HBT (Heterophilic Blocking Tube)

Scantibodies

Elimination of Heterophilic Interference for Immunochemistry Assays

(Part Number: 3IX762)

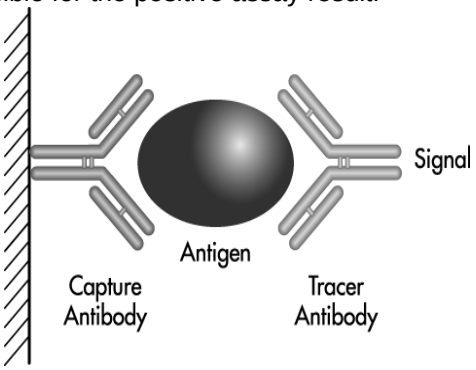
For Investigational Use Only

Store at 2º - 8º C

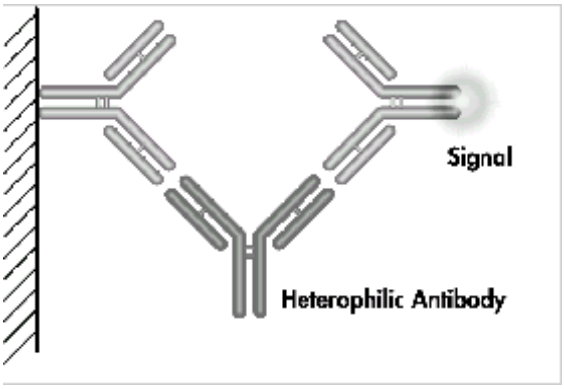
THE HETEROPHILIC INTERFERENCE PROBLEM

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 assay 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 block heterophilic interference.

INTENDED USE

The HBT allows for the rapid and simple elimination of false positive heterophilic interference in plasma or serum for immunoassays (i.e., FSH, LH, Prolactin, TSH, Ferritin, CEA, AFP, hCG, HBsAg, CK-MB, CA 125[1], CA 19-9[1], NSE, etc.). HBT represents a sample pretreatment/second assay intended to confirm or disqualify the original FDA licensed non pretreatment assay result. The assay result from the pretreatment is NEVER TO BE USED AS A REPORTABLE RESULT. The pretreatment is only a confirmation aid designed to assist the lab to know whether to report the original non pretreatment assay result. In other words, if the pretreatment assay result is the same as the original assay result the original result is reported. However, if the pretreatment sample assay result is lower than the original result, the original result is not reported and the sample is submitted for further study for potential false positive assay interference.

REAGENT

The HBT contains a unique blocking reagent composed of specific binders which inactivate heterophilic antibodies. Once the specific binders have bound to the heterophilic antibodies, the antibodies are no longer able to cause immunoassay interference. Each tube contains enough reagent to inactivate the heterophilic antibodies in 500 µL of sample. The reagent is in the form of a lyophilized pellet at the bottom of the tube.

STORAGE AND STABILITY

Upon receipt, store the tubes at 2º - 8º Celsius.

NOTE: Studies have shown that there is no significant impact on HBT performance when temporarily storing the tubes for up to 6 weeks at room temperature or below - 20° C.

MATERIALS REQUIRED BUT NOT PROVIDED

Pipetting device with tips for 500 µL

[1] CA 19-9 and CA 125 are trademarks of Centocor, Inc.

PROCEDURE

1. Use one tube for each sample.
2. Holding the HBT upright, gently tap the bottom of the tube on a hard surface. This action brings all of the reagent to the bottom of the tube.
3. Remove the cap from the tube.
4. Pipette 500 µL of the patient sample into the bottom of the tube.
5. Avoid sample carryover contamination by using a new pipette tip for each sample.
6. Cap the tube and invert 5 times to mix the sample with the reagent.
7. Incubate for 1 hour at room temperature (18º - 28º C).
8. Assay the now treated sample to obtain a result that is free from heterophilic antibody interference.

PRECAUTIONS

1. For investigational use only.
2. Once a patient sample has been added to the HBT, do not interchange caps among different tubes.
3. A new dispensing tube or pipette tip should be used for each patient sample.

INTERPRETATION OF RESULTS

If the HBT is used for the initial assay, consider the immunochemistry result to be unaffected by heterophilic antibody interference.

If the HBT is used for a secondary confirmation assay, compare the results from the first assay (initial sample not treated with HBT) and the confirmation assay (second sample treated with HBT). If the assay result from the HBT treated sample is different from the assay result from the untreated sample, the difference is due to heterophilic interference.

LIMITATIONS OF PROCEDURE

1. For diagnostic purposes, the results obtained by this sample treatment should be used as an adjunct to other data (e.g., symptoms, results of other testing, clinical impression, etc.) available to the physician.
2. There may be some samples with extremely strong heterophilic interference. In such cases the HBT may not be able to block all of the assay interference.
3. The HBT is designed for application in analyte determinations.

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