

**Solidscreen® II** Microplate for Solid Phase Antibody Tests with TANGO® instruments

**FOR IN-VITRO DIAGNOSTIC USE**

**Package size**

<table>
<thead>
<tr>
<th>REF</th>
<th>VOL</th>
</tr>
</thead>
<tbody>
<tr>
<td>806521100</td>
<td>10 Microplate (12 strips each)</td>
</tr>
</tbody>
</table>

**Intended Use**

The Solidscreen® II solid phase antibody test is intended for the detection of red blood cell antibodies and antigens in the indirect and direct antigen tests with the solid phase assay Solidscreen® II on TANGO® instruments. Following immunohematological solid phase antibody 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 Dipartial D antigen (DVI and DVIi).
- *Crossmatch on TANGO infinity is not approved by the FDA.*

**Summary**

Moorsch described the use of Anti-Human Globulin in 1908.1 Coombs rediscovered the test in 1945.2 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.3 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 death.
2. To detect the presence of red blood cell antibodies in maternal or newborn samples for antibody screening and antibody identification with the indirect antiglobulin test.

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 (D VI and DVII) of samples.
- the detection of red blood cell antibodies in human plasma or serum.

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 assay to work, sensitization of the red cells 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 an antigen is present on the red blood cell.

Front line incubation, and two wash processes to remove unbound protein, Antibody 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. The 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

**Specification Collection**

- For antibody screening and antibody identification (Indirect Antiboglobin Test (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 and citrated 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. 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 Antigen Test (DAT)**

Fresh samples of EDTA anticoagulated whole blood samples and cord blood samples (cord blood samples are used as a positive control for TANGO® optimo) must be used for the Direct Antigen Test (DAT). 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 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, 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 instrument. A minimum volume of 500 µL of red blood cells is required in the secondary tube.

**Materials**

- **Solidscreen® II**
- **Anti-Human Globulin Anti-IgG Solidscreen® II Control (containing diluted Anti-D) or Solidscreen® II Control (containing diluted Anti-c) can be used as the positive control. The Solidscreen® II Negative Control can be used as a negative control.**

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

**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.

**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.

**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.
- Contamination of sample or reagents
- Autoantibodies
- Improper storage or preparation of cells
- Antibodies to antibiotics 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 Rho 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.

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>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>[LOT]</td>
<td>Batch Code</td>
<td>[IVD]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>△</td>
<td>Caution, consult accompanying documents</td>
<td>☑</td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td>⚩</td>
<td>Manufacturer</td>
<td>☑</td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td>🍀</td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
<td>☑</td>
<td>Catalog number</td>
</tr>
<tr>
<td>✓</td>
<td>Temperature limitation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Bibliography
1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakt 1908; 46:49,456
5. KJ Reis et al. Journal of Immunology 1984