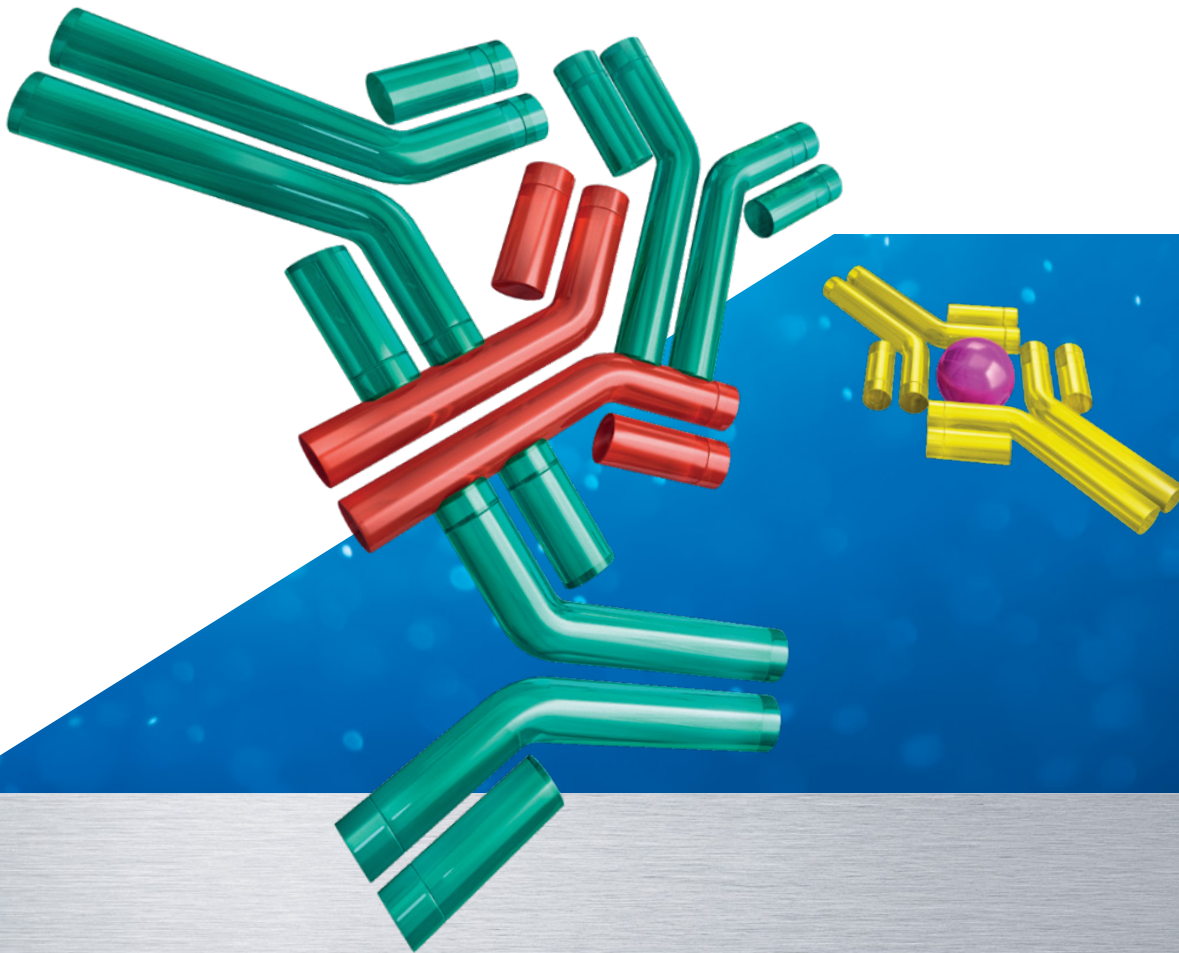


**Enhanced accuracy and quality for
successful diagnostic immunoassays**
Immunoassay Interference Blocker portfolio



Immunoassay Interference Blocker portfolio

Optimal solutions for reliable immunoassays

In diagnostic immunoassay development and kit manufacturing, ensuring consistently high performance quality is key to market success and a good reputation for the manufacturer. Immunoassay interferences pose a significant threat to assay quality, and its impact is far-reaching. **False and unreliable assay outcomes due to interferences can lead to misinterpretation of patient results and inappropriate treatment. In turn, filed complaints lead to mistrust of all products under a brand, and trigger costly and time-consuming troubleshooting and assay rework.** Optimal blocking technology can be the critical element that eliminates potential interferences and positions your product above the competition.

The Roche CustomBiotech Immunoassay Interference Blocker portfolio consists of a broad selection of powerful blockers designed to eliminate the most common types of immunoassay interferences. The Immunoassay Interference Blocker products are part of our well-established immunology portfolio, developed from over 25 years of immunology expertise in raw materials for IVD immunoassays. We understand industry needs and are committed to helping customers not only choose the right blocker, but also define optimal assay parameters (concentration ranges, specificity, etc.) that ensure accuracy, sensitivity, and precision of diagnostic immunoassays.



Enhance assay accuracy

Elevate your business with successful immunoassays

Rely on Roche CustomBiotech for an optimal interference blocking solution that is easily incorporated into your diagnostic immunoassay, and builds efficiencies into your operations. With our Immunoassay Interference Blocker portfolio, it is possible to have it all – efficient blocking performance, consistent quality, a secure supply, and competitive costs.

Proven blocking efficiency

Roche Diagnostics and over 50 other diagnostics customers worldwide already use our high-performance blockers in their diagnostics reagents. In fact, premium blocking technology is a critical element for the strong market position of Roche Diagnostics in heterogeneous immunoassays.

- No guessing – implement blocking strategies with demonstrated effectiveness
- Stay at the forefront – boost your assay with cutting-edge, premium blocking technology
- Secure customer satisfaction, market share and a reputation for quality diagnostics solutions

Cost-effective solutions

Our aim is to create and deliver high-performance assay components that are easily implemented with minimal cost and effort. Thus, our interference blockers have a long shelf life, consistent quality and high purity (e.g., our antibody blockers show >90% purity, as determined by HPLC).¹

- Consistent and large interference blocker lots translates to less frequent lot testing
- High blocking activity allows for usage of the lowest possible blocker concentration
- High purity levels ensure reliable and consistent blocking performance

Transparent formulation and customization

We offer single blockers in transparent formulation and with detailed specifications because you should know every aspect of your assay's performance. Our experts advise you in selecting the right blocker solution, including custom filling and mixing to meet your specific needs.

- Avoid complicated validation and additional costs from using obscure blocking mixes
- Use and pay for only the blocker or blocker combination needed to maximize the performance of your assay
- Create a dedicated blocking solution that is optimal for your application

Enhance assay quality

Elevate your business with successful immunoassays

Consistent quality

Our manufacturing processes ensure minimal lot to lot variation and at least three batches are used for blocker qualification. Thus, rest assured that the quality of your product will not change.

- Streamlined development and validation through reduced variability of assay parameters
- No need to continually adjust assay reagents to optimize performance
- Simplified registration due to stable product quality

Secured global supply at any scale

With global reach, flexible scale up, and extensive quality control, we ensure long-term supply of well-characterized assay components. Professional change management boosts this security, and dedicated risk plans for each product detailed steps to take in the unlikely event of a production halt.

- Source from one partner that grows with your increasing demands and delivers worldwide
- Ease production transfer and validation – use the same qualified lot over long time periods
- No surprises – count on a reliable source and proactive change communications

Find out which CustomBiotech blocker from the clusters below will aid you in preventing common immunoassay interferences:

Antibody interferences

Detection interferences

Surface interferences



Blockers designed for antibody conjugates

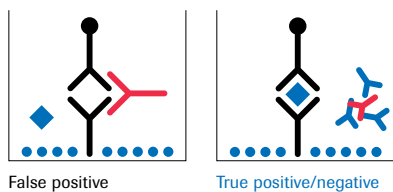
Broad portfolio to improve assay accuracy and precision

Antibody interferences

Heterophilic antibodies and rheumatic factors (RF) can cause significant interferences in any immunoassay. Such antibodies are commonly referred to Human-Anti-Animal-Antibodies (HAAAs). In a patient sample they can interact with analyte-specific antibodies from an assay system. These interactions decrease measurement accuracy and can produce false-positive or false-negative results. Most diagnostic immunoassay reagents use mouse monoclonal antibodies, so human anti-mouse antibodies (HAMA) are the most common cause of interference.²

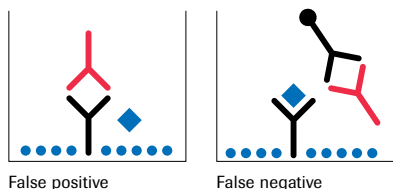
Up to 10% of test samples contain HAMA antibodies, and their characteristics vary greatly with respect to isotype, specificity, and concentration range. Our Immunoassay Interference Blocker toolbox provides effective and highly specific HAMA interference-blocking solutions that account for type of interaction and specific assay design. Plus, our HAMA-interference control sera enable evaluation of assay accuracy against heterophilic interactions during test development, as well as quality control of the final kit.

Sandwich antigen detection ELISA



False positive

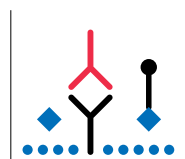
True positive/negative



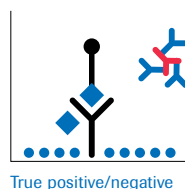
False positive

False negative

Competitive ELISA

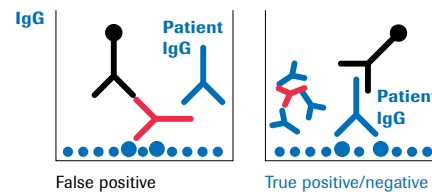


False positive



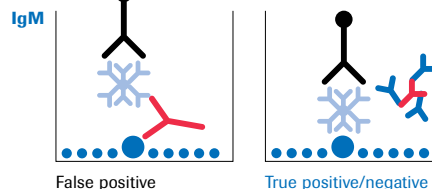
True positive/negative

Serological ELISA assays (e.g. IgG, IgM, IgA, IgE)



False positive

True positive/negative



False positive

True positive/negative

Antibody directed interaction of heterophilic antibodies

Assay conjugate species

Assay conjugate species
Mouse
▪ Human-Anti-Mouse-Antibodies (HAMA)
Human
Sheep, Rabbit
▪ Human-Anti-Animal-Antibodies (HAAA)

Product

MAB33 IgG1
Framework IgG
MAB33 IgG1/IgG1 Poly
MAB33 IgG1/Fab1 Poly
MAB IgG2b/Fab2a Poly
PAB H-IgG/Fab Poly
PAB Sheep IgG
PAB Rabbit IgG
HAMA Serum Type I, positive control
HAMA Serum Type II, positive control

Catalog number

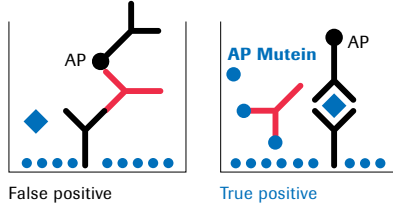
11 200 941 103
03 369 846 103
11 939 661 103
11 368 338 103
11 355 830 103
11 668 544 103
10 717 606 103
10 912 280 103
11 767 275 103
05 167 060 103

Blockers for enzyme labels and streptavidin

Powerful solutions for specific needs

Detection interferences

Label directed interaction of heterophilic antibodies

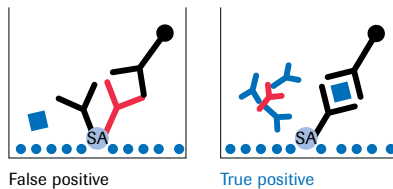


Detection interferences can arise from heterophilic antibodies in patient samples cross-reacting with assay detection components, such as streptavidin or alkaline phosphatase labels of reagents. These interactions can lead to a signal even in the absence of the analyte, producing false-positive results.

Label directed interaction of heterophilic antibodies

Label	Product	Catalog number
Enzymes (Alkaline phosphatase, β -Galactosidase, Peroxidase)	AP-Mutein rec.	04 781 007 103
Direct (e.g. Acridiniumester, Ruthenium)	β -Gal Mutein	11 184 024 103
	please ask for customized solutions	

Streptavidin directed interaction of heterophilic antibodies



Our Immunoassay Interference Blocker portfolio provides a powerful selection of blockers designed to prevent interferences with conjugated detection reagents. The best blocker for your detection system depends on the particular enzyme or conjugates in use and may include a non-active mutated enzyme (mutein) or a customized solution.

Streptavidin directed interaction of heterophilic antibodies

Label	Product	Catalog number
Streptavidin-/Biotin system (e.g. SA-enzymes)	SA rec. inactive, Poly	11 922 122 103

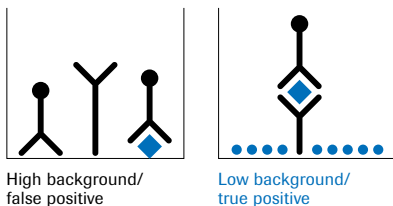
Blockers for solid-phase interactions

Efficient background reduction for improved sensitivity

Surface interferences

Surface interferences arise from nonspecific interactions between serum/plasma proteins or hydrophobic analytes in a test sample and unprotected solid-phase surface materials in the immunoassay. Such interactions increase assay background noise and can result from the use of a variety of surface types, including coated/uncoated microtiter plate wells and other disposables.

Solid-phase saturation of unoccupied binding sites



Our bovine serum albumin (BSA) blocker solutions are designed to effectively block all types of solid phases involved in immunoassays. These blockers cover a broad spectrum of interactions that might occur in the complex network between assay surfaces, assay components, and target analytes. Efficiently blocking surface interference reduces background signals, increases assay sensitivity and dynamics, and improves reagent stability.

Analyte-specific background reduction

Analyte	Product	Catalog number
Infectious diseases assays (IgM, viral antigens)	Poly BSA Type I	11 866 737 103
	Poly BSA Type II	11 816 438 103
Steroid assays, hormones	BPLA Type I	11 726 536 103
	Bovine Serum Albumin (BSA), Fraction V, fatty acid free	10 774 111 103
	Bovine Serum Albumin (BSA), reduced sodium and potassium	11 297 368 103
Protease sensitive assays (e.g. cardiac, small protein marker assays, HIV peptides)	PAB Bovine IgG	11 293 621 103
	please ask for customized solutions of protease free BPLA Type IV	
Standard sensitive assays	Bovine Serum Albumin (BSA), Fraction V	10 738 328 103
	BPLA Type IV	11 726 544 103

Be successful with more accurate assays

High-performance interference blocking boosts sensitivity and reliability of diagnostic immunoassays.

Make your diagnostic kit stand above the competition by incorporating the right constellation of interference blocker technologies from our Immunoassay Interference Blocker portfolio.

With decades of experience in immunoassays, we have unique insights into developing and manufacturing diagnostic solutions. Thus, we complement our product portfolio with expert guidance in determining the right blocker combination, concentration ranges, specificity and other assay parameters that lead to the best results.

Contact us to discuss your immunoassay, and implement an optimal interference blocking solution that ensures its accuracy and, ultimately, its success.

Stand out with innovative solutions for effective blocking in immunodiagnostics.

References

- 1) Roche Diagnostics internal document data base; please refer to product identification numbers
- 2) The Immunoassay Handbook. D. Wild, Theory and applications of ligand binding, ELISA and related techniques, 2013, Elsevier

Regulatory disclaimer

For further processing only.

Regulatory disclaimer for Poly BSA Typ I and Poly BSA Typ II

For further processing into IVD products and medical devices only.

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