Solidscreen II
Microplate for solid phase Antigen Test with TANGO® oplimo

IN-VITRO DIAGNOSTIC USE

Package size
REF 80521100 VOL 10 Microplate (12 strips each)

Intended Use
Solidscreen II is used for the TANGO® oplimo. The Solidscreen II solid phase antigen test is used as an indirect antigen (IAT) test for crossmatch, antibody screening and antibody identification, as well as direct antigen test (DAT) for the detection of weak D and partial D antigens (Dw and Dw) in donor blood samples.

Summary
Mareeck first described the use of Anti-Human Globulin in 1980. 

Principle

Solidscreen II is a solid phase assay for:
1. The detection of red blood cell antibodies or auto-antibodies in human plasma or serum.
2. The detection of weak D and partial D antigens (Dw and Dw) of samples which have tested negative with IgM anti-D using Erytype S and the TANGO® oplimo.

The Solidscreen II well is coated with Protein A, Protein B is a component of the cell wall of Staphylococcus aureus and has a very high affinity for the FC portion of most immunoglobulins.

For all the plasma or serum and Reagent Red Blood Cells are added to the Protein A coated well. Sample dilution occurs if the corresponding antibody is present for the antigen on the red 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 the neighboring 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 micronizer 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 microplate consists of twelve strips containing eight wells per strip. Each well is coated with Protein A. Each Solidscreen II microplate 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® oplimo may be stored, uncovered, in a dry area, at not to exceed 24 hours.
- Reconstitute Red Blood Cells prior to use and insert cell mixers before loading on TANGO® oplimo.
- Do not use beyond the expiration date.
- Do not freeze.
- Do not use beyond seven days on the TANGO® oplimo.
- Do not attempt to reuse unused portions of the strip.
- Let plates come to room temperature before opening the foil 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® oplimo

For antibody screening and antibody identification (Indirect Antigen Test (IAT))
Fresh samples of clotted EDTA or EDTA anticoagulated whole blood can be used for antibody screening and antibody identification with the indirect antigen test. Samples collected following standard blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA specimens should be stored at 2 to 8°C, citrated specimens (10% citrate) at 2 to 8°C. Use of EDTA anticoagulated specimens older than seven days should be avoided, since antibody reactivity has been shown to decrease in older samples. 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 plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

For crossmatch (Indirect Antiglobulin Test)
Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for 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, citrated specimens at 2 to 8°C. Use of EDTA anticoagulated samples older than seven days should be avoided, since antibody reactivity has been shown to decrease in older samples. 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 plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

For Direct Antiglobulin Test (DAT)
Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the Direct 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 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 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 plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

For weak D and partial D antigen typing (Indirect Antiglobulin Test (IAT))
Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the IAT. Samples collected following standard blood sampling guidelines are acceptable. The specimen 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 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. The red blood cells to be tested must be prepared prior to testing. Refer to Instructions in the TANGO® oplimo User’s Guide. 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 plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

Materials

Materials Provided
- Solidscreen II microplates

Materials required but not provided
- TANGO® oplimo
- Isotonic saline
- MLB 2 (modified ISS Hia Rap) REF 80200100
- Biocitrost® Pod REF 80665100, Biocitrost® 1 & 2 REF 80614100, Biocitrost® 3 REF 80658500, Biocitrost® 1 & 2 REF 801020100, Biocitrost® 3 REF 80661300
- Search-Cyte® Psi, or Search-Cyte Dia®, or Search-Cyte Trio for the TANGO® oplimo
- Donor or patient red blood cells
- Solidscreen II Anti-D (Dw) Blend REF 80555100
- AlereMia Solution REF 80561000
- Anti-Human Globulin Anti-IgG (Solidscreen II) REF 80558160
- Solidscreen II Control REF 80551410
- Solidscreen II Control B REF 80651500
- Solidscreen II Negative Control REF 80690100
- PBS pH 7.5 ± 0.2
- Centrifuge
- Cell Mixers

Test Procedure
Indirect Antiglobulin Test (IAT)

Crossmatch, antibody screening and antibody identification
1. TANGO® oplimo dispenses 50μl of patient serum/plasma or control reagents into the Solidscreen II microplate.
2. TANGO® oplimo prepares a 1% suspension of Reagent Red Blood Cells with MLB 2. An approx 1% suspension of donor red blood cells is prepared with MLB 2 and AlereMia Solution.
3. TANGO® oplimo 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 pipetted off and the wash is discarded. Centrifugation follows each wash process.
7. 500μl of Anti-Human Globulin Anti-IgG Solidscreen II is added to each well and mixed.
8. Centrifugation by TANGO® oplimo
9. The test is evaluated and interpreted by TANGO® oplimo.

Direct Antiglobulin Test (DAT)

1. TANGO® oplimo prepares an approx 1% suspension of patient or donor red blood cells with MLB 2 and AlereMia Solution.
2. TANGO® oplimo 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. 200 µl of Anti-Human Globulin Anti-IgG Solidscreen II is added to each well and mixed.

5. Centrifugation by TANGO® optimo.

6. Reaction is evaluated and interpreted by TANGO® optimo.

**Week D and partial D antigen (DVI and DVI-II) typing**

1. The TANGO® optimo dispenses 50 µl of Solidscreen II Anti-D (RhI) Blend onto an assigned solidwell.

2. TANGO® optimo prepares a 1% suspension of donor red blood cells with ULP 2 and Allovert Solution.

3. TANGO® optimo dispenses 50 µl of the donor red blood cells prepared in (2) into the well with Solidscreen Anti-D (RhI) 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, analyzer and analyzer are functioning properly. Controls should be run whenever:

- Lot numbers change (plate, reagent).
- A new bottle or preparation is placed on the system (red blood cells, Anti I, ULP 2).
- After service/repair of the analyzer.

Two positive controls, Solidscreen II Control and Control D are available for testing on the TANGO® optimo. The Solidscreen II Control contains diluted anti-D and the Control D 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 D 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/control 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 it 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, with no lattice has been formed.

The operator performs validation of the final results.

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

<table>
<thead>
<tr>
<th>Reagent seen with donor red blood cells</th>
<th>Anti-D</th>
<th>Control</th>
<th>DVI test</th>
<th>DVI-II*</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>+</td>
<td>0</td>
<td>0</td>
<td>Rh positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Rh negative</td>
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<td></td>
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<tr>
<td>0</td>
<td>0</td>
<td>+</td>
<td>Rh positive</td>
<td></td>
<td></td>
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<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>Invalid Test</td>
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<td></td>
</tr>
<tr>
<td>+</td>
<td>0</td>
<td>0</td>
<td>Invalid Test</td>
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<td></td>
</tr>
<tr>
<td>* = agglutination</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
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</tr>
</tbody>
</table>

*A test for week D may be performed on samples that test negative with Anti-D to determine the Rh status. Solidscreen II Anti-D (RhI)Blend is used to test donor blood samples which have been tested negative with light anti-D using Enzyme B 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 test control exhibiting a negative direct antiglobulin test.**

**Positive Results**: A layer of cells across the bottom of the well.

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

**Limitations**

- The intended use of the anti-D reagent is to detect anti-D in recipients due to Rh antibodies. It is not intended for the detection of DBO incompatibilities.
- Low frequency antigens may not always be present on recipient 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 antigens constitution matrix.
- Insufficient or inappropriate washing can lead to false negative or false positive reactions. Small amounts of residual patient sample can neutralize the Anti-D Globulin.
- There is no add-component 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. Antibody to antibodies 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).

**Specific Performance Characteristics**

Testing is performed in accordance with FDA recommended methods. The final test result is performed according to the product specific SOPs. Each lot of Anti-D reagent is tested in the Quality Control by package insert method to ensure suitable reactivity.

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

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

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

**Bio-Rad Solidscreen II Anti-D (RhI) Blend is a monocholinol blend of two IgG classes suitable for the Solidscreen II Anti-D test with the TANGO® optimo to determine week D's except RH 33 (previously typed samples which have tested negative with light anti-D using Enzyme B and the TANGO® optimo). No blood grouping reagent of monocholinol edred 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 Diagnostics Corporation at 800-294-6723.

**Note**

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>D</td>
<td>Dash Code</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>Δ</td>
<td>Caution, consult accompanying documents</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>M</td>
<td>Manufacturer</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>V</td>
<td>Contains sufficient quality for on tests</td>
<td>REF</td>
<td>Catalog number</td>
</tr>
<tr>
<td>†</td>
<td>Temperature limitation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Bibliography**

5. KJ Reif et al. Journal of Immunology 1984

**Key:** Underline = Addition of changes. ▲ = Deletion of text

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