THE NON-SPECIFIC ANTIBODY INTERFERENCE PROBLEM

A Non-Specific Antibody sample is a serum or plasma sample which contains antibodies which are able to bind non-specifically in an immunoassay. These antibodies cause false positive assay results.

The following diagram illustrates a normal antibody detection immunoassay where the concentration of the specific antibody is responsible for the positive assay result.

The following diagram illustrates an antibody detection immunoassay where the non-specific antibody is responsible for the false positive assay result.

INTENDED USE

The NABT allows for the rapid and simple elimination of false positive non-specific antibody interference in plasma or serum for antibody detection assays (i.e., anti-HCV, HIV, Toxoplasmosis, Rubella, CMV, Herpes, Tg, TPO, etc.). The NABT is used as a sample treatment in preparation for testing. It can either be used in conjunction with the initial assay or in a secondary confirmation assay.

REAGENT

The NABT contains immunoglobulins. The non-specific antibodies in the serum or plasma samples bind to these immunoglobulins and are blocked from interfering in antibody detection immunoassays. Each tube contains enough reagent to inactivate the non-specific 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 2° - 8° Celsius.

MATERIALS REQUIRED BUT NOT PROVIDED

Pipetting device with tips for 500 µL
PROCEDURE

1. Use one tube for each sample.
2. Holding the NABT 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 (18° - 28° C).
8. Assay the now treated sample to obtain a result that is free from non-specific antibody interference.

PRECAUTIONS

1. For investigational use only.
2. Once a patient sample has been added to the NABT, 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 NABT is used for the initial assay, consider the Immunochemistry result to be unaffected by non-specific antibody interference.

If the NABT is used for a secondary confirmation assay, compare the results from the first assay (initial sample not treated with NABT) and the confirmation assay (second sample treated with NABT). If the assay result from the NABT treated sample is different from the assay result from the untreated sample, the difference is due to non-specific antibody 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 non-specific antibody interference. In such cases, the NABT may not be able to block all of the assay interference.
3. The NABT is designed for application in analyte determinations.

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