Anti-Human Globulin
Anti-IgG Solidscreen II (Rabbit)

Package size
REF 806516100 FDA Lic. 1702

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.

Note: This product does not contain antibodies to human complement components.

Intended Use
Anti-IgG Solidscreen II is used to detect the sensitization of red blood cells by IgG with the TANGO® System.

Summary
Moreschi first described the use of Antihuman 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 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.

Reagent
Anti-IgG Solidscreen II is an Anti-IgG that is prepared by immunizing rabbits with human IgG. Anti-IgG Solidscreen II may agglutinate IgM and IgA sensitized cells (if reactive at 37°) as well as IgG sensitized cells. There is no reactivity towards complement components. The rabbit serum, containing the Antihuman Globulin, is diluted to a final protein concentration of 8-20g/L. The reagent is supplied in a 55mL glass vial. The final pH is 6-8.

Preservative: 0.1% Sodium Azide.

Meets FDA minimum potency requirements.

Precautions
- **CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.**
- For in vitro diagnostic use
- Resuspend Search-Cyte® Reagent Red Blood Cells for and insert cell mixers before loading on TANGO®.
- Store between 2-8°C.
- Do not use if markedly turbid. Marked turbidity may indicate reagent contamination. Contamination may lead to false negative and/or false positive reactions.
- **Warning: Contains sodium azide, which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the build-up of explosive metal azides.**
- Do not dilute. Do not use beyond the expiration date printed on the vial.
- Do not use beyond seven days when opened and loaded on the TANGO® Automated Blood Bank Analyzer.
- Do not freeze.
- Do not use samples collected in gel separator tubes.

Specimen Collection and Preparation
Serum or plasma can be used for the indirect antiglobulin test on the TANGO® Automated Blood Bank Analyzer. Samples should be collected using standard, accepted aseptic phlebotomy techniques. If the samples are not tested within 24 hours of collection, store samples between 2-8°C. For transfusion purposes, the sample can be used no longer than dictated by state and federal regulatory agencies. Samples may be tested for up to seven days on the TANGO®.

There must be a distinct separation of the cellular and plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

Procedure
Materials Supplied
- Anti-IgG Solidscreen II

Materials and Equipment Not Supplied
- TANGO® Automated Blood Bank Analyzer.
- Solidscreen II Microplates
- MLB 2 (Modified LISS Biotest 2)
- **Search-Cyte® Pool, or Search-Cyte Duo, or Search-Cyte® Trio for TANGO® System.**
- Centrifuge
- Isotonic Saline
- PBS pH 7.3
- Cell Mixers

Test Method
1. TANGO® dispenses 50uL 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 50uL of the antibody screen cells prepared in (2.) into the well with patient serum/plasma.
4. The mixture is incubated for 20 minutes at 37°C.
5. The mixture is centrifuged following incubation.
6. The supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
7. 100uL of Anti-IgG Solidscreen II is added to the well and mixed.
8. Centrifugation by TANGO®
9. 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 (Reagent Red blood cells, Anti-IgG Solidscreen II, MLB 2).
- After service/repair of the TANGO® Automated Blood Bank Analyzer.

A positive control, Solidscreen II Control is available for testing on the TANGO®. The Solidscreen II Control contains diluted 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 Analyzer Software evaluate, and provide an interpretation (positive or 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 center 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-IgG Solidscreen II.
- There is no anti-complement activity with this product. Cells coated with complement should 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

- Each lot of Anti-IgG Solidscreen II meets FDA potency requirements.

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. Moreschi C. Neue Tatsache uber die Blutkorperchen 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.

Please contact OLYMPUS Immunohematology Technical Services (Tel: 800-447-5852) if controls repeatedly fail to give expected results.

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