



GTI DIAGNOSTICS

Good science starts with people.®

FOR IMMEDIATE RELEASE

Contact:

Karen Smith Zdroik

Marketing Manager

GTI Diagnostics

262.754.1051

ksmith@gtidiagnostics.com

GTI Diagnostics Gains FDA Clearance for TMDONORSCREEN-HLA on QUICKSTEP[®]

(August 6, 2008) – GTI Diagnostics has announced that it has received FDA clearance to market its TMDONORSCREEN-HLA on the QUICKSTEP[®] Automated ELISA platform. TMDONORSCREEN-HLA is intended to be used by Blood Banks and other blood collecting agencies to test for the presence of HLA antibodies in serum or plasma of blood donors. A recent advisory from the AABB has recommended that blood collection and transfusion facilities begin taking steps to reduce the presence of donor blood containing leukocyte antigen derived antibodies as a means to reduce the incidence of transfusion related acute lung injury (TRALI). Many labs have begun testing (or will start testing) donated blood for leukocyte-derived antibodies as one way to meet this recommendation.

GTI Diagnostics has built upon its extensive history in HLA antibody screening to produce TMDONORSCREEN-HLA, a kit specifically designed for use in Blood Banks. TMDONORSCREEN-HLA on QUICKSTEP[®] has been tested in external studies conducted in Blood Bank laboratories. The kit has been shown to detect class I and class II HLA antibodies in serum or plasma of blood donors. To provide a complete, automated system, the QUICKSTEP[®] ELISA platform was chosen to run the TMDONORSCREEN-HLA assay and process the results. QUICKSTEP[®] is an ELISA workstation with a proven track record in the clinical laboratory environment. Able to handle 4 plates and 176 samples at one time, QUICKSTEP[®] provides full ELISA processing from sample dilution to result interpretation. Technician hands-on time has been reduced to a minimum and with bar coded reagent bottles that go directly from the kit to the instrument, TMDONORSCREEN-HLA is quick to set up and run. All necessary reagents and controls are provided in one kit. Positive and negative controls are run on every plate eliminating time consuming and costly instrument calibration and QC.

Implementation of TMDONORSCREEN-HLA testing by Donor Testing Labs has been simplified with the aid of an in-depth training guide specific for TMDONORSCREEN-HLA and the QUICKSTEP[®] instrument. GTI Diagnostics has produced a training manual and program for users who have just started with TMDONORSCREEN-HLA or for established users who wish to train new technicians on the system. GTI Diagnostics also provides a validation guide to simplify the Test Validation process. Multiple test cases have been set up to validate the instrument and assay. Provided with each test case is a comprehensive worksheet and record for easy documentation.

Finally, GTI Diagnostics is making available a panel of well-characterized HLA antibody positive and negative sera for use on TMDONORSCREEN-HLA and QUICKSTEP[®]. The panel is a collection of weakly, moderately and strongly positive HLA Class I and Class II antibody sera. The panel also contains a set of HLA Class I and Class II negative sera. The panel can be used to validate the TMDONORSCREEN-HLA assay on the QUICKSTEP[®] during initial installation and any subsequent validations. The panel can also be used as test material during training or if new kit lot validation is required by the user's institution. Each serum is packaged in its own bar coded vial that can be placed directly onto the QUICKSTEP[®] instrument. GTI Diagnostics is the only manufacturer that currently provides such a panel of HLA positive/negative sera qualified for this use.

For more information on TMDONORSCREEN-HLA and the QUICKSTEP[®] instrument or to set up a demonstration, contact GTI Diagnostics at 1.800.233.1843 or e-mail to tmiller@gtidiagnostics.com.