Partnership Opportunity

# QC REAGENTS FOR HLA ANTIBODY TESTING


To learn more

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**BACKGROUND:** The major impediment to successful solid-organ transplantation is the presence of antibodies in recipient serum against donor Human Leukocyte Antigens (HLA). Exposure to HLA through prior transplants, blood transfusions, or pregnancies increases the likelihood of these donor-specific alloantibodies, thereby increasing the risk of antibody-mediated rejection. Prior to transplantation, specialized histocompatibility labs use HLA crossmatching and antibody assays to detect clinically-relevant HLA antibodies in recipient serum through cell-based and more contemporary solid-phase immunoassays.

**PROBLEM:** Most positive controls used for quality control of HLA crossmatching and antibody assays are pooled sera from highly sensitized patients. These reagents are difficult to create and the inherent variability between patients make it difficult to ensure consistent reactivity against lymphocytes.

Effective positive controls for HLA testing are critical because:

1. HLA crossmatching and antibody assays are sensitive to variability in HLA expression levels, technician handling, and assay conditions.
2. False negatives in HLA crossmatching can result in acute and chronic graft rejection. Causes of false negatives include:
    - Strong sensitization effects or high-titer antibodies, leading to the prozone effect in single antigen bead (SAB) and C1q assays.
    - Low levels of HLA expression, known to be caused by statins and other drugs.

**SOLUTION: Bloodworks has created a humanized monoclonal antibody pan-reactive for HLA Class I that can serve as an effective control for HLA expression level in HLA crossmatching and antibody assays. This technology will allow for standardization of HLA assays across runs and amongst different clinical laboratories.**

These antibodies can be used to:

1. Validating the specificity of AHG/secondary antibodies used as detection reagents
2. Validating and characterizing antibody assays dependent on complement-fixation (i.e. AHG-CDC and C1q)
3. Standardization and normalization of single antigen bead (SAB) and flow crossmatching (FXCM) assays
4. Prozone mitigation (SAB and C1q testing)
5. Examining FcR-mediated Natural Killer Cell Reactivity (ADCC)

**PARTNERSHIP OPPORTUNITIES:**

1. Ongoing research and development opportunities
2. Licensing agreement