

TMDONORSCREEN-HLA Class I and Class II

INTENDED USE

TMDONORSCREEN-HLA Class I and Class II is a qualitative Enzyme Linked Immunosorbent Assay (ELISA) for use on the Biotest QUICKSTEP[®] instrument. TMDONORSCREEN-HLA Class I and Class II ELISA is designed to detect anti-HLA class I and class II antibodies in human serum or plasma of blood donors.

For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

Human Leukocyte Antigens (HLAs) are highly polymorphic glycoproteins. HLA antibodies can be acquired through alloimmunization of pregnancy, transfusions, or previous transplantation. In general alloimmunization leads to the production of HLA antibodies in approximately 33% of exposed individuals¹. The formation of these antibodies in a transfusion or transplant recipient can result in the immune destruction of transfused platelets or the transplanted organ². The presence of pre-existing HLA antibodies in blood donors has also been implicated in Transfusion-Related Acute Lung Injury (TRALI) and TRALI-like transfusion reactions in the recipients of blood products from the donors³⁻¹⁴. However, in 10-15% of TRALI reactions no antibodies are found in the donor(s) and in 45-60% of TRALI reactions neutrophil specific antibodies are found in the donor(s).

TMDONORSCREEN-HLA has been specifically designed to be used on the QUICKSTEP[®] automated ELISA instrument for the detection of class I or class II HLA antibodies in blood donors.

PRINCIPLE OF THE PROCEDURE

All assay steps described below including sample dilution, sample and reagent addition, plate washing, photometric analysis and data evaluation are carried out by the QUICKSTEP[®] automated ELISA instrument. Minimal reagent preparation by the user is required (refer to PROCEDURE section).

Donor serum or plasma is diluted with Specimen Diluent and added to microwells coated with affinity purified HLA class I or HLA class II glycoproteins allowing antibody, if present, to bind. Unbound antibodies are then washed away. An alkaline phosphatase labeled anti-human globulin (Anti-IgG) is added to the wells and incubated. The unbound Anti-IgG is washed away and the substrate PNPP (p-nitrophenyl phosphate) is added. After incubation at ambient temperature, the reaction is stopped by a Stopping Solution. The optical density of the color that develops is measured in a spectrophotometer at 405 nm with a reference wavelength of 492 nm. All of the above steps are carried out by the QUICKSTEP[®] automated ELISA instrument.

REAGENTS

Maximum number of tests per kit: 176 (Class I) and 176 (Class II).

There are sufficient reagents provided in the kit for 2 runs on the QUICKSTEP[®] instrument.

All reagents should be stored as directed by the label.

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| MSI | 1. Microwells: Flat-bottom microwell strips to which affinity purified HLA class I glycoproteins have been immobilized. The microwell strips are enclosed in a foil pouch. Wells are color-coded black. Ready for use. Single use. |
| MSII | 2. Microwells: Flat-bottom microwell strips to which affinity purified HLA class II glycoproteins have been immobilized. The microwell strips are enclosed in a foil pouch. Wells are color-coded pink. Ready for use. Single use. |
| CWD | 3. Concentrated Wash (10X): Tris (hydroxymethyl) aminomethane buffered solution containing sodium chloride, Tween [®] 20, and 1% sodium azide. Dilute with deionized or distilled water before use. Store Working Wash solution up to 48 hours at room temperature or up to seven days at 2 to 8°C. |
| SD | 4. Specimen Diluent: Phosphate buffered saline solution containing bovine albumin, and 0.1% sodium azide. White cap. Ready for use. |
| SB | 5. Substrate Buffer: This solution contains diethanolamine, magnesium chloride, and 0.02% sodium azide. Ready for use. Single use. |
| SS | 6. Stopping Solution: 3 M Sodium Hydroxide. Ready for use. |
| AG | 7. Anti-Human IgG Conjugate: Alkaline phosphatase conjugated goat affinity purified antibody to human immunoglobulin G (IgG), and 0.1% sodium azide. Blue cap. Dilute in Conjugate Diluent before use. |

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| CDD | 8. Conjugate Diluent: Phosphate buffered saline solution containing bovine albumin, and 0.1% sodium azide. Blue cap. Ready for use. Single use. |
| PN | 9. PNPP (p-nitrophenyl phosphate) Substrate: Crystalline powder. Reconstitute with deionized or distilled water and dilute in Substrate Buffer before use. Protect from light. Single use. |
| PC I | 10. Positive Serum Control-Class I: Human serum containing 0.1% sodium azide. Black cap. Ready for use. |
| NC I | 11. Negative Serum Control-Class I: Human serum containing 0.1% sodium azide. Gray cap. Ready for use. |
| PC II | 12. Positive Serum Control-Class II: Human serum containing 0.1% sodium azide. Red cap. Ready for use. |
| NC II | 13. Negative Serum Control-Class II: Human serum containing 0.1% sodium azide. Pink cap. Ready for use. |

PRECAUTIONS

- Do not use reagents that are turbid or contaminated.
- Care must be taken to avoid contamination of Specimen Diluent and Conjugate Diluent. Inadvertent contamination of these reagents with human serum or plasma will result in the neutralization of the conjugate and subsequently to test failure.
- Do not use reagents beyond their expiration date.
- When making dilutions, follow pipet manufacturer’s instructions for appropriate dispensing and rinsing techniques.
- Microwells and reagents contained in the kit are not to be used in conjunction with any other test system.
- Discard any unused portions of diluted Conjugate, Substrate Buffer and reconstituted PNPP reagent after each run.
- The Anti-Human IgG Conjugate, Positive and Negative Controls may be re-used. When re-capping after use, be certain to place the cap onto the correct associated vial. The caps are color coded to help avoid errors when re-capping.
- The QUICKSTEP® instrument should be maintained according to the manufacturer’s recommendations to ensure proper functioning.

CAUTION

- All human serum used in the Positive and Negative controls was found negative when tested in accordance with current FDA required tests. No known test method can offer assurance that products derived from human blood will not transmit infectious agents. Therefore all blood products should be treated as potentially infectious.
- Some of the reagents in this kit or in accessory kits contain sodium azide as a preservative. WARNING: Sodium azide reacts with lead and copper plumbing forming highly explosive metal azides. When discarded in a sink, the sink should be flushed with a large volume of water to prevent azide buildup. Sodium azide is a poison and is toxic if ingested.
- Stopping Solution (NaOH) is corrosive. Avoid contact with skin and eyes. Spills should be cleaned up immediately.
- Discard all components when completed according to local regulations.

INSTRUMENTATION

The Biotest QUICKSTEP® instrument is to be used for performing the™DONORSCREEN-HLA Class I and Class II assay. The Biotest QUICKSTEP® instrument is a fully automated microplate analyzer and includes such functions as sample dilution, sample and reagent addition, plate washing, photometric analysis and data evaluation.

Installation of the QUICKSTEP® instrument is scheduled through GTI Diagnostics and is performed by Biotest. The assay files required to use the™DONORSCREEN-HLA Class I and Class II assay are installed by GTI Diagnostics and are password protected files which cannot be modified by the user.

The instrument operating instructions, safety instructions, and a list of error codes are provided in the QUICKSTEP® instrument User Guide. Specific information on the instrument operating instructions regarding the set up and processing of the™DONORSCREEN-HLA assay on the QUICKSTEP® can be found in the™DONORSCREEN-HLA QUICKSTEP® Training Guide.

The user should contact GTI Diagnostics for any product related concern (both QUICKSTEP® instrument or™DONORSCREEN-HLA Class I and Class II assay product concerns). Product specific service for the™DONORSCREEN-HLA Class I and Class II assay will be provided by GTI Diagnostics. If it is determined that servicing of the QUICKSTEP® instrument is required, GTI Diagnostics will contact Biotest for servicing. Preventative maintenance of the QUICKSTEP® instrument is scheduled through GTI Diagnostics® and is performed by Biotest.

SPECIMEN COLLECTION

Blood should be collected in either EDTA (plasma) or without anticoagulant (serum) using aseptic technique. The primary collection tubes may be stored up to 96 hours at room temperature (21 to 26°C) or at 2 to 8°C before centrifuging to obtain the serum or plasma. To obtain the serum or plasma, the tubes should be centrifuged according to the instructions from the manufacturer of the collection tube. Once centrifuged, the sample may be tested immediately, directly from the primary tube. If not tested immediately, the samples may be stored up to 5 days at 2 to 8°C in the primary collection tube. Alternatively, the serum or plasma can be transferred to a separate tube for storage. Once transferred, samples can be stored up to 1 week at 2 to 8°C or can be frozen at -20°C or below for up to 3 years. To avoid multiple freeze/thaw cycles, it is recommended that the sample be aliquoted in small volumes and then stored frozen. Avoid frost free freezers. Particulates or aggregates in the sample can cause false positive results. Samples containing particulates, or those that have been frozen should be clarified by centrifugation prior to testing.

PROCEDURE

Materials provided:

Unless indicated some vials may contain more reagent than described on the label.

1. 2 microwell frames Class I, each containing 12-1x8 microwell strips; color coded black
2. 2 microwell frames Class II, each containing 12-1x8 microwell strips; color coded pink
3. 2 x 80 mL Concentrated Wash (10x)
4. 1 x 22 mL Specimen Diluent (white cap)
5. 2 x 25 mL Substrate Buffer (exact fill)
6. 1 x 50 mL Stopping Solution
7. 1 x 350 µL Anti-Human IgG Conjugate (blue cap)
8. 2 x 14 mL Conjugate Diluent (exact fill)
9. 2 x 50 mg PNPP Substrate
10. 1 x 250 µL Positive Serum Control-Class I (black cap)
11. 1 x 350 µL Negative Serum Control-Class I (gray cap)
12. 1 x 250 µL Positive Serum Control-Class II (red cap)
13. 1 x 350 µL Negative Serum Control-Class II (pink cap)

Additional Materials Required:

1. Adjustable micropipettes to deliver 100-1000 µL and disposable tips
2. Deionized or distilled water
3. Centrifuge for centrifugation of primary collection tubes
4. Biotest QUICKSTEP® instrument
5. Graphite tips 300 µL for QUICKSTEP®
6. Graphite tips 1100 µL for QUICKSTEP®

Test Procedure

1. Bring all needed reagents to room temperature.
2. Make Working Wash solution by diluting Concentrated Wash (10x). Add 1 volume of Concentrated Wash to 9 volumes of deionized water. Mix well. Add Working Wash to Wash Container (refer to QUICKSTEP® User Guide section 6.1.2). If testing ≤ 88 samples, prepare 750 mL of Working Wash Buffer. If testing > 88 samples, prepare 1500 mL of Working Wash Buffer.
3. Start system (refer to QUICKSTEP® User Guide section 5.1.1). Proceed with an assay run only if all of the self-check parameters are marked “passed” (refer to QUICKSTEP® User Guide section 5.1.2 Initialization).
4. Uncap and place sample tubes into the sample racks. Ensure that any barcode label is oriented with the open slot side of the sample rack and available to the barcode reader. Barcoded and non-barcoded samples may be mixed on any rack.
5. Uncap the Control Sera vials (PCI, NCI, PCII, NCII) and place into any open positions at the end of the sample rack. Make sure the barcode is visible through the slot in the rack. Retain the Control Sera vials and caps if a partial kit is used.
6. Open the front loading door. Insert the first sample rack according to QUICKSTEP® User Guide section 5.1.4.
7. As the sample rack is read a dialogue window will open. Ensure that each sample barcode has been read. Information for non-barcoded samples can be entered at this time. For each sample select and apply the DS-Class I and DS-Class II assays (DS-CI-ver1.0.asy and DS-CII-ver1.0.asy respectively) according to QUICKSTEP® User Guide section 5.1.4. **Do not apply an assay to the Control Sera vials.**

8. After all samples and controls have been placed on the QUICKSTEP[®] create a worklist (refer to QUICKSTEP[®] User Guide section 5.1.6).
9. Enter kit and lot information for each reagent listed. Complete the kit and reagent lot information for each plate in the appropriate fields (refer to QUICKSTEP[®] User Guide section 5.1.6 Step 16).
10. Re-hydrate one vial of PNPP Substrate by adding 0.5 mL deionized or distilled water to the vial. Replace the stopper and mix well. Protect from light.
11. Make the following reagents according to the number of samples in the worklist.

Number of Samples	Bottles of Diluted Conjugate Required	Bottles Diluted Substrate Required
≤ 88	1	1
89-176	2	2

12. Make the Diluted Conjugate as follows. To each bottle of Conjugate Diluent add 140 µL of Anti-Human IgG Conjugate. Re-cap the bottle(s) and mix gently by inverting several times. Once prepared, the diluted conjugate is stable for up to 8 hours at room temperature (21 to 26°C) prior to using it in the [™]DONORSCREEN-HLA Class I and Class II assay.

NOTE: The conjugate is viscous and should be thoroughly mixed with the Conjugate Diluent to assure proper performance of the assay. Un-cap and place the bottle(s) into the silver reagent rack.

13. Make the Diluted Substrate as follows. To each bottle of Substrate Buffer add 250 µL of PNPP Substrate. Re-cap the bottle(s) and mix well by inverting several times. Un-cap and place the bottle(s) into the silver reagent rack. Once prepared, the diluted PNPP substrate is stable for up to 8 hours at room temperature (21 to 26°C) prior to using it in the [™]DONORSCREEN-HLA Class I and Class II assay.
14. Un-cap and place one bottle of Stopping Solution into the reagent rack. Retain the cap to seal the bottle for further use if needed.
15. Un-cap and place one bottle of Specimen Diluent into the reagent rack. Retain the cap to seal the bottle for further use if needed.
16. Start the run by pressing the green triangle button on the control menu.
17. Ensure that all the barcodes on the reagent bottles are facing the barcode reader.
18. Open the access door and insert the reagent rack into the QUICKSTEP[®]. Ensure that there are no unallocated resources. Check the system status window and load any additional pipette tips as needed (refer to QUICKSTEP[®] User Guide section 6.1.4). **DO NOT fill a tip rack location with the incorrect tip size. This may cause the pipettor to become contaminated or the pipettor to crash resulting in serious damage.** After insuring that there are no unallocated resources confirm by clicking OK. A volume check of all reagents is performed automatically. If the volume of one reagent is too low, a System Error dialogue box appears. To refill a reagent or to replace it with a new bottle, the reagent rack has to be moved out, refilled or replaced and the rack re-inserted. Once re-inserted click on the “Refill Bottle” button to continue the assay.
19. Add the microwell plates as prompted. Remove the microwell plate from the foil pouch and place it into the plate carrier (refer to QUICKSTEP[®] User Guide section 5.2.3). If less than a full plate is required, the unused strips may be removed and returned to the resealable pouch. A unique plate ID should be entered for each plate (proposed format mmddyy-plateX).

NOTE: The plate ID must not exceed 20 characters. If the plate ID exceeds 20 characters, an error message will be reported and the worklist/run can not be started until the plate ID is re-written such that it is 20 characters or less in length.

20. Check the field immediately to the right of the Plate ID field to verify the assay name. Ensure that the correct plates are loaded for the indicated assay. [™]DONORSCREEN-HLA Class I microwell plates are color-coded black. [™]DONORSCREEN-HLA Class II microwell plates are color-coded pink. After confirming that the correct plate has been loaded for the assay, close all loading doors.
21. Once all the plates have been added and all loading doors have been closed, the system will start automatically.
22. Sample racks may be removed after the samples have been pipetted.
23. After processing is complete follow the instructions for unloading (QUICKSTEP[®] User Guide section 6.2), disposal (QUICKSTEP[®] User Guide section 6.3) and shutdown (QUICKSTEP[®] User Guide section 7.1).
24. Unused Stopping Solution and Specimen Diluent may be re-capped and used for one additional run. Discard any remaining diluted conjugate and substrate.
25. The remainder of the control materials (Positive and Negative Serum Controls) may be re-capped and used for one additional run. Be certain to place the correct cap onto each control. The caps are color coded to help avoid errors when re-capping.

QUALITY CONTROL

Quality control of the TMDONORSCREEN-HLA Class I and Class II assay is built into the assay by inclusion of Positive and Negative Serum Controls. Two replicates of the Positive Serum Control and four replicates of the Negative Serum Control are automatically processed with each assay. The Quality Control values listed below are pre-programmed into the TMDONORSCREEN assay file. If any one of these values is not met, the O.D. values for each sample will still be printed but the Qualitative Result will not appear on the electronic or printed report. An error code of FAILED will appear on page 1 of the report and computer screen.

TMDONORSCREEN Class I Control Requirements

Mean of PC \geq 1.500

Mean of NC $>$ 0.040 and $<$ 0.150

TMDONORSCREEN Class II Control Requirements

Mean of PC \geq 1.500

Mean of NC $>$ 0.100 and $<$ 0.250

INTERPRETATION OF RESULTS

The cutoff for the TMDONORSCREEN HLA assay is automatically calculated by the QUICKSTEP[®] instrument and is equal to 2x the mean of the O.D. values obtained from the Negative Control. Separate cutoff values are determined for the class I and the class II assay. A qualitative result (positive or negative) is automatically calculated and printed on the test report along with the O.D. value for each sample that is tested. The qualitative result is determined relative to the cutoff for the assay. A sample in which the O.D. value is less than the cutoff for the assay is reported as negative in the TMDONORSCREEN HLA assay. This indicates that the sample does not contain HLA antibodies that are detectable by the TMDONORSCREEN HLA assay. A sample in which the O.D. value is greater than, or equal to the cutoff for the assay is reported as positive in the TMDONORSCREEN HLA assay.

LIMITATIONS OF THE PROCEDURE

Erroneous results can occur from bacterial contamination of test materials.

The presence of immune complexes or other immunoglobulin aggregates in the sample may cause an increased non-specific binding and produce false-positives in this assay.

Some low titer, low avidity antibodies may not be detected using this assay.

This product does not detect IgM or IgA antibodies.

This product is not intended to diagnose TRALI. Use of this test in TRALI or TRALI like reactions, which are clinical syndromes has not been evaluated.

SPECIFIC PERFORMANCE CHARACTERISTICS

Precision

The within run, between run, and total imprecision of the DONORSCREEN-HLA Class I and Class II assay were determined. Four samples of varying antibody concentrations (negative, low, medium, and high positive) were tested in the DONORSCREEN-HLA Class I and Class II assay in duplicate in 10 separate assays. To obtain the imprecision of the O.D. values, the data were analyzed by ANOVA according to CLSI Document EP-5A2. The calculations are shown in the table below. The results demonstrated \leq 15% CV for the O.D. values for each of the positive samples that were tested. The negative samples showed acceptable standard deviations. In addition, the reportable results were analyzed according to CLSI Document EP12-A. There was 100% agreement between the reportable results within run and between run for each sample tested.

Sample	Mean O.D. Value	Within Run SD	Within Run %cv	Between Run SD	Between Run %cv	Total SD	Total %cv
Negative Class I	0.086	0.009	10.5	0.007	8.1	0.010	11.6
Low Positive Class I	0.569	0.049	8.6	0.051	9.0	0.061	10.7
Medium Positive Class I	0.826	0.061	7.4	0.092	11.4	0.102	12.3
High Positive Class I	1.519	0.075	4.9	0.097	6.4	0.111	7.3
Negative Class II	0.111	0.027	24.3	0.016	14.4	0.025	22.5
Low Positive Class II	0.736	0.102	13.8	0.076	10.3	0.105	14.3
Medium Positive Class II	1.227	0.09	7.3	0.148	12.1	0.161	13.1
High Positive Class II	2.737	0.202	7.4	0.244	8.9	0.283	10.3

Method Comparison to Manual ELISA QuikScreen® and B-Screen®

Three separate studies were conducted in which the™DONORSCREEN- HLA Class I and Class II assay was compared to both the GTI QuikScreen® and B-Screen® assays. QuikScreen® is a manual ELISA which detects antibodies to HLA class I and B-Screen® is a manual ELISA that detects antibodies to HLA class II.

The studies were conducted using CLSI EP9-A2; Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline, as a basis for the study design. Study 1 was conducted as an internal study at GTI. In this study serum samples were collected from 203 random female donors. Study 2 was conducted as an external study at LifeBlood Mid-South Regional Blood Center located in Memphis, TN. In this study serum samples were collected from 264 random female donors. Study 3 was conducted at Florida Blood Services located in St. Petersburg, FL. In this study serum samples were collected from 264 random female donors and 178 random male donors. For each study the samples were tested in the™DONORSCREEN- HLA Class I and Class II assay and the QuikScreen® and B-Screen® assays. The results of each study were analyzed for concordance using 2x2 tables. The™DONORSCREEN- HLA Class I assay was compared to the GTI QuikScreen® and the™DONORSCREEN- HLA Class II assay was compared to the GTI B-Screen® assay. The following tables show the combined results from these studies (n = 909).

		QuikScreen®		Total
		Positive	Negative	
™DONORSCREEN- HLA Class I	Positive	108	0	108
	Negative	2	799	801
	Total	110	799	909

Agreement: 99.8%
 Co-positivity: 98.2% (95% Confidence Interval = 93.6 – 99.5%)
 Co-negativity: 100% (95% Confidence Interval = 99.5 – 100.0%)

		B-Screen®		Total
		Positive	Negative	
™DONORSCREEN HLA- Class II	Positive	88	3	91
	Negative	2	816	818
	Total	90	819	909

Agreement: 99.4%
 Co-positivity: 97.8% (95% Confidence Interval = 92.3 – 99.4%)
 Co-negativity: 99.6% (95% Confidence Interval = 98.9 – 99.9%)

™DONORSCREEN-HLA Class I and Class II Testing using Non-Transfused Male Donors/Rate of False Positive Results

One hundred and seventy six serum samples were obtained from non-transfused male donors who stated that they did not have a blood transfusion within the last year. The samples were tested for class I and class II HLA antibodies in™DONORSCREEN-HLA Class I and Class II. Any sample found to be positive was tested in a Luminex HLA antibody identification assay. The presence of defined antibody specificities was used to confirm that the sample did indeed contain an antibody to HLA class I or class II. There were 9 samples which showed a positive result in™DONORSCREEN-HLA Class I. When tested by the Luminex HLA antibody identification assay, 8 of the samples had defined specificities and were considered true positives. The single sample which was not positive

in the Luminex assay was only very weakly positive in the TMDONORSCREEN-HLA Class I assay. Of the 168 true negatives (176 minus 8), TMDONORSCREEN-HLA detected 1 sample as positive resulting in a false positive rate of 0.6%.

There were 4 samples which showed a positive result in TMDONORSCREEN-HLA Class II. All of these samples had defined specificities when tested by the Luminex HLA antibody identification assay. Therefore, all 4 samples were considered to be true positives. TMDONORSCREEN-HLA Class II showed a false positive rate of 0%.

Interfering Substances

Interfering Substance studies were conducted using CLSI EP7 Interference Testing in Clinical Chemistry; Approved Guideline.

The following substances showed no interference in the TMDONORSCREEN-HLA Class I and Class II assay at the concentration indicated:

Hemoglobin	≤ 500 mg/dL
Triglycerides	≤ 500 mg/dL
Bilirubin	≤ 20 mg/dL

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TMDONORSCREEN-HLA Class I and Class II

- FOR *IN VITRO* DIAGNOSTIC USE
- STORE AT 2 to 8°C

GTi DIAGNOSTICS®

Good science starts with people.®

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