Individuals using assistive technology may not be able to fully access the information contained in this file. For assistance, please send an e-mail to: ocod@fda.hhs.gov and include 508 Accommodation and the title of the document in the subject line of your e-mail.
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® optima**: antibody screening, antibody identification, crossmatch, DAT, antigen typing of weak D, partial D antigen (DV and DVI).
- **TANGO® infinity®**: antibody screening, antibody identification, crossmatch, autocontrol, DAT, antigen typing of weak D, partial D antigen (DV and DVI).

Summary
Moreschi first described the use of Anti-Human Globulin in 1908. Coombs and Cross later adapted this for use in the indirect antiglobulin test. Following immunohematological solid phase antiglobulin assays can be tested with the instruments:

- **TANGO® optima**: antibody screening, antibody identification, crossmatch, DAT, antigen typing of weak D, partial D antigen (DV and DVI).
- **TANGO® infinity®**: antibody screening, antibody identification, crossmatch, autocontrol, DAT, antigen typing of weak D, partial D antigen (DV and DVI).

For crossmatch and autocontrol (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 samples should be stored at 2 to 8°C. EDTA citrate samples (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 used until the expiration date of the donor unit. Donor samples 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.

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® optima**) 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 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, EDTA samples should be stored for up to seven days following collection. Donor red blood cell stored in citrate anticoagulant at 1 to 6°C may be tested at the expiration date of the donor unit. Donor samples 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.

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

Materials

- **Materials Provided**
  - Solidscreen® II

Material required but not provided
- **TANGO® optima** [REF] 816014000
- **TANGO® infinity®** [REF] 850000010
- Deionized water
- MLB 2 (modified LIS Bio-Rad) [REF] 805200100
- Donor or patient red blood cells
- Solidscreen® II Anti-D (RH1) Blend [REF] 806530100
- Althesers Solution [REF] 806551010
- 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
- isotonic saline
- TANGO® optimo (optional)
- Cell Mixers

Test Procedure

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 systems components are functioning properly.

Solidscreen® II Control (containing diluted Anti-D) or Solidscreen® II Control B (containing diluted Anti-d) can be used as the negative 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 antigen-antibody 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

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® instruments

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® instruments. 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® instruments.

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.

<table>
<thead>
<tr>
<th>Test</th>
<th>Results from Clinical Trials</th>
<th>Results from In-House Study with well-characterized samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative Agreement</td>
<td>Positive Agreement</td>
</tr>
<tr>
<td>IAT Crossmatch</td>
<td>N</td>
<td>Point Estimate (one-sided Exact 95% LCL)</td>
</tr>
<tr>
<td></td>
<td>539</td>
<td>98.70% (97.57%)</td>
</tr>
</tbody>
</table>

All discrepancies in positive and negative percent agreement were at one clinical site. During resolution testing (antiglobulin crossmatch/tube method) at a reference laboratory, four initially discrepant results were in agreement, and six remained discordant (including 4 resulting from the TANGO® infinity as equivocal).

Glossary of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
</tr>
<tr>
<td>CA</td>
<td>Caution, consult accompanying documents</td>
</tr>
<tr>
<td>M</td>
<td>Manufacturer</td>
</tr>
<tr>
<td>U</td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td>S</td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
</tr>
<tr>
<td>T</td>
<td>Temperature limitation</td>
</tr>
<tr>
<td>VD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>REF</td>
<td>Catalog number</td>
</tr>
</tbody>
</table>

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

For Technical Support or further product information, contact Bio-Rad Laboratories Inc. at 1-800-224-6723.

Note

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

Bibliography

1. Moresch C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakt 1908; 46:49,506
5. KJ Reis et al. Journal of Immunology 1984