US

Solidscreen II

Microplate for solid phase Antiglobulin Test with TANGO® optimo

FOR IN-VITRO DIAGNOSTIC USE

Package size

REF 806521100 VOL 10 Micotestplate (12 strips each)

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 for the determination of weak D and partial D antigens (DVI and DVII)in donor blood samples.

Summary

Moreschi first described the use of Anti-Human Globulin in 1908[1]. Coombs rediscovered the test in 1945.[2,3] By injecting rabbits with human IgG, they were able to produce a protein (Anti-IgG) that reacted with incomplete antibodies (IgG). Most "incomplete" antibodies (IgG) fail to agglutinate red blood cells suspended in saline.[4] 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 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.

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.

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[5].

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 Blood Grouping Reagent and test red blood cells are added to the Protein A coated well. Sensitization of the red blood 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 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® optimo may be stored, uncovered, in a dry area, not to exceed 24 hours.
- Resuspend Reagent 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 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® optimo

For antibody screening and antibody identification (Indirect Antiglobulin 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 specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted specimens should be stored at 2 to 8°C. Use of samples older 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.

For crossmatch (Indirect Antiglobulin 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 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 (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. These red blood cells to be tested must be prepared prior to testing. Refer to instructions in the TANGO® otimo Users Guide [6].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 Antiglobulin Test (DAT)

Fresh samples of EDTA anticoagulated whole blood samples and cord blood samples must be used for the Direct Antiglobulin 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 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 Antiglobulin 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 specimen should be tested as soon as possible after collection. If testing is delayed the EDTA anticoagulated 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. The red blood cells to be tested must be prepared prior to testing. Refer to instructions in the TANGO® optimo Users Guide. [4] 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

Materials Provided

- Solidscreen II microplates

Material required but not provided

- TANGO® optimo REF 848900010
- Isotonic saline
- MLB 2 (modified LISS Biotest) REF 805200100
- Biotestcell® Pool REF 816065100, Biotestcell® 1 & 2 REF 816014100, Biotestcell® 3 REF 816085100, Biotestcell®-I 8 REF 816020100, Biotestcell®-I 11 REF 816021100
- 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)

Crossmatch, antibody screening and antibody identification

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 Solidscreen II is added to each the 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 Solidscreen II is added to each the 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 uL 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 uL 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 or 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 uL 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 numbers 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.

Reagent sera with donor red blood cells				
Anti-D	Control	D^{weak}Test	DAT**	Interpretation
+	0	/	/	Rh positive
0	0	0	0	Rh negative
0	0	+	0	* Rh positive
0	0	+	+	Invalid Test
+	+	/	/	Invalid Test

+ = 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 (RH1)Blend is used to test donor blood samples which have been tested negative with IgM anti-D using Erytype 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., Rhmod and Rhnull. The reactions with enzyme treated red blood cells has not been determined.
Biotest Solidscreen II Anti-D (RH1) 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 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

Symbol	Definition	Symbol	Definition
LOT	Batch Code	IVD	*In vitro* diagnostic medical device
⚠	Caution, consult accompanying documents		Consult instructions for use.
	Manufacturer		Use by YYYY-MM-DD
	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation		

Bibliography

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4. Pittiglio, D. Harmening. Modern Blood Banking and Transfusion Practices. Philadelphia, PA: F.A. Davis, 1983.
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Key: Underline = Addition of changes ◄ = Deletion of text

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