ASSAY DEVELOPMENT BLOCKING KIT

(Part Number: 3KG775)

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

For research use only

Store at or below -20° C

SCANTIBODIES LABORATORY, INC.

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Assay Development Blocking Kit

Scantibodies

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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 murine 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 murine 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 **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 murine 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-21 **3KC002**
Store at or below -20° C

The HBR-21 is also one of our newly formulated products. In addition to the products listed above, the HBR-21 provides our customers with more selection for heterophilic blockage. Each vial of this product contains approximately 10 mg of

immunoglobulins

HBR-22 **3KC003**
Store at or below -20° C

The HBR-22 is also one of our newly formulated products. In addition to the products listed above, the HBR-22 provides our customers with more selection for heterophilic blockage. Each vial of this product contains approximately 10 mg of immunoglobulins

HBR-23 **3KC006**
Store at or below -20° C

The HBR-23 is also one of our newly formulated products. This product is formulated with murine immunoglobulins. In addition to the products listed above, the HBR-23 provides our customers with more selection for heterophilic blockage. Each vial of this product contains approximately 10 mg of immunoglobulins

HBR-24 **3KC007**
Store at or below -20° C

The HBR-24 is also one of our newly formulated products. This product is formulated with murine immunoglobulins. In addition to the products listed above, the HBR-24 provides our customers with more selection for heterophilic blockage. Each vial of this product contains approximately 10 mg of immunoglobulins

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.

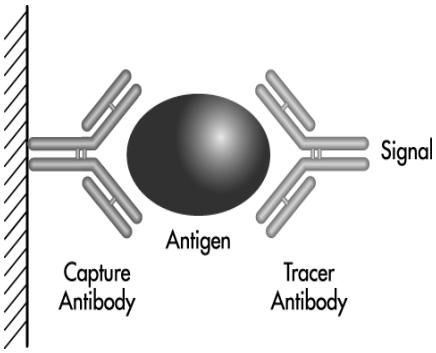
INTENDED USE

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.

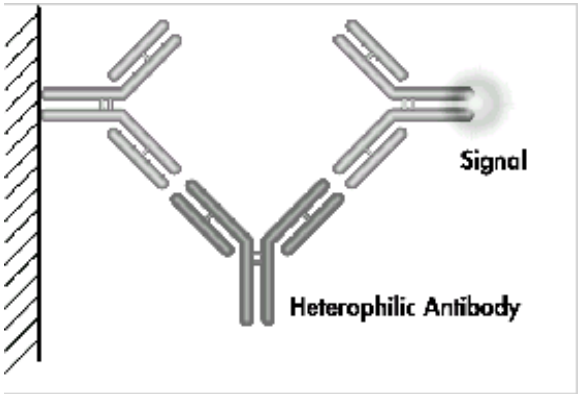
THE HETEROPHILIC INTERFERENCE PROBLEM

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 research 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

assay.

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 research 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

   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%

试剂盒研发阻断剂套件

(产品编号: 3KG775)

试剂盒用于开发免疫测定的阻断制剂。

仅供研究使用

储存于-20°C 或以下

SCANTIBODIES LABORATORY, INC.
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Assay Development Blocking Kit

Scantibodies

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

For research use only.

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概要

该试剂盒作为辅助剂,用于开发试剂阻断剂配方,以消除假阳性或阴性干扰。组件中包含的组件对于主动和被动阻断都是有用的。在这个工具包中的组件已被选择，以提供一个数组的选项，其中可以选择开发试剂阻断制剂.

这些样品通常是测定依赖性的，并且通过使用试剂阻断制剂正在开发的实际测定法通过大量样品筛选获得最佳。 Scantibodies 可提供多达 10,000 个样品的定制筛选程序，有可能从每个供体样品中提供 225 毫升。

有可能的使用

提供开发用于免疫测定的试剂阻断制剂所需的组分材料。

试剂

HBR-1- Purified **3KC533**

储存于-20°C或以下

它包含特定的小鼠免疫球蛋白阻断嗜性相互作用的活性结合的异嗜性抗体，可交联用于免疫检测中的捕获和检测抗体，造成假阳性读数。对HBR-1的异嗜性抗体阻断这种交联附件,并消除在体液的异嗜性抗体的干扰。除了其活性阻断，此产品也是其异嗜性相互作用的特点以及被动阻断。如 SDS-PAGE 所示，该产品中的免疫球蛋白纯度大于或等于 95%。为方便起见，将 HBR-1 包装在各自含有约 40mg HBR-1 的小瓶中。

HBR-3- Purified **3KC576**

储存于-20°C或以下

每个小瓶含有约 4mg 的鼠免疫球蛋白。与 HBR-1 纯化相比，该产品代表具有相似基本特征的制剂变化。特殊配方旨在提高其在较低浓度免疫球蛋白下的阻断能力。

HBR-6- Purified **3KC542**

储存于-20°C或以下

每个小瓶的 HBR-6 含有约 10mg 的鼠免疫球蛋白。该 HBR-6 专门 用于增强其异极性阻断 能力。 该试剂中的免疫球蛋白纯度大于或等于 95%， 如 SDS-PAGE 所示。

HBR Plus **3KC545**

储存于-20°C或以下

HBR Plus 是我们作为 HBR-1 替代品开发的新配方产品之一。。因此，除了其主动阻塞特性之外，特殊配方和生产程序也提高其被动阻塞能力的功效。每个 HB R Plus 小瓶含有大约 20 毫克的免疫球蛋白。

HBR-9- Purified **3KC564**

储存于-20°C或以下

HBR-9 也是我们作为 HBR Plus 3KC545 替代品的新配方产品之一。它特别配制用于免疫测定，其中捕获和检测抗体都是鼠源。像 HBR Plus 一样，该产品具有活性和被动阻断功效的特点。该产品的每个小瓶含有约 20mg 的纯度大于 90%的免疫球蛋白，如 SDS-PAGE 所示.

HBR-11- Purified **3KC565**

储存于-20°C或以下

HBR-11 也是我们新配制的产品之一。除上述产品外，HBR-11 还为客户提供了更多的异嗜性阻塞选择。该产品的每个小瓶含有约 20mg 的纯度大于 90％的免疫球蛋白，如 SDS-PAGE 所示。

HBR-21 **3KC002**

储存于-20°C或以下

HBR-21 也是我们新配制的产品之一。除了上述产品之外，HBR-21 还为客户提供了更多的异嗜性阻塞选择。该产品的每个小瓶含有大约 10mg 的免疫球蛋白。

HBR-22 **3KC003**

储存于-20°C或以下

HBR-22 也是我们新配制的产品之一。除上述产品外，HBR-22 还为客户提供更多的异嗜性阻塞选择。该产品的每个小瓶含有大约 10mg 的免疫球蛋白。

HBR-23 **3KC006**

储存于-20°C或以下

HBR-23 也是我们新配制的产品之一。该产品与鼠免疫球蛋白配制。除上述产品外，HBR-23 还为客户提供了更多的异嗜性阻塞选择。该产品的每个小瓶含有大约 10mg 的免疫球蛋白。

HBR-24 **3KC007**

储存于-20°C或以下

HBR-24 也是我们新配制的产品之一。该产品与鼠免疫球蛋白配制。除了上述产品之外，HBR-24 还为客户提供了更多的异嗜性阻塞选择。该产品的每个小瓶含有大约 10mg 的免疫球蛋白。

HBR (Heterophilic Blocking Reagent)

Scantibodies

A Unique Reagent To Eliminate Heterophilic Interference

一种独特的试剂消除亲和干扰

介绍

血清中异源抗体的存在已被证明在免疫测定中引起假阳性干扰。异嗜性抗体也被证明会导致假阴性干扰。在共轭物中使用 HBR 可消除免疫测定中的异嗜性干扰。

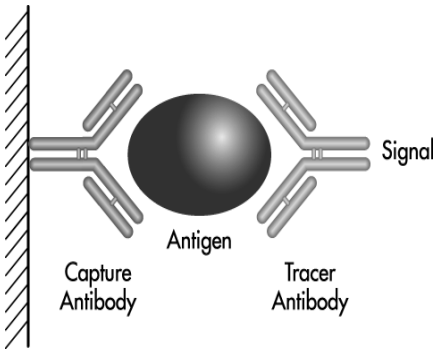
预期用途

重组的 HBR 是一种液体试剂，当添加到测定缀合物时，将消除由一些人源样品引起的异嗜性干扰（假阳性和阴性）。

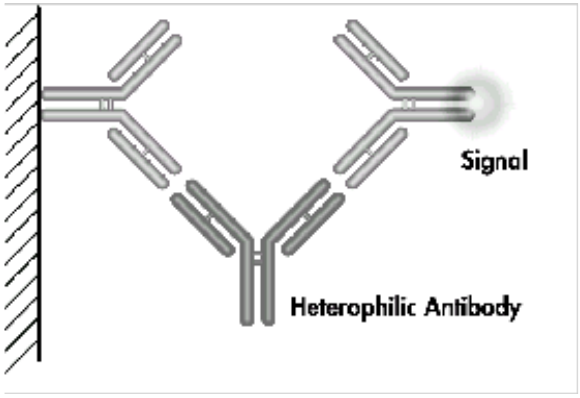
异常干扰问题

异嗜性样品是血清或血浆样品，其含有能够结合免疫化学测定中使用的动物抗体的抗体。最常报告的异源抗体的测定干扰效应是假阳性测定结果。文献中也报告了假阴性检测结果。

下图说明了正常的夹心免疫测定法，其中分析物的浓度负责阳性测定结果。



下图说明了夹心免疫测定，其中异嗜性抗体负责假阳性测定结果。



已经发现，多达 22％的某些夹心免疫测定结果是由异嗜性抗体干扰引起的假阳性结果。具有免疫测定假阳性值的巨大潜力，重要的是确认阳性测定值不是异嗜性干扰的结果。

HBR

HBR 含有具有特异性结合物的鼠来源的免疫球蛋白，通过与异嗜性抗体的活性连接中和。将 HBR 连接到异嗜性抗体使得异嗜性抗体不能在免疫测定中交联捕获物和标记抗体。

用户注意事项

1. 仅供研究使用

2. 将HBR储存在-20°C或以下

3. 重复冻融会导致不影响功能的浊度。

4. HBR 的每种应用必须采用适当的HBR 型选择，浓缩优　化作为阻断混合物的一部分，并且验证测定性能符合 要求。

储存条件

收到后，储存在-20°C 或以下。

使用 HBR 的程序

1. 以浓度将HBR直接加入到测定缀合物中，使得对于每个测定管，每个样品的HBR通常以40微克（20微升）的量使用。

   例：

   a. 将HBR加入到缀合浓缩物中。相应地将HBR-缀合物浓缩物与正常的缀合物稀释缓冲液浓缩至达到工作体积。

   b. 湾在ELISA测定中使用的微量滴定板上，向每个孔中加入100µL稀释的HBR-缀合的溶液。

   c. 按照测定方案中所述进行测定。

   然而，对于每个具体测定，所使用的HBR浓度应根据血清样品的体积和测定形式进行优化。

限制

1. 为了研究目的，用HBR获得的结果应该用作医生可用的其他数据（例如，其他检查的结果，其他检查结果，临床印象等）的辅助。
2. 可能有一些具有非常强的异质干扰的样品，其中HBR可能不能阻挡所有的干扰。

性能特点

1. 与CA125测定的亲和干扰

生产运行：CA 125在第1天完成

与CA 125和HBR治疗CA 125并列完成重复

总数= 585（代表一天的运行）

检测到的阳性：

54个样品证实为假阳性结果（通过线性稀释试验）

46个样品可用于HBR处理和线性稀释测试

通过线性稀释法，HBR处理后9个样品仍然不可接受

因此[（9/46 x 54）÷585]×100％=不受HBR影响的样品的1.8％。

2. 与主要制造商的CEA测定的亲和干扰。

生产运行：CEA测定在第1天完成

重复与CEA和HBR治疗的CEA测定并排完成

总数= 396（代表一天的运行）

检测到的阳性：

89个样品证实为假阳性结果（通过线性稀释试验）

74个样品可用于HBR处理和线性稀释测试

通过线性稀释处理HBR后5个样品仍然不可接受

因此[（5/74 x 89）÷396] x 100％=不受HBR影响的样品的1.5％。

	发现与索赔	**准确性改进 - HBR**
-CA 125	- 10% vs 1%-2%	90% → 98.2%
-CEA	- 22% vs 1%-2%	78% → 98.5%