For in-vitro diagnostic use.

**Package size**

**Ref.** 806521100  **VOL** 10 Microplate (12 strips each)

**Intended Use**

The Solidscreen® II solid phase anti-globulin test is intended for the detection of red blood cell antibodies and antigens in the indirect and direct anti-globulin tests with the solid phase assay Solidscreen® II on TANGO® instruments.

Following immunohematological solid phase anti-globulin assays can be tested with the instruments:

- **TANGO® optimo**: antibody screening, antigen identification, crossmatch, DAT, antigen typing of weak D, partial D antigens (DVI and DVII).
- **TANGO® infinity**: auto-detection, antigen identification, crossmatch, auto-control, DAT, antigen typing of weak D, partial D antigens (DVI and DVII). *Crossmatch on TANGO infinity is not approved by the FDA.*

**Summary**

Morschedt first described the use of Anti-Human Globulin in 1908. Coombs rediscovered the test in 1945. 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. 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 blood group antigens in the plasma of a patient/donor sample is a useful tool for pretransfusion studies. Routine pretransfusion studies always include tests for alloantibodies or autoantibodies directed against human red blood cells.

**Principle**

Solidscreen® II is a solid phase assay for:

- the detection of red blood cell antibodies in human plasma or serum.
- the determination of weak D and partial D antigens (DVI and DVII) of samples which have tested negative with IgM and IgG anti-Erytpe®.

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 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 cell occurs if D antigen is present on the red blood cell.

Prior to incubation, 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 coated well will form a red blood cell button. Following centrifugation the well is evaluated. A coated well will form a red blood cell button. The well is evaluated. A coated well will form a red blood cell button. Following centrifugation the well is evaluated. A coated well will form a red blood cell button. The well is evaluated.

**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 pack to limit condensation.
- Store foil packs at 2 to 8°C when not in use.
- Do not use samples collected in gel separator tubes.

**Specimen Collection**

- For antibody screening and antigen identification (Indirect Antiglobulin Test IAT)
  - Fresh samples of EDTA or citrate anticoagulated whole blood samples can be used for antigen 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 citrate blood 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. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor. Donor samples must be transferred to a secondary blood bank for testing on TANGO® optimo. A minimum volume of 500 µL of red blood cells is required in the secondary bank.
  - 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.
  - Crossmatch testing is not approved by the FDA for the use with TANGO® infinity. *Crossmatch 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 and samples collected following standard blood sampling guidelines must be used on the 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. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. Donor samples must be transferred to a secondary blood bank for testing on the instruments. A minimum volume of 500 µL of red blood cells is required in the secondary bank.
  - Donor and patient samples can be tested on TANGO infinity.
  - For direct antiglobulin testing on the TANGO® optimo, 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.

**Testing of blood samples on TANGO infinity is only approved by Health Canada.**

**Materials provided**

- **Solidscreen® II**
- **TANGO® optimo**
- **TANGO® infinity**
- **MLB 2 (modified Liss Bio-Rad)**
- **Biotestcell® Pool**
- **Biotestcell® 1 & 2**
- **Biotestcell® 3**
- **Biotestcell® I & II**
- **Biotestcell® I & II Plus**
- **II Anti-D Control**
- **II Control B**
- **II Anti-Human Globulin Anti-IgG Solidscreen® II**
- **II Control**
- **II Control B**
- **II Negative Control**
- **II Conjugate Concentrate**
- **Centrifuge (optional)**
- **Cell Mixers**

**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. 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 failure.

**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 failure.

**Interpretation of Results**

For control samples, 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 antigens or other reagent components.
  - 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.
  - 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 ensure 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.

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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
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<tr>
<td>DVD</td>
<td>In vitro diagnostic medical device</td>
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<td>Caution, consult accompanying documents</td>
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<td>Consult instructions for use.</td>
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<tr>
<td>☢️</td>
<td>Temperature limitation</td>
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Bibliography
1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakter 1908; 46:49,456
5. KJ Reis et al. Journal of Immunology 1984

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