

CUSTOM SERVICES & CAPABILITIES

# INTRODUCTION

Rockland Immunochemicals, Inc. is a global biotechnology company manufacturing leading edge research tools for basic, applied and clinical research in functional genomics, gene therapy and drug discovery markets. Founded in 1962, Rockland is privately held and occupies an approximately 70-acre site with animal husbandry facilities which houses several species of large and small animals, as well as state-of-the-art laboratories. Rockland is well equipped to fulfill its core mission of developing antibodies, immunoassays and cell based assays.

Rockland's facility in Limerick, PA is located in the greater Philadelphia biotechnology district, home to dozens of well established pharmaceutical and biotechnology companies, as well as several premier biomedical research colleges and universities.



#### CONTRACT MANUFACTURING ORGANIZATION

As a CMO, Rockland provides critical reagents to major manufacturers of research and clinical laboratory assays. Examples of our products include bulk IgG fractions, gamma globulins, substrates and detection reagents, bulk secondary antibodies and antibody conjugates. Rockland's facilities offer the ability to produce products at the hundreds of grams to kilogram scales with the ability to meet strict raw material specifications. Additional products and services offered include:

- · Small Scale Manufacturing > Bulk Manufacturing
- Primary & Secondary Antibodies

· Proteins & Peptides

• Dye, Enzyme, and Magnetic Conjugated or Modified Reagents

# CONTRACT RESEARCH ORGANIZATION

As a CRO, Rockland specializes in antibody development, antibody characterization, assay development and cell-based assay performance. GLP compliant services are provided to the biopharmaceutical and diagnostic industries.

Rockland's scientists have contributed to the development of accepted methods for immunochemistry and are continually developing, validating and transferring to biopharmaceutical and the life science industries new methods for their bioanalytical laboratories.

Contract Research Services include:

Rockland is able to perform immunogenicity testing, neutralizing antibody testing, biomarker discovery, and other bioanalytical assay services

· Cell Culture

- ELISA
- Cell-based Assay Development & Validation
- Biomarker Discovery

· Cell-line Development

Flow Cytometry

Molecular Biology

Mass Spectrometry

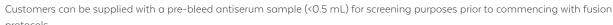
# MONOCLONAL ANTIBODY DEVELOPMENT

Each monoclonal project is performed in stages, and our clients can decide on when to proceed to each project stage. Rockland's custom monoclonal antibody service can meet all of our customers' specific needs in any stage of the research process.

#### CUSTOM MONOCLONAL ANTIBODY DEVELOPMENT PROCESS

Rockland has decades of experience in producing monoclonal antibodies in multiple host animals including mouse, rat and Armenian hamsters. We make use of electrofusion technology to produce large numbers of hybridoma clones from each fusion experiment. Rockland's electrofusion technology and screening processes allow us to be successful in producing fit-for-purpose monoclonal antibodies against the most difficult targets.

- **Immunization**: Rockland offers variable immunization schedules and use of special adjuvants on a custom basis depending on client needs.
- Pre-fusion Screening: Rockland's experience and monitoring of the antibody-mediated immune response translates into recommendations to the client prior to fusion of splenocytes.



• **Hybridoma Screening**: Rockland uses proprietary screening in peptide-immunogen based fusions. Rockland's modified ELISA methods produce more specific hybridomas faster than classical ELISA approaches. Additional screening against primary targets and additional antigens can be performed upon request.



# CELL BANKING/CYROPRESERVATION SERVICES

Custom Cell Banking services are flexible and allow us to meet client specific requests. Our Custom Services group creates both master and working cell banks specific to each client's individual requirements. Upon request, cell line stability services can also be provided.

· Research Cell Banks

Working Cell Banks

Master Cell Banks

Cyropreservation of Parental Cell Lines

#### **CELL LINE TESTING**

- Mycoplasma Testing: We use multiple methods to evaluate potential contamination of cell lines with mycoplasma. Our test methods can evaluate the biological activity or the presence of DNA from all the common mycoplasma species.
- MAP Testing: We use immunologically based methods for the detection of murine viral contaminants in cell culture and other biologic specimens. The methods used exposure of susceptible hosts to test material followed by serological assays for immunological response to potential agents.

# CELL STORAGE SERVICE/CYROSTORAGE

Cell storage for small and large cell banks can be provided on an annual basis. Consider Rockland's robust cell storage facilities as a primary or secondary storage location for your most respected cell lines. Protect your valuable research cell line by investing in multiple storage locations.

#### **ANTIBODY PURIFICATION**

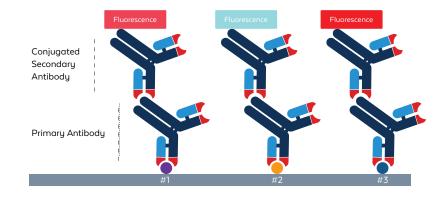
Commercially produced antibodies will often contain a number of substances from the production process that can adversely affect research results. The best way to ensure accurate findings is to purify antibodies prior to use. Rockland offers a variety of purification services for the purification of developed antibodies.

Polyclonal and monoclonal antibodies are commonly purified by Protein A, Protein G or Protein A/G affinity chromatography under optimal conditions. Furthermore, Rockland offers the generation of custom resins for the immobilization of target-specific peptides or recombinant proteins for the affinity purification of generated antiserum and serum depletion.

# **CONJUGATION SERVICES**

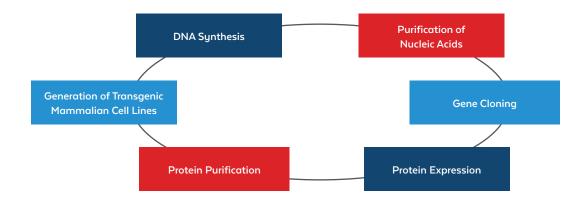
Rockland provides customizable, on-demand conjugation services to meet specific research, development and manufacturing needs of both primary and secondary antibodies and associated proteins.

- · Horseradish Peroxidase (HRP)
- Biotin
- · Alkaline Phosphatase (ALP)
- ATTO
- · Fluorescein
- DyLight™
- · Glucose Oxidase (GO)
- Beta Galactosidase (BGAL or ß-gal)
- Phycoerythrins
- Rhodamine
- · Texas Red®
- · Allophycocyanin (APC)



# **MOLECULAR BIOLOGY SERVICES**

- DNA Synthesis: Complete genes, gene fragments and oligonucleotides can be synthesized and sequenced according to your
  specific requirements. This service also includes codon optimization for gene expression and oligo modifications. Purification of
  Nucleic Acids Preparation of genomic DNA, mRNA and cDNA derived from frozen tissue or cultured cell preparations.
- Gene Cloning: Rockland will design, synthesize and clone your gene insert into the desired vector. Alternatively, you can provide your gene insert either as purified DNA, within a purified plasmid or contained in a slab culture and we will ligate it into the appropriate vector.
- **Protein Expression**: Recombinant proteins will be expressed at the desired scale in the expression system of your choice including bacterial, yeast, insect or mammalian cells.
- Protein Purification: Affinity purification of recombinant proteins expressed in house or from cell pellets provided by the customer. Depending on the purity requirements, it can also include additional multi-step purifications and enzymatic cleavage of epitope tags.
- Generation of Transgenic Mammalian Cell Lines: Cell lines overexpressing or silencing the gene of interest can be generated by a variety of methods including transient or stable transfection and cell transduction of constitutive or inducible systems.



### **ASSAY DEVELOPMENT**

Rockland's full-service immunoassay development bridges the path from discovery to product. Rockland's scientific expertise provides highly customized solutions to meet your basic, applied and clinical research demands in the development of unique in vitro assays.

To enable innovative biomarker development for drug discovery and diagnostic applications, we offer highly customized solutions. From the generation of highly specific antibodies to the development of unique in vitro assay systems, Rockland is your partner by providing scientific expertise for your biomarker evaluation and bioassay development needs. Our services include: Assay Development, Assay Qualification, Assay Validation, and Lot Release Testing and other related supporting services such as accelerated stability studies, antigen production and antibody development.

- · Assay Development
- · Assay Validation
- Assay Qualification
- Accelerated Stability Studies
- Bridging Studies

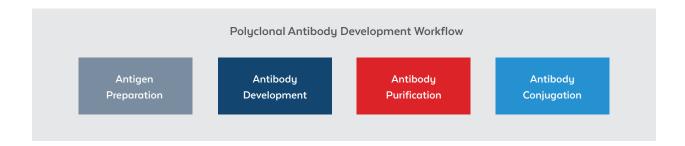
- Western Blot
- ELISA
- Immunohistochemistry
- Immmunofluorescence
- Flow Cytometry

# POLYCLONAL ANTIBODY DEVELOPMENT

Rockland has offered polyclonal antibody manufacturing services for more than four decades. With expertise using a variety of different hosts for the development of polyclonal antibodies, including New Zealand white rabbits, goats, sheep, guinea pigs, chickens, rats, and donkeys.

Let Rockland's expertise aid you in the design and synthesis of your antigenic peptide. Antigens conjugated to KLH represent the starting point of our antibody development program. Should you choose to utilize a recombinant protein as the primary antigen, our expertise in bacterial and insect cell-based recombinant protein expression will ensure production of antigen for immunization and screening regimens.

When combined, these services form the foundation to create a custom antibody reagent capable of performing in the desired immunoassay. Clients may select only antisera generation, or may choose to perform purification and more.



#### MASS SPECTROMETRY SERVICES

Rockland provides mass spectrometry (MS) analysis of proteins and peptides at maximum sensitivity using state-of-theart instruments and methods.

The most commonly used services are identifications of either purified proteins or complex protein mixtures, such as sub-proteomes or complete proteomes, using electrospray ionization tandem mass spectrometry (ESI MS/MS). Typically, either individual bands are excised from 1-D SDS gels, or the entire gel lane is analyzed by slicing it into uniform fractions followed by trypsin digestion and nanocapillary HPLC interfaced directly with hybrid ion trap mass spectrometry (Gel/LC-MS/MS). Data is analyzed and filtered to produce low false-positive rates. Several options are available for quantitatively comparing protein changes in related samples, and additional options are always being added.

- LC-MS/MS Protein Identifications: Identification of proteins from tryptic peptides using nano-capillary LC-MS/MS and database searching.
- GeLC-MS/MS | Comprehensive analysis of a subproteome or proteome: Identification (and potentially quantitation) of large numbers of proteins.
- MudPIT (LC/LC-MS/MS) Analysis | Comprehensive analysis of a subproteome or proteome: Identification of large numbers of proteins from in-solution protease digests.
- Reverse Phase Microbore HPLC Peptide Mapping Reverse phase HPLC separation of tryptic peptides with UV detection.
- MALDI MS Determine masses of purified peptides or proteins in solution including screening HPLC peaks. ESI of Intact Proteins High resolution, highly accurate mass determination of purified proteins that are less than 40 kDa.
- Post-translational Modification (PTM) Identifications Identification of PTMs such as phosphorylation, ubiquitination, methylation, and acetylation. Combinations of services and specialized methods are typically required.

# **BIOPROCESSING SUPPORT**

Rockland is a global leader in the development of analytical reagents for the pharmaceutical and biopharmaceutical industries, we provide you with the tools and support to better manage your process development methods and quality control testing. With Rockland you have access to our vast know-how and capabilities along with our significant experience in reagent development. Our mission is to provide high quality process specific and critical reagents to meet our clients' testing needs.

### HCP ANTIBODY GENERATION TIMELINE (MOS.)

### Setup

· Antigen Preparation

#### Immunization & Boost

Repeat Boost Period

#### Reagent Generation

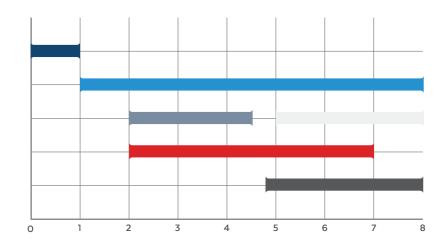
- Test Bleeds
- · Production Bleeds

#### Sampling & Analysis

- ELISA
- Western Blot

#### Reagent Qualification

· 2D Western Blots



# PRODUCTS AVAILABLE IN BULK

Rockland is a global leader in the development of analytical reagents for the pharmaceutical and biopharmaceutical industries, we provide you with the tools and support to better manage your process development methods and quality control testing. With Rockland you have access to our vast know-how and capabilities along with our significant experience in reagent development. Our mission is to provide high quality process specific and critical reagents to meet our clients' testing needs.

Product Name	Catalog Number	Applications	Size
Blocking Buffer for Fluorescent Western Blotting	MB-070	WB	500 mL
ELISA Microwell Blocking Buffer with Stabilizer	MB-064-1000	ELISA	1L
Anti-MOUSE IgG (H&L) (GOAT) Antibody Peroxidase Conjugated (Min X Human Serum Proteins)	610-1319	WB, ELISA, IHC	2 mg
Anti-RABBIT IgG (H&L) (GOAT) Antibody Peroxidase Conjugated (Min X Human Serum Proteins)	611-1322	WB, ELISA, IHC	2 mg
TMB ELISA PEROXIDASE SUBSTRATE	TMBE-1000	ELISA	1 L
Mouse TrueBlot® ULTRA: Anti-Mouse Ig HRP	18-8817-31	WB	50 μL
Rabbit TrueBlot®: Anti-Rabbit IgG HRP	18-8816-31	WB	50 μL
Anti-GFP (GOAT) Antibody	600-101-215	WB, ELISA, IHC, IF, IP	1 mg
Anti-RFP (RABBIT) Antibody Min X Hu Ms and Rt Serum Proteins	600-401-379	WB, ELISA, IHC, IF	100 µg
Anti-6X HIS EPITOPE TAG (RABBIT) Antibody	600-401-382	WB, ELISA, IHC	100 µg

# ROCKLAND IMMUNOCHEMICALS, INC.

For 55 years, Rockland has supported the research, diagnostic, and biopharma communities by providing the highest quality antibodies, assays, and research services including primary and secondary antibodies, chemiluminescent substrates, custom polyclonal and monoclonal antibody production, and assay development.

Rockland antibodies, substrates, buffers, and services adhere to QSR / cGMP with full reporting and traceability (CFR:21H part 820), as well as optional analysis options that include ELISA, WB, IF, IHC, HPLC, and SDS-PAGE (1-D, 2-D).

Protect your experiment with Rockland antibodies and services.



+1 484.791.3823 P.O. Box 5199 Limerick, PA 19468, USA sales@rockland-inc.com www.rockland.com









