Solidscreen II

Package size
REF 806521100

Please note: The use of symbols was implemented for product labeling associated with the TANGO® System. A glossary of symbols and their definitions is available in this package insert.

Intended Use
Solidscreen II is used for the detection of red blood cell alloantibodies in human plasma or serum with the TANGO® System.

Summary
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.

Principle
Solidscreen II is a solid phase assay for the detection of red blood cell alloantibodies or autoantibodies 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.[1]

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. Following incubation, and two wash processes to remove unbound protein, Anti-Human Globulin is added to the well. Following centrifugation, the well is evaluated. A smooth monolayer of 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® Automated Blood Bank Analyzer may be stored, uncovered, in a dry area, not to exceed 24 hours.
- Resuspend Search-Cyte® Reagent Red Blood Cells for and insert cell mixers before loading on TANGO®.
- Do not use beyond the expiration date.
- Do not freeze.
- Do not use beyond seven days on the TANGO® Automated Blood Bank Analyzer.
- 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 2-8°C when not in use.
- Do not use samples collected in gel separator tubes.

Specimen Collection
Collect specimens using a standard accepted aseptic collection method. Plasma or serum is suitable for testing. Fresh samples are preferred for antibody screening. If the samples are not tested within 24 hours of collection, store samples between 2-8°C. Allow the sample to reach room temperature before testing. Samples may be tested up to seven days after collection.

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.

Procedure
Materials Provided
- Solidscreen II Microplate

Materials required but not supplied
- TANGO® Automated Blood Bank Analyzer
- Isotonic saline
- MLB 2
- Search-Cyte® Pool, or Search-Cyte Duo®, or Search-Cyte® Trio for the TANGO® System
- Anti-IgG Solidscreen II
- PBS pH 7.3
- Centrifuge
- Cell Mixers

Test Method
1. The TANGO® Automated Blood Bank Analyzer dispenses 50 uL of patient serum/plasma into the Solidscreen II microplate well.
2. TANGO® prepares a 1% suspension of antibody screen cells with MLB 2.
3. TANGO® dispenses 50 uL of the antibody screen cells prepared in (2.) into the well with patient serum/plasma.
4. The TANGO® Automated Blood Bank Analyzer mixes the serum/plasma and 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 is washed twice. Centrifugation follows each wash process.
8. 100 uL of Anti-IgG Solidscreen II is added to the well and mixed.
9. Centrifugation by TANGO®
10. Reaction is evaluated and interpreted by Tango.

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.

A positive control, Solidscreen II Control is available for testing on the TANGO®. The Solidscreen II Control contains dilute anti-D. The negative control may be selected from previously tested blood samples. Controls should be selected from samples that are less than 7 days old. Clotted, hemolyzed, or grossly lipemic samples should not be used for Quality Control samples.

A minimum of one positive and one negative plasma/serum should be run for the Solidscreen II assay. The Solidscreen II Control can be used as the positive control.

Interpretation
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
The results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® Automated Blood Bank Software evaluate, and provide an interpretation (positive/negative) for the well. 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
- Low frequency antigens may not always be present on Search-Cyte® 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. Cells coated with complement will not give a positive reaction.
- False test results may occur, but are not limited to:

    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® Test System
    5. Cold Antibodies
    6. Screen cells not being mixed prior to loading on the TANGO®. (Please see **Precautions** section in this package insert regarding preparation of Search-Cyte® Reagent Red Blood Cells for TANGO® .

- Positive reactions may be seen from individuals who have received Rh Immunoglobulin.

Specific Performance Characteristics
Series of tests have shown that at least 0.06 IU (WHO standard) anti-D/mL can be detected using Solidscreen II.

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
Σ	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation		

References

1. KJ Reis et al. Journal of Immunology 1984

In case of questionable results of unknown origin contact Biotest (800-522-0090) or Olympus Technical Services (800-223-0130) for assistance.

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