

July 3, 2008

Mike Cecka, PhD
Chair, OPTN/UNOS Histocompatibility Committee
P.O. Box 2484
Richmond, VA 23218

Dear Dr. Cecka,

The ASTS is concerned about the planned implementation of calculated PRA based on antibody determination by single-antigen beads.

Our first concern is based on the following observations as noted at the recent Histocompatibility Committee meeting in Chicago:

- 1) Antigen density on the beads varies by antigen, so the same antibody level to two different antigens can be reported as two different levels
- 2) Antigen density on the beads varies by vendor
- 3) Antigen density on the beads varies by lot from the same vendor

Because of lack of standardization, the same sample could give different readings if different beads (from the same vendor) or if different vendors are used. In addition, it has not yet been determined what level of MFI should be considered positive. Until there is standardization, we believe this test should not become part of a national allocation system.

- 4) In addition, there is debate in the literature if maximum MFI to a single bead is the most relevant to outcome or whether the sum of all MFIs is more relevant.

The second, and related concern, is that if there is no standardization there may be variation in the number of patients who have a PRA of over 80% and therefore eligible for extra points. The system will be open to gaming: without any standardization of what is considered positive (level of the MFI), the centers can call very weak MFIs positive in order to get a low sensitized patient to above 80% (and therefore get 4 extra points).

At the same time, those with PRA >80% based on antiglobulin testing can list a limited number of unacceptable antigens and therefore be crossmatched against more kidneys.

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In addition, because, there is no standardization, a multi-listed patient could have different PRAs depending on the center and the center's laboratory.

Sincerely,

A handwritten signature in black ink, appearing to read 'JPR', with a stylized flourish at the end.

John P. Roberts, MD
President

Cc: Robert S. Higgins, OPTN/UNOS President
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