Solidscreen® II

Microplate for Solid Phase Antiglobulin Tests with TANGO® instruments

FOR IN-VITRO DIAGNOSTIC USE
Rx only

PACKAGE SIZE
REF 806521100 VOL 10 Microplate (12 strips each)

INTENDED USE

The Solidscreen® II solid phase antiglobulin test is intended for the detection of red blood cell antibodies and antigens in the indirect and direct antiglobulin tests with the solid phase assay Solidscreen® II on TANGO® instruments.
Following immunohematological solid phase antiglobulin assays can be tested with the instruments:

- **TANGO® optimo**: antibody screening, antibody identification, crossmatch, DAT, antigen typing of weak D/partial D antigen (DVI and DVII).
- **TANGO infinity™**: antibody screening, antibody identification, crossmatch, auto control, DAT, antigen typing of weak D/partial D antigen (DVI and DVII).

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. 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 pre-transfusion studies always include tests for alloantibodies or autoantibodies directed against human red blood cells

PRINCIPLE

Solidscreen® II is a solid phase assay for
a) the detection of red blood cell antibodies 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.

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 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® instruments may be stored, uncovered, in a dry area, not to exceed 24 hours.
- Do not use beyond the expiration date
- Do not freeze
- Do not use beyond seven days on the TANGO® instruments
- 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
- Consult **downloads.bio-rad.com** to download the valid version of this instruction for use.

SPECIMEN COLLECTION

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 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.

For crossmatch and auto control* (IAT)

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 red blood cells stored in citrate anticoagulant CPD, CP2D, CPDA-1, AS-1 or AS-3 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® instruments. 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.
* Auto control testing is not approved for the use with TANGO® optimo.

For Direct Antiglobulin Test (DAT)

Fresh samples of EDTA anticoagulated whole blood samples and cord blood samples (cord blood samples are not approved for TANGO® optimo) 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, 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 (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. Donor segments must be transferred to a secondary tube prior to testing on the instruments. A minimum volume of 500 µL of red blood cells is required in the secondary tube.
Donor and patient samples can be tested on TANGO infinity™.
Testing of cord blood samples on TANGO infinity™ is only approved by Health Canada.
Only donor samples are approved for testing on the TANGO® optimo.
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

Material required but not provided

- TANGO® optimo REF 848900010
- TANGO infinity™ REF 850000010
- Deionized water
- MLB 2 (modified LISS Bio-Rad) 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, Biotestcell®-I 11 Plus REF 816022100
- 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
- Washing Solution Concentrate REF 848000091
- Sodium hydroxide solution (0.5 N NaOH)
- Centrifuge (optional)
- Cell Mixers

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TEST PROCEDURE
Please refer to the instructions for use in the appropriate instrument User Manual.

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 and automated system components are functioning properly.

Solidscreen® II Control (containing diluted Anti-D) or Solidscreen® II Control B (containing diluted Anti-c) 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 instrument the results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the 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.

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® instruments is the detection of incompatibilities due to IgG antibodies, it is not intended for the detection of ABO 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 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:
- Contamination of sample or reagents
- Autoantibodies
- Improper storage or preparation of cells
- Antibodies to antibiotics or other reagent components
- Drug therapy with monoclonal antibodies
  Reagent Red Blood Cells not being mixed prior to loading on the TANGO® instruments
- Positive reactions may be seen from individuals who have received Rh Immunglobulin.
- Sample hemolysis prior testing may lead to false negative results.
- 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 artificial 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.

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

The performance of the Bio-Rad reagents for Solidscreen® II was confirmed against a FDA approved reference reagent in a multi-center clinical trial.

Performance Characteristics for crossmatch (Indirect Antiglobulin Test) on the TANGO infinity
A multi-center clinical trial, which included testing at two different US clinical sites and an internal site, was conducted to evaluate the performance of Anti-Human Globulin Anti-IgG Solidscreen II for AHG crossmatch testing on the TANGO infinity. The clinical trial included testing of patient and donor samples. The positive and negative percent agreements were calculated for the Anti-Human Globulin Anti-IgG Solidscreen II for AHG crossmatch testing in comparison to the FDA licensed reference methods. Additional internal studies have been performed with well-characterized samples to evaluate the performance of the AHG crossmatch testing on the TANGO infinity™.

Results of the positive percent agreement and negative percent agreement, with the one-sided Exact 95% Lower Confidence Limit (LCL) are listed in the data table below. Note: See the TANGO infinity User Manual for more information on verification of results.

Results from Clinical Trials

Test	Negative Agreement N	Negative Agreement Point Estimate (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement Point Estimate (one-sided Exact 95% LCL)
IAT Crossmatch	539	98.70% (97.57%)	449	99.33% (98.28%)

Results from In-House Study with well-characterized samples

Test	Negative Agreement N	Negative Agreement Point Estimate (one-sided Exact 95% LCL)	Positive Agreement N	Positive Agreement Point Estimate (one-sided Exact 95% LCL)
IAT Crossmatch	344	100% (99.13%)	320	100% (99.07%)

All discrepancies in positive and negative percent agreement were at one clinical site. During resolution testing (antiglobulin crossmatch/tube method) at a referee laboratory, four initially discrepant results were in agreement, and six remained discordant (including 4 resulted by the TANGO infinity as equivocal).
Agreement between the methods does not imply which method obtained the correct result.
The results in the above tables do not reflect any discrepancy resolution between the methods.

For Technical Support or further product information, contact Bio-Rad Laboratories Inc. at 800-224-6723.

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
⚠	Consult the instructions for use for important cautionary information such as warnings and precautions		Consult instructions for use
	Manufacturer		Use by YYYY-MM-DD
	Contains sufficient quantity for <n> tests	REF	Catalog number
	Temperature limitation		

Bibliography
1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakt 1908; 46:49,456
2. Coombs, RRA, Mourant, AE and Race, RR: "A new test for the detection of weak and "incomplete" Rh agglutinins." Br J Exp Pathol 26:255, 1945
3. Coombs, RRA, Mourant AE and Race, RR: "In vivo isosensitization of red blood cells in babies with hemolytic disease." Lancet i: 264, 1946
4. Pittiglio, D. Harmening. Modern Blood Banking and Transfusion Practices. Philadelphia, PA: F.A. Davis, 1983.
5. KJ Reis et al. Journal of Immunology 1984

Key: Underline = Addition of changes ◄ = Deletion of text

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2020-11-27