

Modified 510(k) Summary for Lifecodes LifeScreen

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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This notification is being submitted by GTI, Inc., as the original developer and manufacturer of Lifecodes LifeScreen, on behalf of Tepnel Lifecodes, formerly of Orchid Diagnostics, the seller.

Device Name: Lifecodes LifeScreen

Proprietary Name: A Luminex¹⁰⁰ Screening Assay for the Detection of IgG Antibodies to HLA Class I and Class II Molecules of Human Origin.

Classification Name: A bead-based assay to qualitatively detect IgG antibodies to HLA Class I and Class II molecules.

Summary and Explanation: Human Leukocyte antigens (HLA) are a system of glycoproteins that have a functional role in the presentation of peptides to the immune system. However, as a highly polymorphic system HLA molecules can become targets of antibody responses in people during pregnancy, transfusion of blood products or organ transplant rejection. Generally, alloimmunization leads to the production of HLA antibodies in approximately 33% of exposed individuals. The presence or absence of these HLA-specific antibodies has a role in determining the survival of transplant allografts.

Description: Lifecodes LifeScreen is designed to detect IgG antibodies to HLA Class I and Class II molecules, and is composed of affinity purified Class I HLA and Class II HLA glycoproteins conjugated to unique Luminex¹⁰⁰ beads.

An aliquot of the LifeScreen Beads is allowed to incubate with a small volume of test serum sample. The sensitized beads are then washed to remove unbound antibody. An anti-human IgG antibody conjugated to phycoerythrin is then added. After another incubation, the test sample is diluted and analyzed on the Luminex¹⁰⁰ instrument. To determine if a specific HLA bead is positive or negative for bound alloantibody, the signal intensity of the specific bead is compared to the signal intensity of three different control beads. A specific bead, and thus the sample, is considered positive when it is scored as positive for one of the three control beads.

Intended Use: Lifecodes LifeScreen will be used to qualitatively detect IgG antibodies to HLA Class I and Class II molecules. This kit is intended for *In Vitro* Diagnostic (IVD) use.