HBR 1, Purified (Heterophilic Blocking Reagent 1)

Scantibodies

A Unique Reagent To Eliminate Heterophilic Interference

(Part Number: 3KC534-075)

For Research or Further Manufacturing Use Only

Store at or below -20° C

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 is designed to eliminate heterophilic interferences in immunoassays.

INTENDED USE

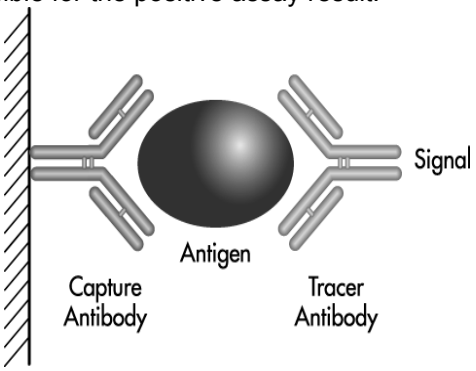
HBR is a liquid reagent that when added to the assay conjugate acts to eliminate the heterophilic interference (false positives and negatives) caused by some human source samples.

SUMMARY AND PRINCIPLE OF THE TEST

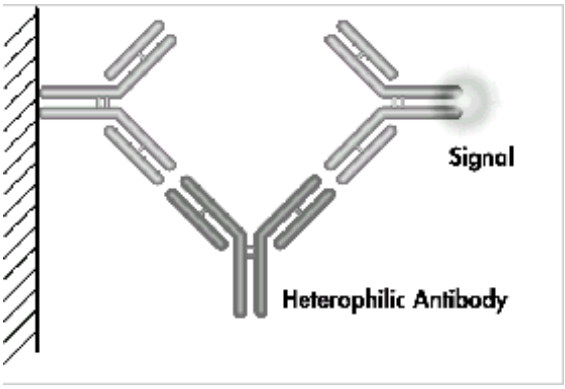
THE HETEROPHILIC INTERFERENCE PROBLEM

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 heterophilic interference.

THE HBR

The HBR contains immunoglobulins of murine origin with specific binders that neutralize by active attachment to the heterophilic antibody. 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. The HBR is a liquid reagent with a protein concentration of 2 ± 0.1 mg/ml. The immunoglobulins are dissolved in a 0.075 M phosphate buffer, pH of 7.3 - 7.5. The immunoglobulins in the HBR are at a purity of greater than or equal to 95%.

PRECAUTIONS FOR USERS

1. For research or further manufacturing use only.
2. Store HBR at or below -20° C. Once the HBR is thawed the reagent should be aliquoted and refrozen. The reagent should not be subjected to multiple freeze/thaws.
3. The HBR concentration used to make the blocking cocktail must be optimized and validated in order to obtain the best assay performance.

STORAGE CONDITIONS

Upon receipt, store the HBR at or below -20° Celsius.

PROCEDURE FOR THE USE OF HBR

1. Thaw the HBR and mix the reagent well by gentle inversion (do not foam the reagent). Add HBR directly to the assay conjugate concentrate at a concentration so that for each assay tube/well the HBR will be used at a rate of 40 µg of HBR per sample.

   For example:

   a. Thaw the HBR and add 20 mL (equal to 40 mg at 2 mg/mL HBR concentration) into 25 mL of conjugate concentrate.

   b. Bring the volume of the conjugate-HBR preparation to 100 mL by adding normal conjugate diluting buffer.

   c. Mix the preparation well. This preparation will now contain 40 µg of HBR per 100 µL of diluted conjugate-HBR. Dispense 100 µg to each tube/well.

   d. Proceed with the assay. This recommended starting HBR concentration may need to be further optimized based on the type of assays and the interference of the Heterophile in the specimens.

LIMITATIONS

1. The results obtained with HBR use should considered 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 a representative 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% - 98.2%
-CEA	- 22% vs 1%-2%	78% - 98.5%

SCANTIBODIES LABORATORY, INC.
9336 Abraham Way, Santee, CA 92071
Phone 1-619-258-9300, Fax 1-619-258-9366