

## 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR section 807.92

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**Device Name:** Antibody Monitoring System: HLA Class I and Class II (AMS1 and AMS1+2)

**Proprietary Name:** Antibody Monitoring System: HLA Class I and Class II (AMS1 and AMS1+2) is a Solid Phase Enzyme Linked Immunoassay (ELISA) for the detection of IgG antibodies to donor-specific HLA class I and class II antigens.

**Classification Name:** Solid Phase Enzyme Linked Immunoassay (ELISA) for the Detection of IgG Antibodies to Donor-Specific HLA Class I and Class II Antigens. (Unclassified)

**Summary and Explanation:** The highly polymorphic human leukocyte antigens (HLA) are widely distributed on all nucleated cells. HLA Class I and Class II molecules are polymorphic membrane glycoproteins. Functionally, these molecules play important roles in the presentation of antigenic peptides to CD4<sup>+</sup> T lymphocytes. Antibodies to HLA antigens have been shown to contraindicate successful transplantation. Post-transplant monitoring of HLA Class I and Class II antibodies is important in assessing potential graft survival.

**Description:** This is a qualitative ELISA capture assay with a colorimetric endpoint. HLA glycoproteins are first prepared from donor lymphocyte cells obtained from spleen or peripheral blood. Once harvested, cells are lysed with a detergent and the solubilized protein lysate is obtained using a centrifugation step. The lysate is then added to microwells that contain immobilized monoclonal antibodies specific for HLA Class I or HLA Class II proteins. After an incubation step that allows the glycoproteins to bind to the antibodies, unbound material is removed by washing. Serum from the transplant patient is then allowed to react with the bound donor antigens. Antibodies to HLA Class I or Class II arising in the patient that are directed toward the donor will bind to the donor antigen. Bound antibodies are indirectly detected by incubation with a secondary antibody-enzyme conjugate (anti-human IgG-Alkaline Phosphatase). After another incubation and wash step, PNPP substrate is reacted with the bound conjugate. The formation of the product can be photometrically detected at 405 nm with a reference wavelength of 490 nm.

**Intended Use:** The AMS1 and AMS1+2 kits will be used for the detection of IgG Antibodies to donor-specific HLA Class I and Class II antigens. This kits are intended for *In Vitro* Diagnostic (IVD) use.