**Solidscreen II**

Microplate for solid phase Antiglobulin Test with TANGO® optimo

**FOR IN-VITRO DIAGNOSTIC USE**

**Package size**

| REF 80521100 | VOL 10 Micotestplate (12 strips each) |

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**Intended Use**

Solidscreen II is used for the TANGO® optimo. The Solidscreen II solid phase antiglobulin test is used as indirect antiglobulin (IAT) test for crossmatch, antibody screening and antibody identification, as well as direct antiglobulin test (DAT) and the determination of weak D and partial D antigens (DVI and DVIi) in donor samples.

**Summary**

Moreschi first described the use of Anti-Human Globulin in 1908. Combs rediscov ered the test in 1943. By injecting rabbits with human IgG, they were able to produce a protein (Anti-IgG) that reacted with incomp lete antibodies (IgG). Most "incomplete" antibodies (IgG) fail to agglutinate red blood cells suspended in saline. Most clinically significant antibodies in red blood cell serology are of the IgG class and can only be detected by the use of Anti-IgG. A stable lattice structure is formed and agglutination occurs when Anti-IgG binds to the IgG sensitized red blood cells. The ability to detect alloantibodies or autoantibodies directed against human red blood cells, in human plasma or serum, is a necessary part of routine laboratory testing as well as the detection of weak D and partial D antigens (DVI and DVIi) in donors. There are very important applications for antibody detection:

1. The detection of red blood cell antibodies prior to red cell or whole blood transfusion to prevent the possibility of a transfusion reaction with a corresponding hemorrhagic reaction.
2. To detect the presence of red blood cell antibodies in maternal or newborn serum that may result in Hemolytic Disease of the Newborn.

Routine pretransfusion studies always include tests for alloantibodies or autoantibodies directed against human red blood cells.

Routine pretransfusion studies always include tests for the D antigen.

**Principle**

Solidscreen II is a solid phase assay for

a) the detection of red blood cell alloantibodies or autoantibodies in human plasma or serum.

b) the determination of weak D and partial D antigens (DVI and DVIi) of samples which have tested negative with IgM anti-D using Erytype S and the TANGO® optimo.

**Materials**

**Materials Provided**

- Solidscreen II microplates

**Material required but not provided**

- TANGO® optimo [REF] 848900010
- Isotonic saline
- MLB 2 (modified LiSS Biotest) [REF] 805200100
- Search-Cyte® Pool, or Search-Cyte Duo®, or Search-Cyte® Trio for the TANGO® optimo
- Donor or patient red blood cells
- Solidscreen II Anti-D (RH1) Blend [REF] 806530100
- Alsevers Solution [REF] 806510100
- Anti-Human Globulin Anti-IgG Solidscreen II [REF] 806516100
- Solidscreen II Control [REF] 806514100
- Solidscreen II Control B [REF] 806519100
- Solidscreen II Negative Control [REF] 806509100
- PBS pH 7.3 ± 0.2
- Centrifuge
- Cell Mixers

Test Procedure

**Indirect Antiglobulin Test (IAT)**

1. TANGO® optimo dispenses 50μL of patient serum/plasma or control reagents into the Solidscreen II well.
2. TANGO® optimo prepares a 1% suspension of Reagent Red Blood Cells with MLB 2. An approx 1% suspension of donor red blood cells is prepared with MLB2 and Alsevers Solution.
3. TANGO® optimo dispenses 50μL of the Reagent Red Blood Cells or donor red blood cells prepared in (2) into the well with patient serum/plasma or control reagents.
4. The mixture is incubated for 20 minutes at 37°C.
5. The mixture is centrifuged following incubation.
6. The supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
7. 100μL of Anti-Human Globulin Anti-IgG Solidcreen II is added to each well and mixed.
8. Centrifugation by TANGO® optimo
9. Reaction is evaluated and interpreted by TANGO® optimo.

**Direct Antiglobulin Test (DAT)**

1. TANGO® optimo prepares an approx 1% suspension of patient or donor red blood cells with MLB 2 and Alsevers Solution.
2. TANGO® optimo dispenses 50μL of the patient or donor red blood cells prepared in (1) into the Solidscreen II well.
3. Following centrifugation, the supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
4. 100μL of Anti-Human Globulin Anti-IgG Solidcreen II is added to each well and mixed.
5. Centrifugation by TANGO® optimo
6. Reaction is evaluated and interpreted by TANGO® optimo.
Weak D and partial D antigen (DVI and DVII) typing

1. The TANGO® optimo dispenses 50 μL of Solidscreen II Anti-D Blend reagent into the Solidscreen II well.
2. TANGO® optimo prepares a 1% suspension of donor red blood cells with MLB 2 and Alsevers Solution
3. TANGO® optimo dispenses 50 μL of the donor red blood cells prepared in (2) into the well with Solidscreen Anti-D (RH) Blend reagent.
4. The TANGO® optimo mixes the reagent and red blood cells.
5. The mixture is incubated for 20 minutes at 37°C.
6. The mixture is centrifuged following incubation.
7. The supernatant is aspirated and the strip (wells) is washed twice. Centrifugation follows each wash process.
8. 100 μL of Anti-Human Globulin Anti-IgG Solidscreen II is added to each well and mixed.
9. Centrifugation by TANGO® optimo.
10. Reaction is evaluated and interpreted by TANGO® optimo.

Stability of the Reactions
For the TANGO® optimo the results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® optimo software evaluate and provide an interpretation (positive or negative) of the well. The operator performs validation of the final results.

Quality Control
A series of quality control samples must be run each day before testing or according to local requirements to ensure that the reagents, antisera and analyzer are functioning properly.
Controls should be run whenever:
• Lot number change (plate, reagent).
• A new bottle or preparation is placed on the system (red blood cells, AHG, MLB 2).
• After service/repair of the analyzer.

Two positive controls, Solidscreen II Control and Control B are available for testing on the TANGO® optimo. The Solidscreen II Control contains diluted anti-D and the Control B diluted anti-c. A negative control, Solidscreen II Negative Control is available for testing on the TANGO® optimo.

A minimum of one positive and one negative control should be run for the Solidscreen II assay. The Solidscreen II Control or Control B can be used as the positive control and Solidscreen II Negative Control as negative control.

Interpretation

Quality Control
The tests are considered valid if the expected results for the controls are obtained. If the controls do not give the expected results, you must determine the cause for the failed QC.

Follow institutional SOP for repeat testing of QC samples, repeat testing of patient/donor samples and documentation of QC results and corrective action if required.

Results
For the TANGO® optimo the results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® optimo software evaluate and provide an interpretation (positive or negative) of the well.

In a positive result, a stable lattice structure is formed and is seen as a layer of red blood cells across the bottom of the well. A negative result is seen as a compact red blood cell button at the center of the well, as no lattice has been formed.

The operator performs validation of the final results.

Donors require testing for weak D. Follow facility specific policies guidance for determining which samples require weak D testing.

<table>
<thead>
<tr>
<th>Reagent sera with donor red blood cells</th>
<th>Anti-D Control</th>
<th>DIP** Test</th>
<th>DAT*</th>
<th>Interpretation</th>
</tr>
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<tbody>
<tr>
<td>+</td>
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<td>+ Rh positive</td>
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<tr>
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<td>Rh negative</td>
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<tr>
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<td>0</td>
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<tr>
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<td>0</td>
<td>+</td>
<td>+</td>
<td>Invalid Test</td>
</tr>
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</table>

* A test for weak D may be performed on samples that test negative with Anti-D to determine the Rh status. Solidscreen II Anti-D (RH1)Blend is used to test donor blood samples which have been tested negative with IgM anti-D using Enzytype S in the TANGO® optimo. A reagent containing an IgG Anti-D must be used.
** Testing is not valid unless the sample can be shown to react negatively with an appropriate Rh control or exhibits a negative direct antiglobulin test.

Positive Result: A layer of cells across the bottom of the well.

Negative Result: A compact cell button at the bottom of the well.

Limitations
• Low frequency antigens may not always be present on Reagent Red Blood Cells, and a double dose of antigen may be required to detect very weakly reacting antibodies. Therefore, negative reactions with the screening cells do not always indicate the absence of unexpected antibodies. Such antibodies are usually directed against the known antigens present on the screening cells, but may be directed against an antigen not indicated on the antigenic constitution matrix.
• Insufficient or inappropriate washing can lead to false negative or false positive reactions. Small amounts of residual patient sera/plasma can neutralize the Anti-Human Globulin.

• There is no anti-complement activity with this product. Red blood cells coated with complement will not give a positive reaction.
• Some conditions that may cause false positive results are:
  1. Contamination of sample or reagents
  2. Autoantibodies
  3. Improper storage or preparation of cells
  4. Antibodies to antibiotics or other reagents in the TANGO® optimo test System
  5. Cold Antibodies
  6. Reagent Red Blood Cells not being mixed prior to loading on the TANGO® optimo. (Please see Precautions section in this package insert regarding preparation of Reagent Red Blood Cells for TANGO® optimo.
• Positive reactions may be seen from individuals who have received Rh Immunglobulin.
• Negative reactions will be obtained if the sample contains antibodies present in concentrations too low to be detected by the test method employed. No test method is capable of detecting all red cell antibodies.

Specific Performance Characteristics
Testing is performed in accordance with FDA recommended methods. The final release testing is performed according to the product specific SOPs. Each lot of Biotest reagent is tested in the Quality control by package insert method to insure suitable reactivity.

Solidscreen II Anti-D (RH1) Blend and Anti-Human Globulin Anti-IgG Solidscreen II meet FDA potency requirements.

For the product performance it is necessary to adhere to the recommended method in the instructions for use.

The Anti-D reagents have not been tested with rare phenotypes – D+, D-, RhD and Rhnull. The reactions with enzyme treated red blood cells has not been determined.

Biotest Solidscreen II Anti-D (RH1) Blend is a monochronal blend of two IgG clones suitable for the Solidscreen II Antiblobulin test with the TANGO® optimo to determine weak D's except RH 33 of previously typed samples which have tested negative with IgM anti-D using Erytype S and the TANGO® optimo.

No blood grouping reagent of monoclonal origin has yet been found that will detect all parts of the D antigen.

The performance of the Biotest reagents for Solidscreen II was confirmed against a FDA approved reference reagent in a Multi Center Field Trial.

For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090

Note:
Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations.

Glossary of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
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<td>☑️</td>
<td>Batch Code</td>
<td>☑️</td>
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<td>Temperature limitation</td>
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Bibliography
5. KJ Reis et al. Journal of Immunology 1984

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