

# HBR 1, Purified (Heterophilic Blocking Reagent 1)

A Unique Reagent To Eliminate Heterophilic Interference

For Research or Further Manufacturing Use Only

# Scantibodies

(Part Number: 3KC534)

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

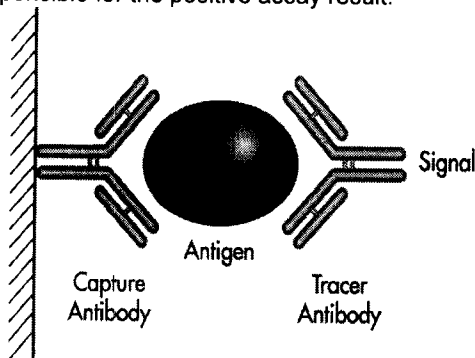
HBR is a liquid reagent that when added to the assay conjugate acts to eliminate the heterophilic interference (false positives and negatives) caused by some human source samples.

## SUMMARY AND PRINCIPLE OF THE TEST

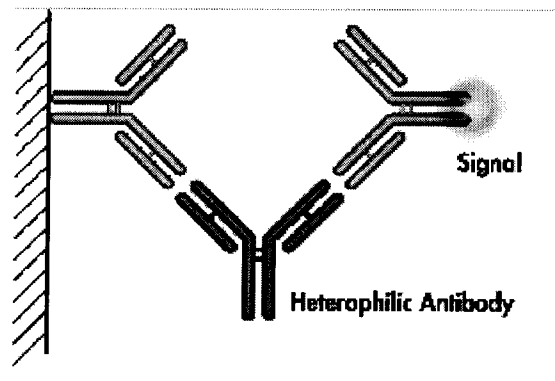
### THE HETEROPHILIC INTERFERENCE PROBLEM

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  $2 \pm 0.1$  mg/ml. The immunoglobulins are dissolved in a phosphate buffer with a pH of 7.0 - 7.4. 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. Repeated freeze thaw may result in minor turbidity development that does not affect its functionality.
3. 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 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 10 times (do not foam the reagent).
2. Add HBR directly to the assay conjugate at a concentration so that for each assay tube the HBR will be used at a rate of 40 micrograms (20 microliters) of HBR per sample.

Example:

1. 100 microliters of conjugate added per sample.
2. Total volume of conjugate concentrate is 25 ml, and the final volume of the conjugate when diluted to the working solution will be 100 ml.
3. The concentration of the HBR is 2 mg/ml.
4. Add 40 mg of HBR which is 20 ml of 2 mg/ml:  
  
(40 micrograms/sample x 100 ml + 100 microliters/sample) to the 25 ml of conjugate concentrate.
5. Dilute the conjugate concentrate with the normal conjugate diluting buffer up to the working volume of 100 ml.
6. The working conjugate is now ready for use and the presence of the HBR will block the interference of heterophilic antibodies.

## LIMITATIONS

1. The results obtained with HBR use should be 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  $[(9/46 \times 54) + 585] \times 100\% = 1.8\%$  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  $[(5/74 \times 89) + 396] \times 100\% = 1.5\%$  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%

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