Your strategic partner in diagnostics innovation

Immunoassays powered by Roche
We are CustomBiotech from Roche
In your operations, behind your decisions, powering your products

You are driving a paradigm shift. Scientific and technological advances emerging from creative companies across the globe are transforming the way we look at disease and breaking down boundaries for treatment. The untapped potential in these innovations is accompanied by many challenges. How do you secure a supply chain in a global landscape? How do you ensure compliance in a demanding regulatory environment? How do you remain competitive in a fast-paced market? Now more than ever, business success hinges on finding suppliers, collaborators, and other partners who understand your needs and allow you to focus on what matters.

What if all of those partners were one single ally — a market leader with decades of experience in biotechnology and in vitro diagnostics standing shoulder to shoulder with your team?

Welcome to Roche CustomBiotech.
**Innovation**
*Count on great ideas that work.* From research and development to manufacturing and logistics, our experts and facilities cover an unparalleled spectrum of skills and technologies to explore any idea.

**Customization**
*Invest time and resources into what you do best.* For everything else, rely on us. With customized development, manufacturing, labeling, packaging and filling of components, we streamline the path of your product to market.

**Service**
*Tackle problems with a smart ally.* From business and regulatory issues to production troubleshooting, we help safeguard your operations and market standing with fast answers to problems, anytime and anywhere.

**Security**
*Set your mind at ease.* Our global reach, stringent standards and state-of-the-art manufacturing mean a secured supply of products and services to drive your business forward, when and where needed.
Benefit from the pioneers’ expertise
Manufacturing excellence sets industry standards

For decades, Roche has been synonymous with excellent performance in the area of in vitro diagnostics. At the core of our market-leading products is an extensive portfolio of carefully designed and expertly manufactured assay components. These components—from antibodies and marker enzymes, to enzyme substrates, recombinant streptavidin, labeling reagents, and interference eliminating proteins—are available to bring your diagnostic product to market.

With longstanding expertise, a versatile product portfolio, large-scale production and customized filling, industry-leading manufacturing, and worldwide technical support, Roche CustomBiotech offers a consolidated and reliable supply of high-quality immunoassay components. We aim to be your single strategic partner to successfully develop and launch your diagnostic solutions.

Roche sets industry standards with recombinant streptavidin
Streptavidin is a core component of countless immunoassays to label or immobilize analytes. Roche CustomBiotech pioneered the development of recombinant streptavidin and is now the world’s largest manufacturer of this protein. We continue to set industry standards through meaningful product improvement. For example, Streptavidin Mutein Sepharose includes a targeted mutation that makes streptavidin-biotin binding reversible, enabling purification of biotinylated compounds with high recovery and purity.

Time-tested components that get you to market faster
Leverage over 25 years of experience researching, developing, and producing state-of-the-art components for in vitro diagnostics. Our immunoassay components are tested for optimal affinity and compatibility to deliver the high performance, such as the antibody pairings of Roche diagnostic kits. These proven components are a welcome alternative to lengthy testing of less characterized reagents, saving valuable time and resources. Furthermore, our global customer support helps to solve problems and keep your development work on track.
**Reliable and consistent products that meet stringent requirements**

Every component in a diagnostic assay must deliver consistent performance, regardless of production lot or assay user. Thus, every detail of our manufacturing process is designed to generate the best assay components in every production lot. Incorporating Roche-quality components into your diagnostic solutions simplifies your production workflow, guarantees lot-to-lot compatibility, and ensures that you meet industry requirements at every step. Plus, our reliable production and worldwide distribution secure a continuous supply of components.

**Roche manufacturing excellence for high quality**

Colloidal gold-conjugated antibodies are used for sensitive detection in diagnostic lateral flow assays. The performance of colloidal gold as a reporter molecule depends strongly on particle size, making production consistency imperative. With advanced manufacturing, Roche CustomBiotech produces gold particles that vary only minimally in size (38 – 43 nm), even in production volumes of up to 240 liters.
Maximize your assay performance

Take advantage of interference elimination solutions

Innovations that maximize the performance of your immunoassay

The complexity of biological specimens poses challenges in immunoassay development. Some issues cannot be solved with high-quality reagents and require innovative approaches. For example, >10% of patient sera contain human anti-mouse monoclonal antibodies (HAMAs), which can lead to false-negative or false-positive results. Our immunoassay portfolio includes powerful interference elimination proteins (IEPs) that can be used singly or in combination to reduce background, inaccurate signal, and HAMA interferences. Select an optimal composition of IEPs to achieve highly specific interference blockage for superior assay accuracy and reliability, or use a nonspecific IEP to streamline assay development.

Roche antibody mix enhances assay specificity

The Roche enzymatic CK-MB test provides a highly specific, quantitative measure of the catalytic activity of creatine kinase isozyme MB to aid in the diagnosis of acute myocardial infarction. The MAB<CK-MM>Mix of antibodies is a core ingredient that enhances the specificity of the test by blocking interference from creatine kinase isozyme MM with over 99% efficiency.
A harmonized component selection for optimal results

The utility of one assay component is relevant only when it works well with others. Most products of our immunoassay portfolio were designed for existing diagnostic assays. Thus, the portfolio features tested reagent configurations to meet every need and save development time. High-quality enzymes are complemented by substrates, antibodies can be coupled to a range of excellent marker enzymes, such as alkaline phosphatase, HRP, and β-galactosidase, and key components are available in different forms — native, recombinant, inactive — to meet specific assay requirements.

Contact us to discuss how you can augment the impact of your diagnostic solution with Roche-quality immunoassay components.

- Antibodies
- Interference elimination proteins
- Streptavidin/Biotin system
- Marker enzymes
- Substrates
- Direct labels and dyes

Build on success. Team up with Roche CustomBiotech.
References
1) Internal manufacturing instruction
2) Creatine Kinase-MB method sheet for c701/702 (0105168562190c701V6.0)

Regulatory disclaimer
Products are for further processing only.