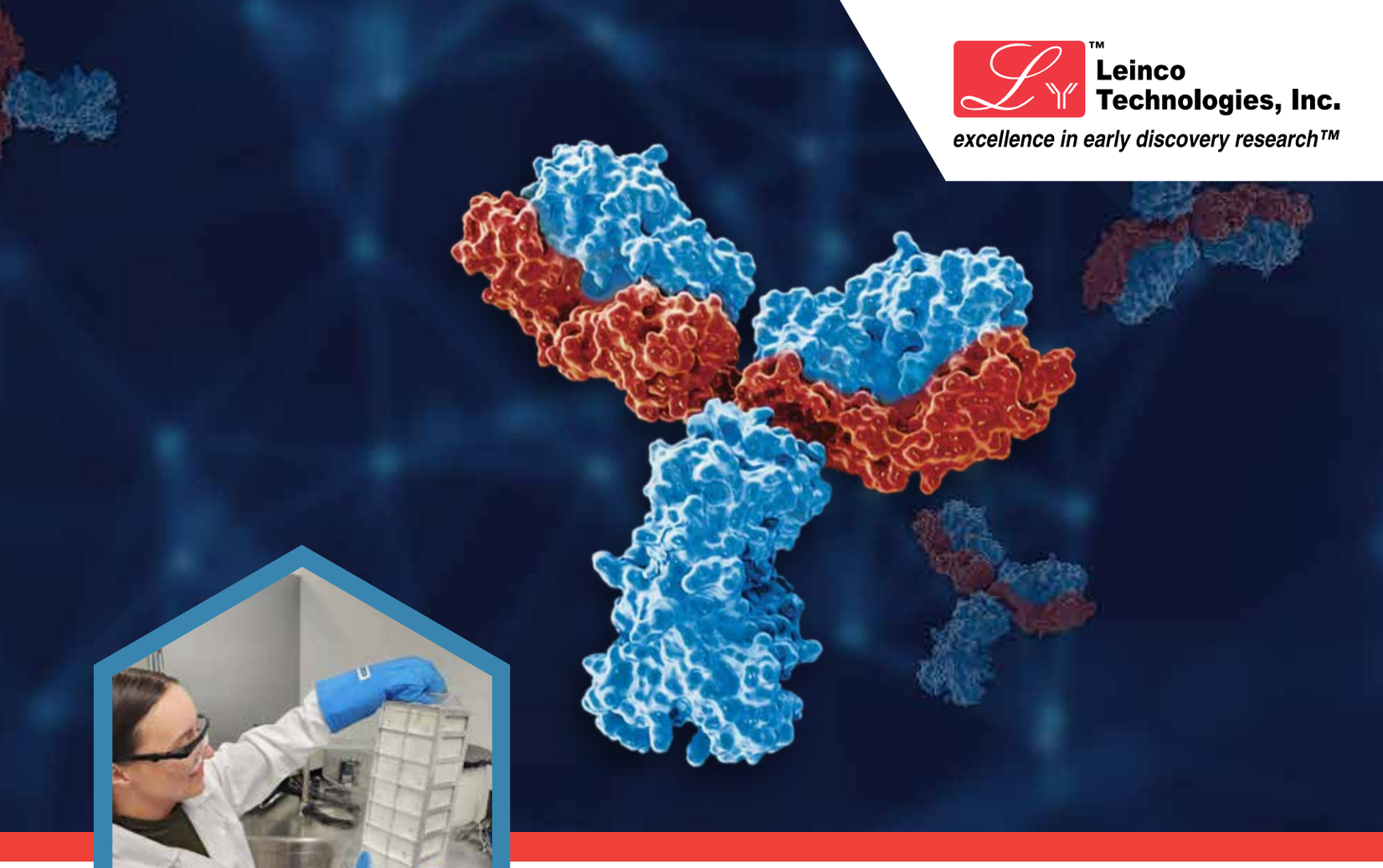
Leinco Technologies, Inc.™

excellence in early discovery research™



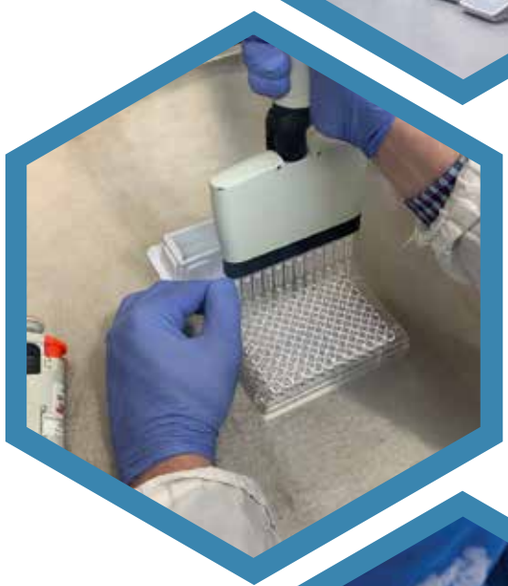
Raising the Bar in Custom Bioreagent Optimization & Scalability

No project is too small or too large

Contract Development & Manufacturing Services

Leinco Technologies has a broad technology toolbox to provide these services to academic, biotechnology, pharmaceutical, and government institutions as well as diagnostics medical device clients.

Cell and Antibody Services



Assay Services

Antibody Development & Production

The development and production of antibodies can be a complex and time-consuming process. With over 30 years of experience, we are accomplished in all aspects of antibody generation and production. Our collaborative and communicative process keeps you informed every step of the way as we move your project from planning through execution and delivery. We offer the same level of dedicated support and service for every project; whether you are a single investigator needing small amounts or a large biopharma company requiring gram quantities, we offer dedicated support & service for any size project.

Key Benefits

Detailed Proposal
Consultation with scientific team to set project goals and benchmarks while identifying potential challenges with recommending solutions.

Scalable Production
Proprietary bioreactor production platforms for mammalian cell culture and hybridomas allow small scale (5 mg) production to large scale production (>50 g).

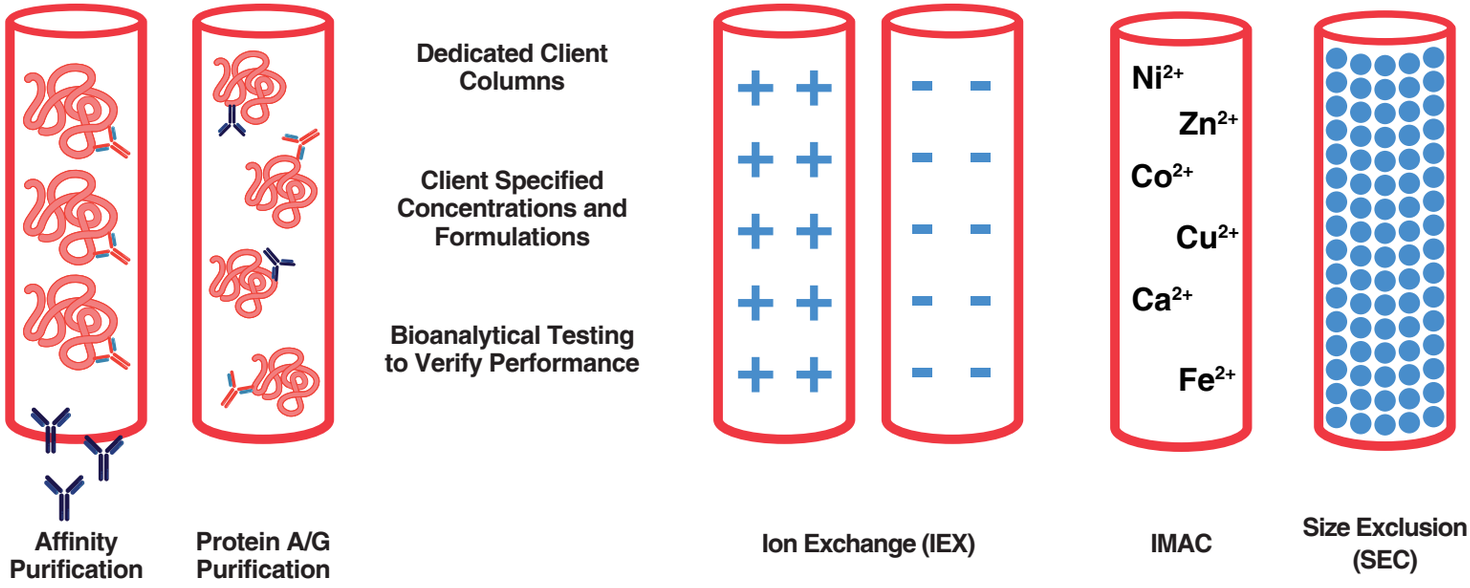
***In vivo* Function Formulations**
Highest purity product (≥ 98% purity) with extremely low endotoxin levels (≤ 0.5 EU/mg), low aggregation (≥ 98% monomer), optional pathogen testing (IDEXX IMPACT™ I), formulated with no preservatives, stabilizers or carrier protein.

Characterization Assays
Optional testing can determine antibody binding efficiency and verify functionality in applications such as Western blotting, flow cytometry, ELISA and other applicable assays.

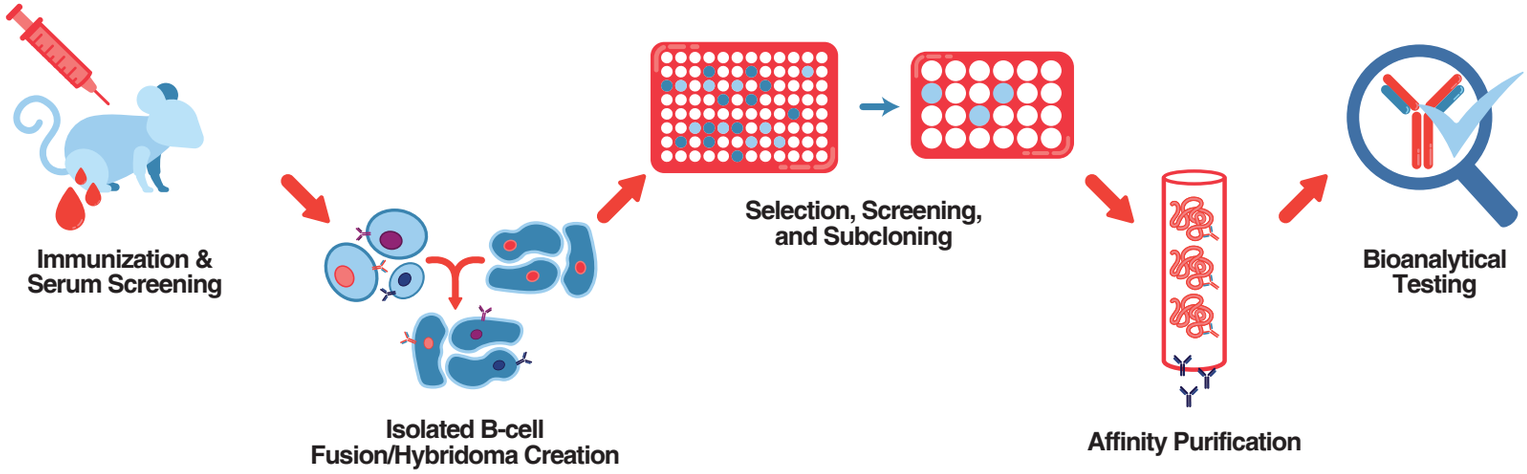
Antibody Engineering
Utilizing molecular tools, antibodies can be sequenced and characterized. With this information, bispecific antibodies, chimeric antibodies and antibodies with Fc modifications to modulate effector function can be generated.

Quality Control Means Consistency
Adherence to cGMP standards including ISO 9001:2015 and ISO 13485:2016 along with stringent standard bioanalytical testing procedures ensure the purity of final products and exceptional lot-to-lot consistency.

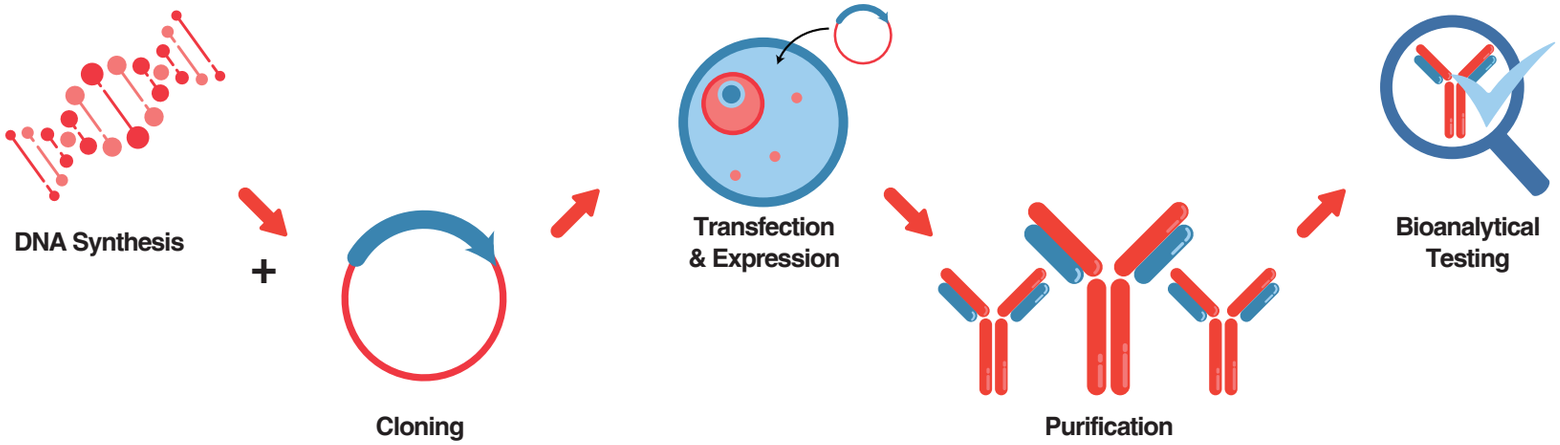
Purification Options



Hybridoma Monoclonal Antibody Workflow



Recombinant Monoclonal Antibody Workflow

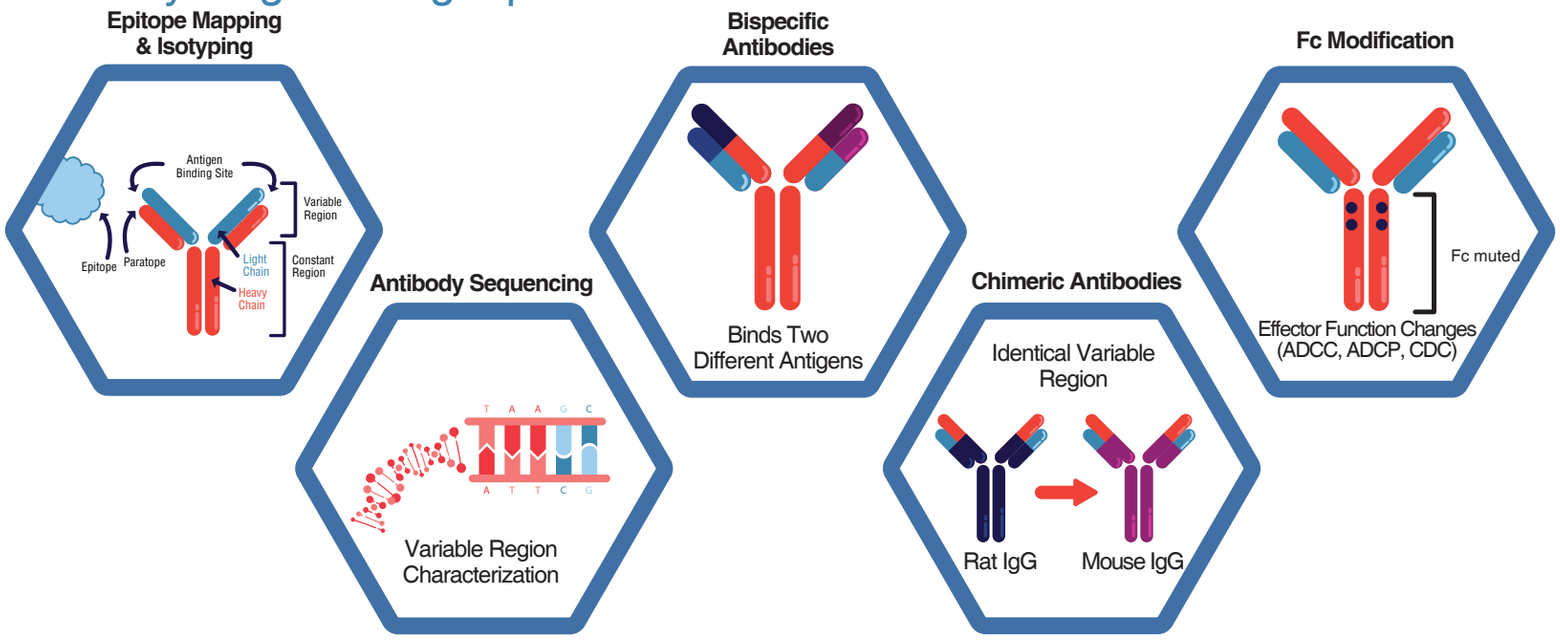


Polyclonal Antibody Workflow

Antibody Engineering and Gene Synthesis

Molecular techniques can be leveraged to synthesize and optimize genes of interest to enhance protein expression and modify protein function or localization. This same technology is used for various forms of antibody engineering where gene sequences for antibodies are manipulated to create novel antibodies that may not exist in nature. Alternatively, naturally occurring antibodies can be epitope mapped, recombinantly created, and modified as desired for production at scale.

Antibody Engineering Options



Gene Synthesis

Key Benefits

No Template Required
Novel sequences or difficult to clone genes can be synthesized *de novo* including long sequences and/or complex genes with high GC content, complex secondary structures or repetitive sequences.

Codon Optimization
To increase protein yield and transcript solubility, codon usage can be adapted *in silica* to match any expression organism while preserving the final amino acid sequence.

Easy Gene Manipulation
Modify the gene sequence to aid in cloning by adding or removing restriction sites. Enhance protein expression through the addition of promoter or enhancer elements. Optimize downstream protein functions and usability by modifying protein-protein interaction domains or designing and inserting signal sequences, localization signals, and/or tags.

Cloning Services
Fast and easy way to generate 100% sequence-verified constructs cloned into the vector of your choice. Create *de novo* gene fragments using our gene synthesis services, or use your own DNA template.

Enzyme & Protein Production

The production of properly folded recombinant proteins that retain their biological activity is a challenge that requires extensive knowledge and troubleshooting skills that are honed by years of experience. Our scientists are accomplished in the optimization of both upstream and downstream processes that can affect yield, stability, purity and the activity of purified proteins. Let the problem solvers at Leinco help with your protein production needs.

Key Features & Benefits

Entire Workflow
From DNA synthesis to finished purified product, every step of the process is optimized to ensure the highest yields.

Mammalian Cells
Proteins can be purified from CHO and HEK-293 cells to ensure proper folding and post-translational modifications.

Activity Assays
Optional testing of purified enzymes to ensure they retain the desired activity.

Troubleshooting
Over 30 years of experience in optimizing both upstream and downstream processes.

Upstream Optimization

- Media Formulations
- Induction Conditions
- Temperature Optimization for Enzyme Stability

Downstream Optimization

- Purification Strategy
- Chromatography Conditions

Bioanalytical Testing

- Purity
- Physical Properties
- Enzyme Activity

Production Scale Up

Manufacturing biological products and buffers at a commercial scale requires expertise, reliability and efficiency. With a proven track record of delivering high-quality products, we offer tailored solutions that meet your specific manufacturing requirements from antibodies to buffers. Our cutting-edge facilities are equipped to handle large-scale production with stringent quality controls. Trust us to be your strategic partner in scaling up your antibody and buffer manufacturing, delivering exceptional results to propel your research or commercial endeavors forward.

Key Features & Benefits

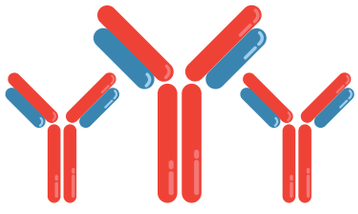
Expertise
We have a proven track record of partnering with academic and commercial entities to meet the most stringent customer requirements.

Development
Accomplished in the development of custom formulations to meet the needs of customers applications.

State-of-the-Art Facilities
With our recently expanded Class 10,000 clean rooms and cutting-edge manufacturing facilities we are capable of taking on any project.

Validation and Quality
Sterile techniques used in manufacturing yield products with low particle counts and lot-to-lot consistency.

Custom Packaging
The freedom to choose exactly how your product will be packaged.

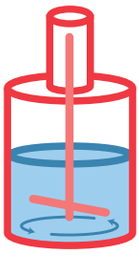


Antibodies

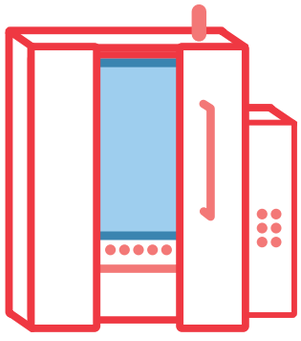
Proteins/Enzymes

Buffers & Other Solutions

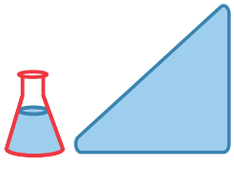
5-100mg



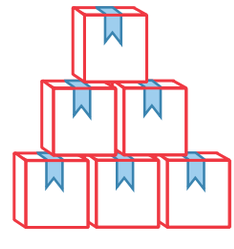
5g-30g+



50g+



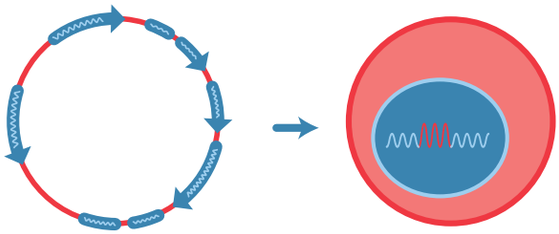
5L



1000L

Stable Cell Line Development

Our expertise in cell line engineering and optimization delivers reliable and robust cell lines tailored to your specific requirements. Our team of scientists utilizes state-of-the-art technologies and industry-leading techniques to ensure the successful generation of stable cell lines that exhibit high productivity, genetic stability, and desirable expression characteristics.

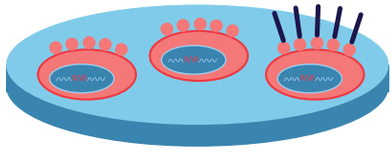


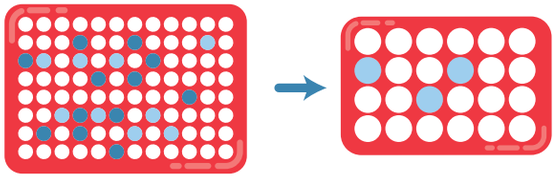
Transfection

Engineered plasmids with gene of interest are transfected into host cell of choice (CHO, HEK-293).

Selection from Pool of Transfected Cells

Drug and physical selection of cells that are stably producing the desired gene product.



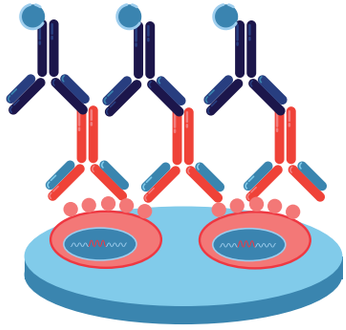


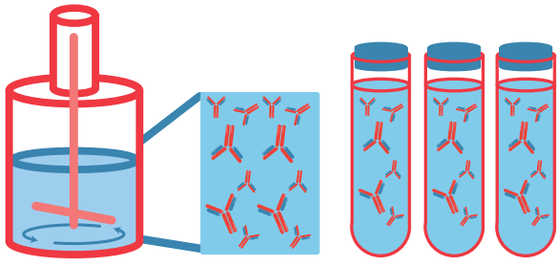
Clonal Screening and Selection

Isolation of single clones and selection of those producing large quantities of desired recombinant protein.

Cell Line Characterization

Specific productivity rate (SPR) and gene stability are used to characterize each clone.





Expansion and Downstream Evaluation

Expansion and master cell banking of the top producing clone, Mycoplasma testing of banked cells to prevent contamination, and cell line optimization are performed.

Cell Banking & Storage

The creation of both Master Cell Banks (MCBs) and Working Cell Banks (WCBs) are the critical first steps in a quality manufacturing system. MCBs give you peace of mind that your optimized cells are safely cryopreserved for future use while WCBs provide Leinco scientists with the necessary cells to begin bioreactor production runs for your custom antibody or protein. Additionally, Leinco can serve as a repository for your cells, providing a safe and secure location to hedge against the worst-case scenario at your local storage facility.

Key Benefits

Risk Mitigation Against Loss
Storage of your cells at a secondary location like Leinco provides protection against loss of your own cell stocks and provides peace of mind that your research and proprietary technology won't be lost due to a freezer malfunction.

Verified Uncontaminated Stocks
Cell banks are tested to ensure they test negative for mycoplasma and can also be screened for murine pathogens with IDEXX IMPACT testing.

Quality
Adherence to stringent quality and cGMP standards including ISO 9001:2015 and ISO 13485:2016.

Custom Buffer Services

The ability to manufacture buffers that consistently meet the same quality standards requires expertise and attention to detail. Small changes to composition can have drastic biological effects that can lead to expensive, time-consuming, and difficult to trace assay failures. Maintaining sterility during the manufacturing process is one of our keys to success. Whether it's a new custom formulation or scale up of existing formulations, don't take the buffers and reagents used in your assays or kits for granted.

Key Benefits

Custom Formulations
We are accomplished in the formulation of custom buffers to meet any assay requirements at any scale.

Scalable Production
Whether you require only a few liters or 1000L of your buffer, we have the production capabilities to meet your needs.

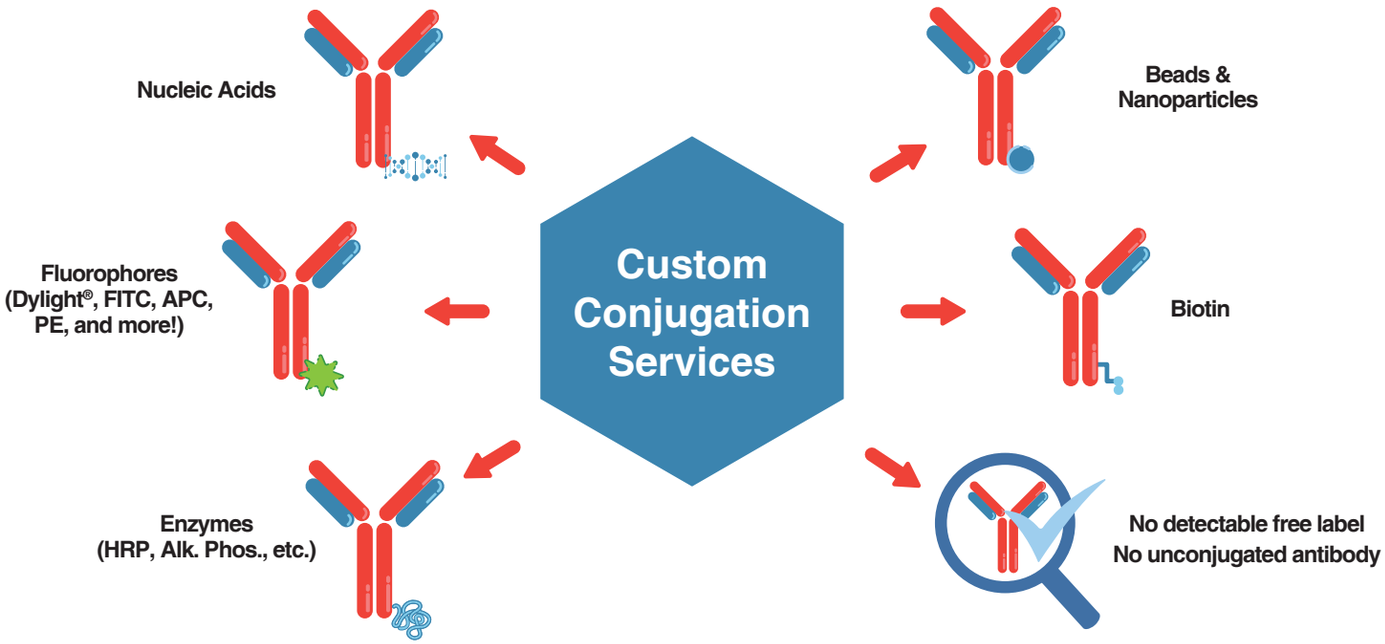
Consistency
Every lot undergoes rigorous quality control testing to ensure that it meets customer requirements and expectations.

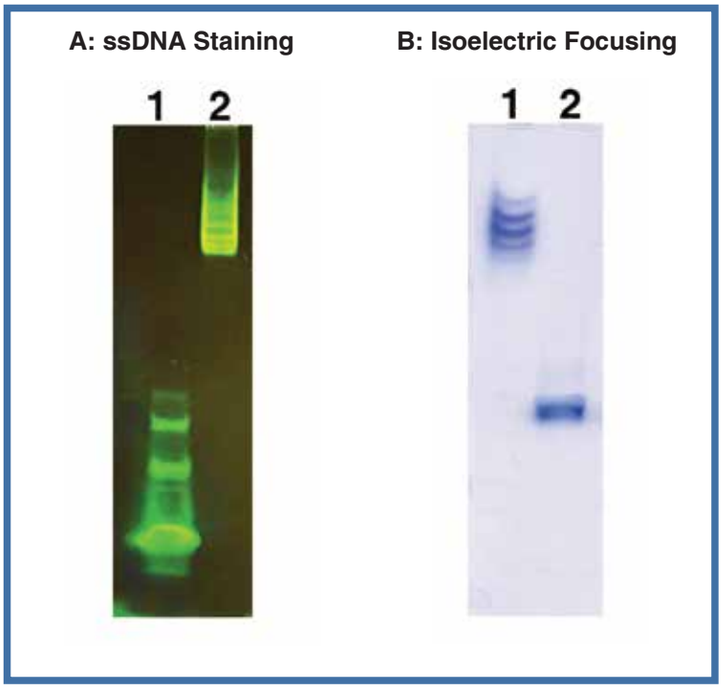
Sterility
Stringent quality controls and our Class 10,000 clean rooms ensure a sterile product for any assay needs including IVD.

Custom Filling and Kitting
Let us take charge of the final step for your kit manufacturing needs by filling and packaging in any size and custom labelling your products.

Custom Conjugation Services

Our custom conjugation services take the guesswork out of antibody conjugation, providing a high-quality product with no detectable free label or unconjugated antibody. Our linkage and post-conjugation purification techniques result in conjugates with higher signal to noise ratios for use in applications such as flow cytometry, ELISA, spatial biology, Western blotting, IHC, and membrane assays.





Conjugation of Antibodies with Oligonucleotides

The presence of unconjugated antibody or free label can drastically affect assays and lead to unreliable results. Strict quality control testing determines the efficiency of the conjugation process. For example, ssDNA staining (A) shows the difference between the ssDNA oligonucleotide tag alone (lane 1) and after conjugation (lane 2) to the antibody of interest where there is no visible unconjugated ssDNA. Isoelectric focusing (B) of unlabeled antibody (lane 1) and labelled antibody (lane 2) show no visible unlabeled antibody present after conjugation.

Lyophilization Services

When it comes to lyophilization, there is no “one process fits all” solution. Leinco has developed proprietary formulations that are used during the lyophilization process to ensure that critical reagents can meet the demands of IVD kits, including shelf stability and reliable activity after reconstitution.

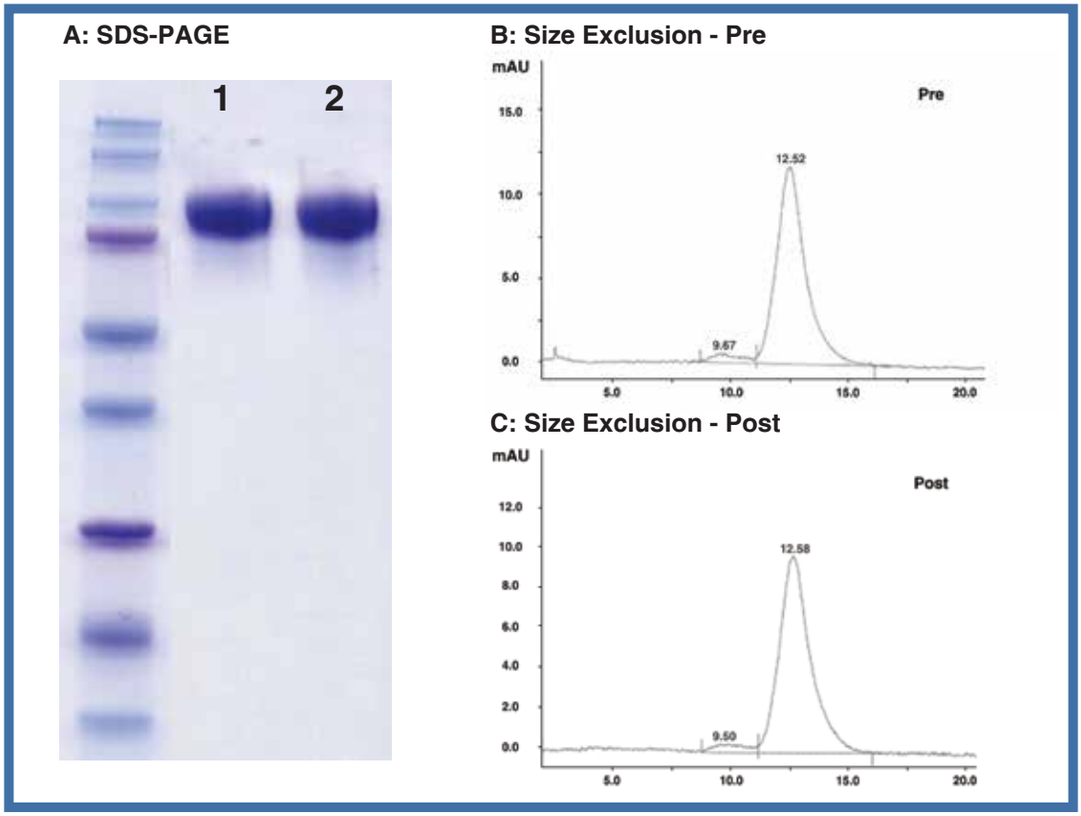
Key Benefits

Avoid Pitfalls
Proper lyophilization can decrease aggregation, denaturation, or degradation that threaten the performance of your final kit.

Enhanced Shelf Life
Antibodies and proteins that are lyophilized are stable for six to twelve months when stored desiccated at -20°C to -70°C.

Lower Shipping Costs
Lyophilized products weigh significantly less than the liquids from which they are derived. This significantly decreases the transportation costs of products throughout the supply chain from raw materials through finished products.

Custom Specifications
Purified products can be lyophilized in single use vials appropriate for each unique assay. It also allows for reconstitution at custom concentrations to meet assay needs.



Lyophilization Does Not Affect Protein Stability

Careful consideration is taken to ensure that lyophilized proteins remain stable and do not degrade during the lyophilization/resuspension process. SDS-PAGE (A) performed on proteins both pre-lyophilization (Lane 1) and post-lyophilization and resuspension (Lane 2) shows that there is no degradation or aggregation of the protein during storage or resuspension. This is further supported by size exclusion chromatography of the same protein prior to lyophilization (B) and after resuspension (C).

Immunoassay Development

When an off-the-shelf assay is not available, our scientists can design and create custom assay solutions to your specifications and deliver the quality results you expect.

Key Features & Benefits

Collaborative Approach
Highly experienced scientific and project management staff focus on transparent communication at every stage to enable data-driven decisions.

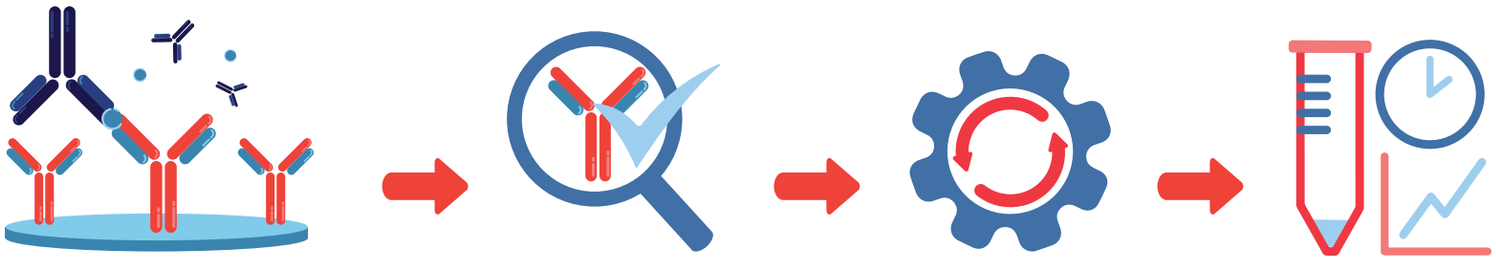
Antibody Screening
Evaluation of potential antibodies for best matched pair identification.

ELISA and LFA
Experience in developing and testing the various components of both ELISA and LFA tests ensures optimal assay performance.

Validation
Testing to determine the limit of detection (LOD), Ka and Kd constants of the antibody binding to the target, calibration curve determination.

Stability Testing
Rigorous testing to ensure assay performance over time.

Quality
Stringent quality and cGMP standards including ISO 9001:2015 and ISO 13485:2016.



Matched Pair Identification & Characterization | **Feasibility & Validation Testing** | **Manufacturing** | **Stability Testing**

Binding Affinity

Blank	Weak	Medium	Strong
0	1	2	3

Nitrocellulose	Nanoparticle		274	8C5E3	657	1078
274	H1N1AV			0	3	3
	Negative			0	0	2
8C5E3	H1N1AV		0		0	0
	Negative		0		0	0
657	H1N1AV		2	0		3
	Negative		1	0		2
1078	H1N1AV		2	0	2	
	Negative		1	0	0	

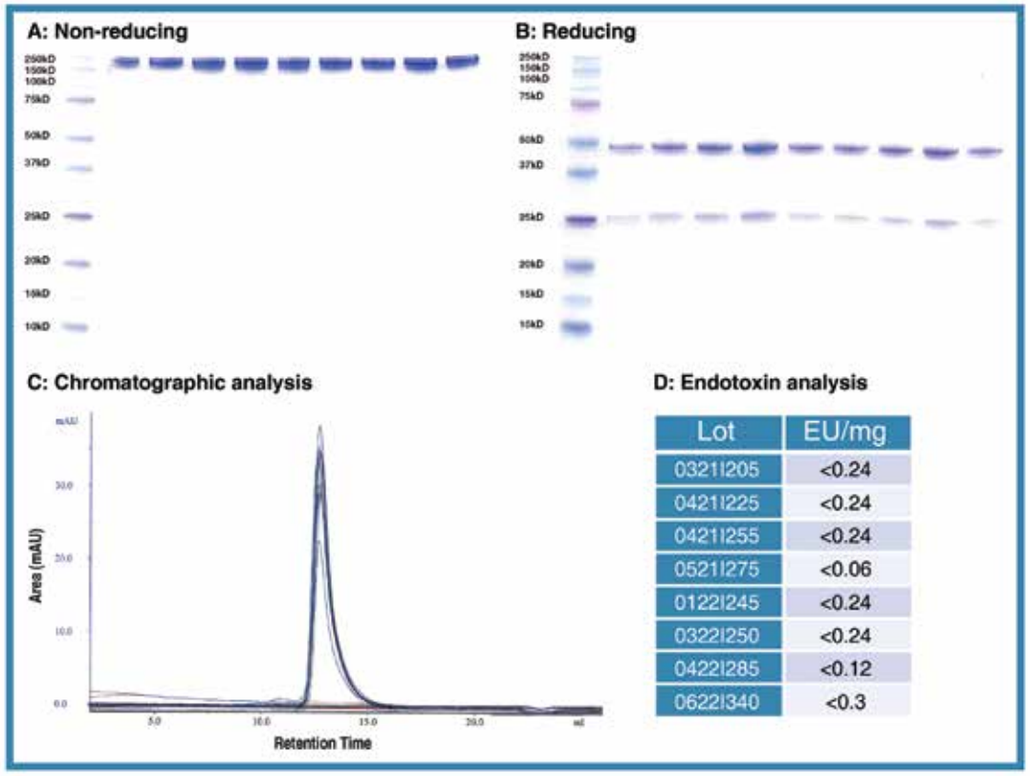
Qualitative ability of antibody pairs to detect Influenza A, H1N1, strain AWS33 by lateral flow test

Case Study: To select the best antibody pairs before commercial prototyping, a half-strip format was used to conjugate Influenza A IgG antibodies (Leinco Technologies, Inc.) with gold nanoparticles, utilizing either passive or covalent binding reactions. The strips were tested using a known stock of H1N1, strain A/WSN/1933 TS61 (GenBank CY010795.1). Combination tests were performed using covalent gold conjugates. One pairing, antibody 657 for the conjugate and 274 for the capture, showed strong conjugation with no false positives.

Quality Control and Bioanalytical Testing

Our commitment to quality is exemplified by our adherence to cGMP standards including ISO 9001:2015 and ISO 13485:2016. This means that your finished products will have exceptional lot-to-lot consistency to meet your expectations and requirements. All of our purified products (antibodies and proteins) undergo our standard bioanalytical testing procedures to ensure their purity meets our stringent specifications. We also offer additional services that go above and beyond our standard testing.

Standard QC	Additional Options
Purity	IDEXX IMPACT I Testing
pH Determination	Binding Assays
Concentration	Functional Assays
Aggregation	Stability Assays
Endotoxin Testing	



Stringent quality controls ensure exceptional lot-to-lot consistency.

Samples from 9 different lots show consistent purity as demonstrated by gels A and B. Further analysis by size exclusion chromatography (C) shows overlapping retention times with minimal baseline noise. Limulus amebocyte lysate (LAL) endotoxin testing (D) indicates all lots meet *in vivo* standards for endotoxin.

About Leinco

For scientists in life sciences discovery, and biopharmaceutical and diagnostics segments utilizing antibodies, biologically active proteins, and assays, reproducible science is the key to unlocking the scientific doors. Leinco Technologies Inc. adheres to ISO 9001:2015 and ISO 13485:2016 quality standards, and provides access to antibodies and proteins used in a broad range of life sciences applications uncovering interactions in cancer, infectious diseases and immunology. Our proprietary techniques result in the highest purity antibodies (monoclonal, recombinant and polyclonal) and proteins enabling scientists globally to generate reproducible science and faster time to scientific results across a broad range of cell, tissue and *in vivo* applications (e.g. spatial biology, flow cytometry, pre-clinical *in vivo* and *in vitro* studies). For our many partners, the Leinco scientists with over 30 years' experience take a consultative approach and are committed to delivering the highest quality CDMO services (e.g. antibody scale-up and purification, optimized conjugation to reporter molecules and assay development/manufacturing) that save time and ensure our customers are successful in their programs.

IT IS OUR GOAL TO…

- Provide leading edge products and services at the best value.
- Provide excellent customer service.
- Provide high quality technical product data.
- Provide world class technical support.

Scan the QR code
to Request Quote!

Leinco Technologies
410 Axminister Dr.
St. Louis, Missouri 63026

B01-2306-A