Beaumont Laboratory
Royal Oak

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Supersedes:

Scantibodies- HBT (Heterophilic Blocking Tube)

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I. Purpose & Principle

A. The HBT (Heterophilic Blocking Tube) allows for the rapid and simple elimination of false positive heterophilic interference in plasma or serum for sandwich immunoassays (i.e. FSH, LH Prolactin, TSH, Ferritin, CEA, AFP, HCG, HBsAg, CK-MB, CA19-9, etc.). HBT represents a sample pretreatment/second assay intended to confirm or disqualify the original FDA licensed non-pretreatment assay result.

B. 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.

C. 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.

II. Precautions

A. The HBT is for investigational use only.

B. Once a patient sample has been added to the HBT, do not interchange caps among different tubes.

C. A new dispensing tube or pipette tip should be used for each new patient sample.

D. Do not use the HBT for urine samples to be assayed in antibody determination assays.

E. 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.

III. Reagent

HBT tube containing a lyophilized pellet reagent able to inactivate heterophilic antibodies in 500 µL of sample.

IV. Storage and Stability

Store HBT tubes at 2º-8º C

V. Procedure

This procedure should only be used when you are directed to do so by a Technical Director or Pathologist to aid in determining if a heterophile antibody is present.

A. Use one (HBT) tube for each sample and QC.

B. Holding the HBT upright, gently tap the bottom of the tube on a hard surface. This action brings the entire reagent to the bottom of the tube.
C. Remove cap from the tube.
D. Pipette 500 µL of the patient sample into the bottom of the tube.
E. Avoid sample carryover by using a new pipette tip for each sample.
F. Cap the tube and invert 5 times to mix the sample with the reagent.
G. Incubate for 1 hour at room temperature (18^o- 28^o C).
H. Assay the now treated sample to obtain a result that is free from heterophilic antibody interference.

NOTE: The assay result from the pretreatment is NEVER TO BE USED AS A REPORTABLE RESULT. Notify requesting Technical Director or Pathologist with results.

VI. Interpretation of Results

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, as determined by the section technical or medical director, the difference is due to heterophilic interference. This method is used for investigational use only.

VII. Limitations of Procedure

A. 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.
B. 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.
C. The HBT is for antigen assays only.

VIII. References

Scantibodies Laboratory, Inc. HBT (Heterophilic Blocking Tube) package insert, May 31 2006

IX. Authorized Reviewers

Section Medical or Technical Director

Scantibodies- HBT (Heterophilic Blocking Tube)

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Document History

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