DonorScreen-HLA® Class I and Class II Additional Reagents

Concentrated Wash (10X)

REF 303456 (DonorScreen-HLA® Class I and Class II Additional Reagents)  IVD
404563 (Concentrated Wash (10X))

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INTENDED USE

DonorScreen-HLA Class I and Class II assay is a qualitative Enzyme Linked Immunosorbent Assay (ELISA) for use on the Bio-Rad QuickStep instrument. DonorScreen-HLA Class I and Class II assay ELISA is designed to detect anti-HLA class I and class II antibodies in human serum or plasma of blood donors.

ADDITIONAL REAGENTS DESCRIPTION

DonorScreen-HLA Class I and Class II Additional Reagents are available in limited quantities. It is recommended to order additional reagents at the time of request of DonorScreen-HLA Class I and Class II kits.

- **DonorScreen-HLA Class I and Class II Additional Reagents** kit provides the extra reagents needed for the DonorScreen assay where less than full plate runs are performed with the DonorScreen kit. Two additional runs are supported with the reagents from the Additional Reagents box.

- **Concentrated Wash** is available to purchase independently from the DonorScreen assay. Additional Concentrated Wash is provided for customers who choose to prepare Working Wash solution for each run performed in lieu of saving diluted Wash for subsequent assay runs.

SUMMARY AND EXPLANATION OF THE TEST

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 individuals\(^1\). The formation of these antibodies in a transfusion or transplant recipient can result in the immune destruction of transfused platelets or the transplanted organ\(^2\). 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 donors\(^3\)\(^-\)\(^14\). 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).

**DonorScreen**-HLA has been specifically designed to be used on the **QUICKSTEP**\(^\text{®}\) automated ELISA instrument for the detection of class I or class II HLA antibodies in blood donors.

PRINCIPLES OF THE PROCEDURE

Refer to the DonorScreen-HLA Class I and Class II Instructions for Use (IFU) for assay steps including assay analysis and data evaluation.

REAGENTS

**DonorScreen-HLA Class I and Class II Additional Reagents**

There are sufficient reagents provided in the DonorScreen-HLA Class I and Class II Additional Reagent kit to support 2 additional runs on the QuickStep instrument using Microwell Strips and Concentrated Wash provided in the DonorScreen-HLA Class I and II kit.

**Concentrated Wash (10x)** is provided as an 80 mL bottle. The wash requires dilution prior to use. See DonorScreen-HLA Class I and Class II Instructions For Use.

All reagents should be stored as directed by the label.

**DonorScreen-HLA Class I and Class II Additional Reagents**

<table>
<thead>
<tr>
<th>REF</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>SD 404581</td>
<td>Specimen Diluent: Phosphate buffered saline solution containing bovine albumin, and 0.1% sodium azide. White cap. Ready for use.</td>
</tr>
<tr>
<td>SB 404586</td>
<td>Substrate Buffer: This solution contains diethanolamine, magnesium chloride, and 0.02% sodium azide. Ready for use. Single use.</td>
</tr>
<tr>
<td>SSD 404584</td>
<td>Stopping Solution: Ready for use.</td>
</tr>
<tr>
<td>AG 404554</td>
<td>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.</td>
</tr>
</tbody>
</table>

PNPP Substrate: (p-nitrophenyl phosphate) Crystalline powder. Reconstitute with deionized or distilled water and dilute in Substrate Buffer before use. Protect from light. Single use.

Positive Serum Control-Class I: Human serum containing 0.1% sodium azide. Black cap. Ready for use.

Negative Serum Control-Class I: Human serum containing 0.1% sodium azide. Gray cap. Ready for use.

Positive Serum Control-Class II: Human serum containing 0.1% sodium azide. Red cap. Ready for use.

Negative Serum Control-Class II: Human serum containing 0.1% sodium azide. Pink cap. Ready for use.

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.

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.
- Reagents included in the Additional Reagent kit are Lot-matched to the DonorScreen-HLA Class I and Class II kit.
- Concentrated Wash may be used with any DonorScreen-HLA kit through expiry of the reagent.
- Reagents included 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.
- Discard all components when completed according to local regulations.

Materials provided

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

DonorScreen-HLA Class I and Class II Additional Reagents

1. 1 x 22 mL Specimen Diluent (white cap)
2. 2 x 25 mL Substrate Buffer (exact fill)
3. 1 x 50 mL Stopping Solution
4. 1 x 350 µL Anti-Human IgG Conjugate (blue cap)
5. 2 x 14 mL Conjugate Diluent (exact fill)
6. 2 x 50 mg PNPP Substrate
7. 1 x 250 µL Positive Serum Control-Class I (black cap)
8. 1 x 350 µL Negative Serum Control-Class I (gray cap)
9. 1 x 250 µL Positive Serum Control-Class II (red cap)
10. 1 x 350 µL Negative Serum Control-Class II (pink cap)

**Concentrated Wash (10x)**

1. 1 x 80 mL Concentrated Wash (10X)

**PROCEDURE, QUALITY CONTROL, INTERPRETATION, LIMITATIONS, PERFORMANCE**

See DonorScreen-HLA Class I and Class II IFU

**REFERENCES**


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**Warning**

<table>
<thead>
<tr>
<th>Warning</th>
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<tbody>
<tr>
<td>Danger</td>
<td>Danger</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H318</td>
<td>Causes serious eye damage</td>
</tr>
<tr>
<td>H412</td>
<td>Harmful to aquatic life with long lasting effects</td>
</tr>
<tr>
<td>EUH032</td>
<td>Contact with acids liberates very toxic gas</td>
</tr>
<tr>
<td>P264</td>
<td>Wash hands thoroughly after handling</td>
</tr>
<tr>
<td>P270</td>
<td>Do not eat, drink or smoke when using this product</td>
</tr>
<tr>
<td>P273</td>
<td>Avoid release to the environment</td>
</tr>
<tr>
<td>P280</td>
<td>Wear protective gloves/protective clothing /eye protection/face protection</td>
</tr>
<tr>
<td>P301 + P312</td>
<td>IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell</td>
</tr>
<tr>
<td>P305 + P351 + P338</td>
<td>IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing</td>
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<tr>
<td>P310</td>
<td>Immediately call a POISON CENTER or doctor/physician</td>
</tr>
<tr>
<td>P330</td>
<td>Rinse mouth</td>
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