Solidscreen II
Microplate for solid phase Anti-globulin Test with TANGO® optimo

FOR IN-VITRO DIAGNOSTIC USE

Package size
REF 806521100 VOL 10 Microplate (12 strips each)

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

Summary
Morescchi first described the use of Anti-Human Globulin in 1900. Combs rediscovered the test in 1945. By injecting rabbits with human IgG, they were able to produce a serum (AIG), that reacted with incomplete antibodies (IgG). Most "incomplete" antibodies (IgG) fail to agglutinate red blood cells suspended in salt. 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 DVI) in donors. There are two very important applications for antibody detection:

1. The detection of red blood cell antibodies prior to red blood cell or whole blood transfusion to prevent the possibility of a transfusion reaction with accompanying red cell destruction.
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.

Structure
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 DVI) of samples which have tested negative with IgM anti-D using Type S and the TANGO® optimo.

The Solidscreen II well is coated with Protein A. Protein A is a component of the cell wall of Staphylococcus aureus and has a very high affinity for the Fc portion of most immunoglobulin classes.

For a) the plasma or serum and Reagent Red Blood Cells are added to the Protein A coated well. Sensitization of the red cell occurs if the corresponding antibody is present for the antigen on the red cell.

For b) Solidscreen II Anti-D Blend Grouping Reagent and test red blood cells are added to the Protein A coated well. Sensitization of the red cell occurs if D antigen is present on the red blood cell.

Following incubation, and two wash processes to remove unbound protein, Anti-Human Globulin is added to the well and acts as a link between the antibody coating of neighbouring red blood cells and induces solid phase. Uncoated red blood cells will form a red blood cell button. Following centrifugation, the well is evaluated. A smooth monolayer of red blood cells is indicative of a positive reaction. A compact button of cells in the middle of the well is indicative of a negative reaction.

Reagent
The Solidscreen II microwell consists of twelve strips containing eight wells per strip. Each well is coated with Protein A. Each Solidscreen II microwell is packaged in a foil container to prevent contamination. Each plate is ready to use.

Precautions
- For in vitro diagnostic use.
- Plates that have been opened and not loaded on the TANGO® optimo may be stored, uncovered, in a dry area, not to exceed 24 hours.
- Reconstituted Red Blood Cells prior to use and insert cell mixers before loading on TANGO® optimo.
- Do not use beyond the expiration date.
- Do not freeze.
- Do not use beyond seven days on the TANGO® optimo.
- Do not attempt to reuse unused portions of the strip.
- Let plate come to room temperature before opening the full packet to limit condensation.
- Store foil packets at 2 to 8°C when not in use.
- Do not use samples collected in gel separator tubes.

Specimen Collection
TANGO® optimo
For antibody screening and antibody identification (Indirect Anti-globulin Test IAT)

Fresh samples of clotted or EDTA anticoagulated whole blood can be used for antibody screening and antibody identification with the indirect antiglobulin test. Samples collected following standard blood sampling guidelines are acceptable. The specimens should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted samples should be stored at 2 to 8°C. Use of samples older than seven days should be avoided, since antibody reactivity has been shown to decrease in older samples. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

Specimen Collection
TANGO® optimo
For crossmatch (Indirect Anti-globulin Test)

Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the crossmatch. Samples collected following standard blood sampling guidelines are acceptable. The specimens should be tested as soon as possible after collection. If testing is delayed, EDTA specimens should be stored at 2 to 8°C, clotted specimens (donor segments) at 1 to 6°C. Use of EDTA anticoagulated samples older than seven days should be avoided, since antibody reactivity has been shown to decrease in older samples. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. Donor segments must be transferred to a secondary tube prior to testing on TANGO® optimo. A minimum volume of 500 µl of red blood cells is required in the secondary tube. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

For Direct Anti-globulin Test (DAT)

Fresh samples of EDTA anticoagulated whole blood samples and cord blood samples must be used for the Direct Anti-globulin Test. Samples collected following standard blood sampling guidelines are acceptable. The specimens should be tested as soon as possible after collection. If testing is delayed, EDTA anticoagulated whole blood samples should be stored at 2 to 8°C. Use of samples older than seven days should be avoided unless there is no other alternative since antibody reactivity has been shown to decrease in older samples. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

For weak D and partial D antigen typing (Indirect Anti-globulin Test IAT)

Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the weak D test. Samples collected following standard blood sampling guidelines are acceptable. The specimens should be tested as soon as possible after collection. If testing is delayed, EDTA anticoagulated whole blood samples should be stored at 2 to 8°C. EDTA anticoagulated whole blood samples may be tested for up to seven days following collection. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. Donor segments must be transferred to a secondary tube prior to testing on TANGO® optimo. A minimum volume of 500 µl of red blood cells is required in the secondary tube. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

Materials
- Solidscreen II microwells

Material required but not provided
- TANGO® optimo REF 849000100
- Isotonic saline
- MLB 2 moulded LISS Bio-Rad REF 605200100
- Biostat* Pool REF 816601000, Biostat* 1 & 2 REF 816014100, Biostat* 3 REF 816085100, Biostat* 4 & 8 REF 816201000, Biostat* 11 REF 816201000, Biostat* 11 Plus REF 816202100
- Donor or patient red blood cells
- Solidscreen II Anti-D (Rh) Blend REF 806530100
- AlloSensor Solution REF 806510100
- Anti-Human Globulin Anti-IgG Solidscreen II REF 806516100
- Solidscreen II Control REF 806519100
- Solidscreen II Control B REF 806519100
- Solidscreen II Negative Control REF 806559100
- PBS pH 7.3 ± 0.2
- Centrifuge (optional)
- Cell Mixers

Procedure
Indirect Anti-globulin Test (IAT)

Crossover, antibody screening and antibody identification

1. TANGO® optimo dispenses a suspension of red blood cells with MLB 2. Suspension of donor red blood cells is prepared with MLB 2 and AlloSensor Solution.
2. TANGO® optimo dispenses a suspension of Reagent Red Blood Cells with MLB 2 and AlloSensor Solution.
3. TANGO® optimo dispenses a prepared Reagent Red Blood Cells into the well with 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. Anti-Human Globulin Anti-IgG Solidscreen II is added to each well, mixed and centrifuged.
8. The reaction is evaluated and interpreted by TANGO® optimo.

Direct Anti-globulin Test (DAT)

1. TANGO® optimo prepares a suspension of patient or donor red blood cells with MLB 2 and AlloSensor Solution.
2. TANGO® optimo dispenses prepared red blood cells of the patient or donor into the Solidscreen II strip well.
3. Following centrifugation, the supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
4. Anti-Human Globulin Anti-IgG Solidscreen II is added to each well, mixed and centrifuged.
5. The reaction is evaluated and interpreted by TANGO® optimo.

BIO-RAD
Weak D and partial D antigen (DV and DVI) typing

2. TANGO® optimo prepares a suspension of donor red blood cells with MLB 2 and AlloStays Solution.
3. TANGO® optimo dispenses prepared donor red blood cells into the well with SolidScreen II Anti-D (RH) Blend Blood Grouping Reagent.
4. 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. Contribution follows each wash process.
8. Anti-Human Globulin Anti-IgG SolidScreen II is added to each well, mixed and incubated.
9. The reaction is evaluated and interpreted by TANGO® optimo.

Stability of the Reaction

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 test. The operator performs validation of the final results.

Quality Control

A minimum of one positive and one negative control should be run each day before testing or according to local requirements to ensure that the reagents, antisera and analyser are functioning properly. SolidScreen II Control (containing diluted Anti-D) or SolidScreen II Control I (containing diluted Anti-D) can be used as the positive control. The SolidScreen II Negative Control can be used as a negative control.

Interpretation of QC

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.

Interpretation of 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 test. The operator performs validation of the final results.

For donors requiring testing for weak D, please follow facility specific policies for weak D testing.

<table>
<thead>
<tr>
<th>Reactions with donor red blood cells</th>
<th>Interpretation</th>
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<tbody>
<tr>
<td>Anti-D Control</td>
<td>DAT**</td>
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<tr>
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<td>0</td>
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<tr>
<td>0+</td>
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<td>0+</td>
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<td>+</td>
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</tbody>
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* = agglutination
0 = no agglutination

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 (RH) Blend is used to test donor blood samples which have been tested negative with IgM anti-D using Erythro 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

- The intended use of the antiglobulin cross matching using Anti-Human Globulin Anti-IgG SolidScreen II on the TANGO® optimo is the detection of incompatibilities due to T cells, it is not intended for the detection of AB incompatibilities.
- 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 constellation matrix.
- Insufficient or inappropriate washing can lead to false negative or false positive reactions. Small amounts of residual patient serum/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:
- Contamination of sample or reagents
- Autoantibodies
- Improper storage or preparation of cells
- Antibodies to antigens or other reagents in the TANGO® optimo test System
- Cold Antibodies
- 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 immunoglobulin.
- 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.
- SolidScreen II is designed to detect antibodies in physiologic samples containing plasma or serum. Antibodies in antigen samples lacking serum or plasma might not be detected.

Specific Performance Characteristics

Testing is performed in accordance with FDA recommended methods.

The final release testing is performed according to the product specific SOPs. As part of the release process each lot of Bio-Rad reagent is tested according to the package insert method to insure suitable reactivity. SolidScreen II Anti-D (RH) 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−, Rhnull and Rhnull. The reactions with enzyme treated red blood cells have not been determined.

Bio-Rad SolidScreen II Anti-D (RH) Blend is a monoclonal blend of two IgG clones suitable for the SolidScreen II Antiglobulin test with the TANGO® optimo to determine weak D's except Rh33. It should be used for samples which have tested negative with IgM anti-D using Erythro 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 Bio-Rad 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 Bio-Rad Laboratories Inc. at 800-224-6773.

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>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td>In vitro diagnostic medical device</td>
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<tr>
<td>☐</td>
<td>Consult accompanying documents</td>
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<td>Consult instructions for use.</td>
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<td>M</td>
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<td>Use by YYY-MM-DD</td>
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<td>Contains sufficient quantity for 100 tests.</td>
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<td>Catalog number</td>
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<td>Temperature limitation</td>
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Bibliography

5. KL Reis et al. Journal of Immunology 1964

Key

+ = Addition of changes
- = Deletion of text

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