16th International Histocompatibility Workshop

Working Title:

Towards Standardization of Microparticle-Based, Solid Phase, HLA Antibody Identification Assays.

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• **Rationale:**

Solid phase antibody detection assays have become a “standard” in many, if not most, clinical histocompatibility laboratories. Although very sensitive, recent studies have shown that not all donor-specific HLA antibodies (DSA) identified by the new technologies are predictive of a positive crossmatch or correlate with a poor clinical outcome. While there are many reasons to explain this lack of direct correlation, lack of standardization for such assays may be a significant contributor. Recent findings from a pilot proficiency testing survey, organized by our laboratory, involving laboratories in Canada and Australia, results demonstrated that a lack of standardization was a major factor contributing to discordant results between laboratories. In addition, inconsistencies between manufactures and between differing product lots from the same manufacture further compound the problem. Finally, calculation and interpretation of the data vary significantly between laboratories. Together, these variables result in data that are not comparable across laboratories. Hence, if we are to have some agreement as to the clinical relevance of antibodies detected by solid-phase methods, strategies are needed to standardize these assays.
• **Proposal**

  1) Send well characterized sera to participant laboratories.
  2) Each lab will perform testing using “in house” protocol as well as a standardized protocol with common reagents.
  3) Results will be analyzed.
  4) Best practice protocol will be developed.
  5) New sera will be sent out to test the robustness of the standardized protocol.
  6) Final data analysis and recommendations.

**Assumptions:**
- Labs can run either platform (Luminex or Flow) and any vendor.
- For the standardized protocol, common reagents will be utilized.
SERUM B

INTRALAB COMPARISON

CLASS II FlowPRA SCREEN

LAB’S Method
(plate, 20ul sera)
SERUM B
INTRALAB COMPARISON

CLASS II FlowPRA SCREEN

LAB’S Method
(plate, 20ul sera)

EMORY Method
(plate, 50ul sera)
SERUM B
INTRALAB COMPARISON
CLASS II FlowPRA SCREEN

LAB'S Method
(plate, 20ul sera)

EMORY Method
(plate, 50ul sera)

EMORY Method
(tube, 50ul sera)

A

B

C
Antibody Screen-Patient  ICANT TELLYOU

Class I

Class II

Control Beads
Discussion points-assay variability

1) Lab to lab variation
2) Bead to bead variation
3) Methodological variability
4) Platform variability
5) Platform agreement