

TRU Block™ ULTRA

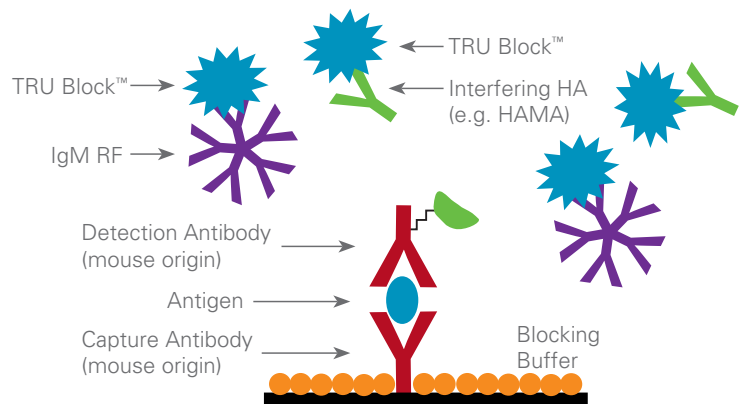
MERIDIAN'S NEW NEXT-GENERATION ACTIVE HAMA BLOCKER

A powerful immunoassay blocker capable of blocking interference created by HAMA, rheumatoid factor (RF) or heterophilic antibodies (HA) within several different assay types including ELISA and Lateral Flow.

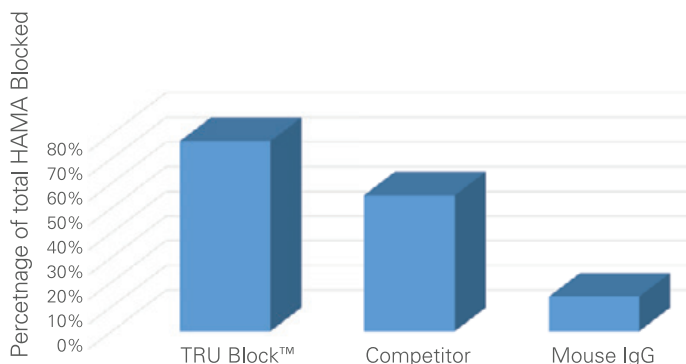


TRU Block™ ULTRA – Cat #8000

After years of R&D aimed at developing a broad-acting, powerful immunoassay interference blocker, Meridian has designed a novel blocker called TRU Block™ ULTRA (Cat# 8000). This new blocking formulation can improve an assay's accuracy by removing interference caused by human anti-mouse antibodies (HAMA), heterophilic antibodies (HA) or rheumatoid factor (RF). Its superior performance over other commercially available blockers has been proven in both ELISA and Lateral Flow assay formats. Even when used at a lower concentration than other blocking formulations, TRU Block™ ULTRA has been shown to remove more HAMA from a patient's sample.



Blocking Power of TRU Block™ ULTRA vs. Other Blockers



About Immunoassay Interference

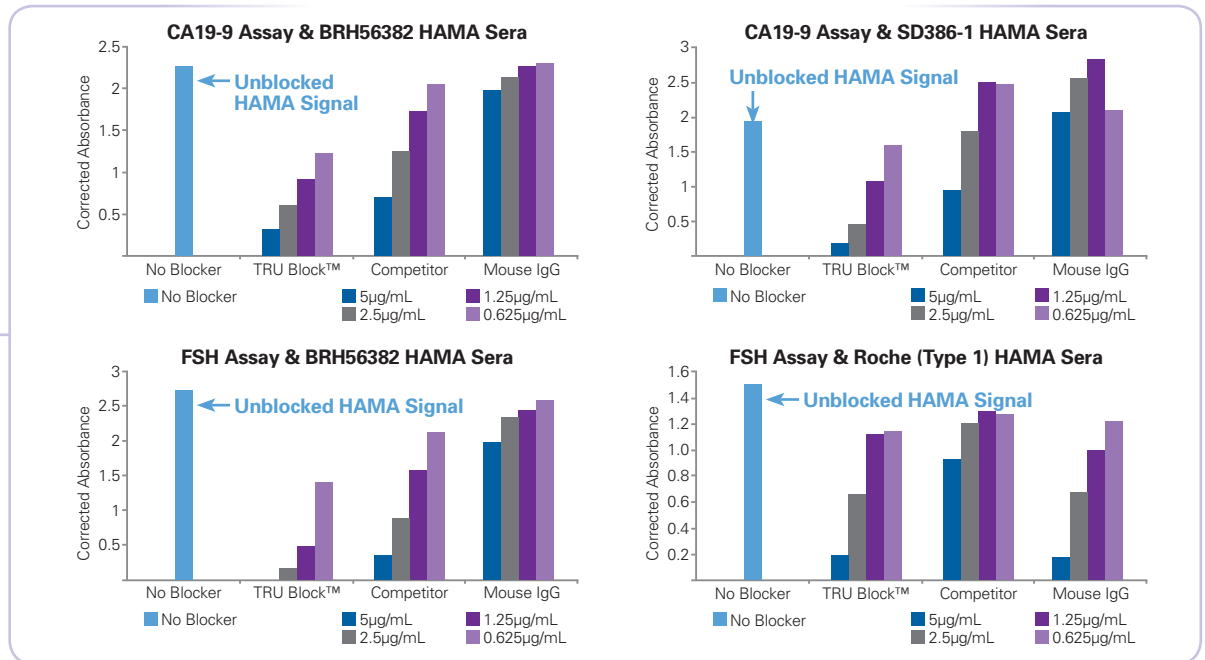
Immunoassay interference is a general term for substances that can change the outcome of an assay by causing a false positive or false negative test result. Examples of potentially interfering particles include endogenous antibodies or other binding proteins present in a patient sample, polyreactive antibodies or autoantibodies (heterophiles), and human anti-animal antibodies. Double mouse monoclonal assays and competitive assays are specifically prone to HA interference and require a specialized blocker to ensure the assay's accuracy.

A HAMA blocker such as TRU Block™ ULTRA, contains a specific binder directed against all types of heterophilic interference including HAMA and RF. Once bound to the interfering antibodies, the HAMA blocker prevents further binding of HA to other assay components through steric hindrance.

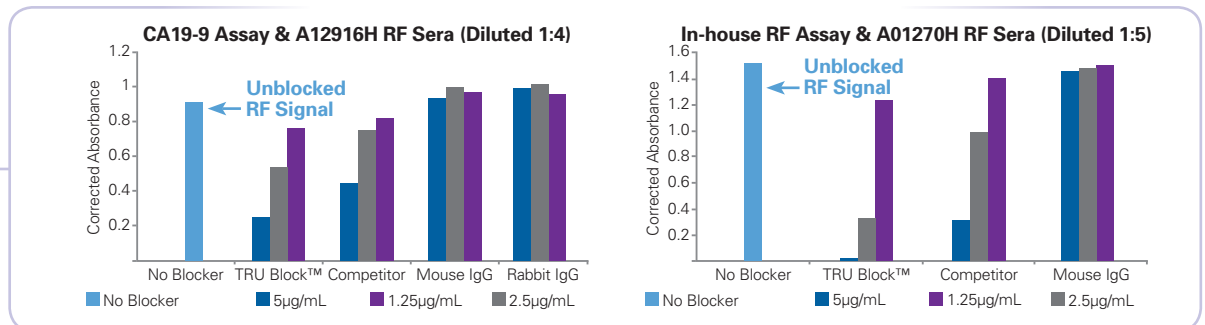
TRU Block™ ULTRA Performance

TRU Block™ ULTRA is a powerful HAMA and RF blocking buffer that can be used in double mouse monoclonal sandwich assays to reduce assay interference. Its advanced performance has been proven by customers who use this blocker in commercial ELISA and Lateral Flow assays to improve assay performance. In-house studies (*shown below*) have also demonstrated TRU Block™ ULTRA to be an effective blocker compared to Mouse IgG and a Competitor's active HAMA blocker.

HAMA Interference



RF Interference



ASSAY METHOD:

Three different double mouse monoclonal sandwich assays (a Commercial CA19-9, a commercial FSH and an in-house RF assay) were used to compare the performance of TRU Block™ ULTRA against Mouse IgG and a Competitor's active HAMA blocker. To quantify the relative amount HAMA or RF activity in each human sera sample within an assay, the assay was performed as per the manufacturer's instructions using a sample diluent buffer containing no Mouse IgG or other blocker. Blocking solutions containing either TRU Block™ ULTRA, Mouse IgG or Competitor Blocker were prepared using the same sample diluent buffer at four different concentrations (5 ml, 2.5 ml, 1.25 ml and 0.625 µg/ml).

The effectiveness of each blocker was determined by the relative suppression HAMA or RF signal (*i.e. comparing the absorbance of samples with no blocker to those with various blockers*). Native HAMA positive sera samples were obtained from Scantibodies, Inc. (SD386-1) and BioReclamation (BRH56382). Another sample was obtained from Roche (*Roche Type 1*) which contains pooled normal human serum spiked with Roche proprietary HAMA. RF sera samples (*MLS Cat No. A12916H and A01270H*) were obtained internally and are available for purchase from Meridian's product catalog (www.meridianlifescience.com).

The study results demonstrate that TRU Block™ ULTRA is equivalent to or better than a Competitor's active blocker on all HAMA and RF sera samples tested.

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