

# Performance Comparison between Bead Array and ELISA Assays for TRALI Risk Reduction in Blood Donors

## Background

Transfusion Related Acute Lung Injury (TRALI) is the third leading cause of transfusion related death in the United States. TRALI can occur in recipients with Human Leukocytes (HLA) antigens or antibodies, when the donor possesses the corresponding antibody or antigen. In 89% of reported TRALI cases, multiparous females with HLA antibodies were implicated. Likewise, components from at-risk donors with large volumes of plasma are most likely to cause TRALI.

The American Association of Blood Banks (AABB) has recommended that blood establishments develop strategies to reduce the incidence of TRALI. Screening blood donors who may be at risk for causing TRALI can employ a test for HLA antibodies to identify and prevent these donors from providing high volume plasma products. A correlation study was conducted on two screening assays for HLA Class I and Class II antibodies, bead array and Enzyme Linked Immunosorbent Assay (ELISA).

## Methods

Using unlinked, serum samples from self reported non-parous and non-transfused blood donors, correlation between the two assays was established. Both bead array and ELISA assays included HLA Class I, Class II antibodies and defined positive and negative sample data based on cutoff values.

Samples < cut-off were considered negative and samples  $\geq$  the cut-off were considered positive. Multiple Normalized Background ratios (NBG) were used in the bead array test during correlation calculation. The purpose of this study was to determine the level of agreement between the two screening assays on a presumed negative donor population for HLA antibodies.

## Results

A total of 105 samples were tested by bead array and ELISA methods. The data show overall higher NBG cut-offs in the bead array test, both Class I and Class II provided increasingly higher correlation between the two assays.

## Bead Array / ELISA Correlation Results

HLA Antibody	NBG $\geq$ 1.5	NBG $\geq$ 2.2	NBG $\geq$ 10
Class I	72%	77%	93%
Class II	86%	90%	93%

## Conclusion

Increasing the NBG ratio in the bead array test did improve agreement to the ELISA assay. However, further studies are needed to determine if the enhanced correlation was due to improved specificity at higher NBG ratios and if specificity was improved at the loss of sensitivity.

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