SCANTIBODIES
ASSAY DEVELOPMENT
BLOCKING KIT

(Part Number: 3KG029)

Kit to aid in the development of a blocking formulation for immunoassays.

For investigational and research use only

Store at or below -20° C

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Assay Development Blocking Kit

Scantibodies

Kit to aid in the development of a blocking formulation for immunoassays. **(Part Number: 3KG029)**

For investigational, research, and manufacturing use only. **Store at or below-20° C**

SUMMARY

This kit is provided as an aid in developing a reagent blocking formulation to eliminate false positive or negative interferences. Components that are included in this kit are useful for both active and passive blocking. The components in this kit have been selected to provide an array of options from which a selection may be made to develop a reagent blocking formulation. The target samples of heterophilic specimens are valuable to have in developing a reagent blocking formulation. These samples are typically assay dependent and are best obtained through a large sample screening using the actual assay for which the reagent blocking formulation is being developed. Scantibodies offers this custom screening program of up to 10,000 samples with a potential to make available 225 ml from each donor sample.

INTENDED USE

To provide component materials required to develop a reagent blocking formulation for immunoassays.

REAGENTS

HBR-1- Purified **3KC533**
Store at or below -20° C

This product contains specific murine immunoglobulins that block the heterophilic interaction by active binding to the heterophilic antibodies, which are capable of cross linking the capture and the detection antibodies used in the immunoassay, resulting in false positive readings. The attachment of HBR-1 to the heterophilic antibodies blocks this cross-linking, and eliminates the interference caused by the heterophilic antibodies in the humoral fluids. In addition to its active blocking, this product is also characteristic of its passive blockage of the heterophilic interaction as well. The immunoglobulins in this product are at a purity of greater than or equal to 95% as shown by SDS-PAGE. For convenience the HBR-1 is packed in individual vials each of which contains approximately 40 mg of HBR-1.

HBR-3- Purified **3KC576**
Store at or below -20° C

Each vial contains approximately 4 mg of immunoglobulins. This product represents a variation in formulation with similar essential characteristics compared to HBR-1-Purified. The special formulation is designed to enhance its blocking capability at a lower concentration of immunoglobulins.

HBR-6- Purified **3KC542**
Store at or below -20° C

Each vial of HBR-6 contains approximately 10 mg of immunoglobulins. This HBR-6 is specially formulated to enhance its heterophilic blocking ability. The immunoglobulins in this reagent are at a purity of greater than or equal to 95%, as shown by SDS-PAGE.

HBR Plus- Purified **3KC545**
Store at or below -20° C

The HBR Plus is one of our newly formulated products developed as an alternative for HBR-1. This product is compounded with immunoglobulins with different characteristics. Therefore, in addition to its active blocking characteristics, the special formulation and production procedures enhance its efficacy in its passive blocking ability as well. Each vial of this HBR Plus contains approximately 20 mg of immunoglobulins.

HBR-9- Purified **3KC564**
Store at or below -20° C

The HBR-9 is also one of our newly formulated products developed as an alternative for the HBR Plus, 3KC545. It contains immunoglobulins with different characteristics. It is specially formulated for application for immunoassays in which both the capture and detection antibodies are of murine origin. Like HBR Plus, this product is characteristic for its active as well as passive blocking efficacy. Each vial of this product contains approximately 20 mg of immunoglobulins, which are at a purity of greater than 90%, as shown by SDS-PAGE.

HBR-11- Purified **3KC565**
Store at or below -20° C

The HBR-11 is also one of our newly formulated products. This product is formulated with murine immunoglobulins. In addition to the products listed above, the HBR-11 provides our customers with more selection for heterophilic blockage. Each vial of this product contains approximately 20 mg of immunoglobulins, which are at a purity of greater than 90%, as shown by SDS-PAGE.

HBR (Heterophilic Blocking Reagent) Scantibodies

A Unique Reagent To Eliminate Heterophilic Interference

INTRODUCTION

The presence of heterophilic antibodies in human serum has been demonstrated to cause false positive interference in immunoassays. Heterophilic antibodies have also been demonstrated to cause false negative interferences. The use of HBR in the conjugate eliminates heterophilic interferences in immunoassays.

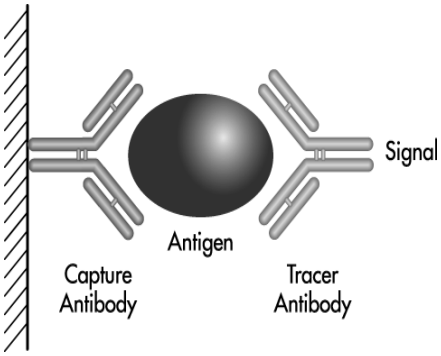
INTENDED USE

Reconstituted HBR is a liquid reagent that when added to the assay conjugate will eliminate the heterophilic interference (false positives and negatives) caused by some human source samples.

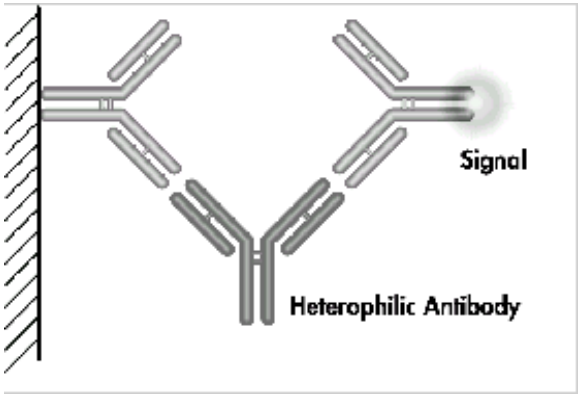
THE HETEROPHILIC INTERFERENCE PROBLEM

A heterophilic sample is a serum or plasma sample which contains antibodies which are able to bind to animal antibodies used in immunochemistry assays. The most commonly reported assay interference effect of heterophilic antibodies is a false positive assay result. False negative assay results have also been reported in the literature.

The following diagram illustrates a normal sandwich immunoassay where the concentration of the analyte is responsible for the positive assay result.



The following diagram illustrates a sandwich immunoassay where the heterophilic antibody is responsible for the false positive assay result.



It has been found that as much as 22% of certain sandwich immunoassay results are false positive results caused by heterophilic antibody interference. With such a large potential for immunoassay false positive values it is important to confirm that a positive assay value is not the result of a heterophilic interference.

HBR

HBR contains immunoglobulins of murine origin with specific binders that neutralize by active attachment to the heterophilic antibodies. The attachment of HBR to the heterophilic antibodies renders the heterophilic antibodies incapable of cross linking the capture and the label antibodies in the immunoassay.

PRECAUTIONS FOR USERS

1. For investigational, research, and manufacturing use only.
2. Store HBR at or below -20° C.
3. Repeated freeze thaw may result in turbidity that doesn't affect functionality.
4. Each application of HBR must be made with an appropriate selection of HBR type, optimization of concentration as part of a blocking cocktail, and validation that assay performance meets claims.

STORAGE CONDITIONS

Upon receipt, store at or below -20° C.

PROCEDURE FOR THE USE OF HBR

1. Add HBR directly to the assay conjugate at a concentration so that for each assay tube the HBR will be used typically at a quantity of 40 micrograms (20 microliters) of HBR per sample.

   Example:

   a. Add the HBR to the conjugate concentrate. Dilute accordingly the HBR-conjugate concentrates with the normal conjugate diluting buffer up to the working volume.

   b. Add 100 μL of the diluted HBR-conjugated solution to each well on the microtiter plates used in the ELISA assay.

   c. Proceed with the assay as described in the assay protocol.

However, for each of the specific assays the HBR concentration used should be optimized, depending on the volume of the serum sample and the assay format.

LIMITATIONS

1. For investigational, research, and manufacturing purposes, the results obtained with HBR should be used as an adjunct to other data (e.g., symptoms, results of other tests, clinical impression, etc.) available to the physician.

2. There may be some samples with extremely strong heterophilic interference in which the HBR may not be able to block all of the interference.

PERFORMANCE CHARACTERISTICS

1. Heterophilic Interference with the CA 125 assay

   The Production Run: CA 125 completed on day 1

   Repeats done side by side with CA 125 and HBR treated CA 125

   TOTAL NUMBER OF SAMPLES = 585 (represents a day's run)

   Of the positives detected:

   54 samples confirmed as false positive results (by linear dilution test)

   46 samples available for HBR treatment and linear dilution test

   9 samples remained unacceptable after HBR treatment by linear dilution

   Therefore [(9/46 x 54) ÷ 585] x 100% = 1.8% of samples unaffected by HBR.

2. Heterophilic Interference with a major manufacturer's CEA assay.

   The Production Run: CEA assay completed on day 1

   Repeats done side by side with the CEA and HBR treated CEA assay

   TOTAL NUMBER OF SAMPLES = 396 (represents a day's run)

   Of the positives detected:

   89 samples confirmed as false positive results (by linear dilution test)

   74 samples available for HBR treatment and linear dilution test

   5 samples remained unacceptable after HBR treatment by linear dilution

   Therefore [(5/74 x 89) ÷ 396] x 100% = 1.5% of samples unaffected by HBR.

	FINDINGS VS CLAIMS	ACCURACY IMPROVEMENT - HBR
-CA 125	- 10% vs 1%-2%	90% $\rightarrow$ 98.2%
-CEA	- 22% vs 1%-2%	78% $\rightarrow$ 98.5%