

# Your strategic partner in diagnostics innovation

Immunoassays powered by Roche



# Manufacturing excellence sets industry standards

Benefit from the pioneers' expertise.



## **Roche sets industry standards with recombinant streptavidin**

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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.

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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.

## **Time-tested components that get you to market faster**

Leverage over 30 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.

# 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.

## 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  $\beta$ -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.**



### 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.<sup>1</sup>

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.<sup>1</sup>



### Roche drives cutting-edge assay technology with recombinant bovine alkaline phosphatases

Alkaline phosphatase is commonly used to produce a detectable chemiluminescent signal in immune diagnostic assays. Roche CustomBiotech carries high-quality native alkaline phosphatase, but is also the exclusive manufacturer of highly active (>3000 U/mg) recombinant bovine intestinal alkaline phosphatase (bIAP<sub>II</sub>). A single point mutation at the active site of our recombinant alkaline phosphatase generates **AP Mutein**, an inactive variant that effectively reduces alkaline phosphatase-related assay interference.

**Regulatory disclaimers, warranty limitations and legal notes**

are listed on the respective product page on [custombiotech.roche.com](https://custombiotech.roche.com)

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**References**

<sup>1</sup> Creatine Kinase-MB method sheet for c701/702  
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