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

FOR IN-VITRO DIAGNOSTIC USE
For Solidscreen II with the TANGO® optimo
U.S. License Number: 1798

Package size

**Intended Use**
Anti-Human Globulin Anti-IgG Solidscreen II for the TANGO® optimo is used for the indirect antiglobulin test to demonstrate the in-vitro IgG coating of red blood cells with antibodies as in antibody screening, antibody identification as well as crossmatch tests and for the use of the Solidscreen II Anti-D Blend Blood Grouping Reagent for weak D and partial D (DV1 and DVII) antigen typing (with the indirect antiglobulin test).

Furthermore Anti-Human Globulin Anti-IgG Solidscreen II for the TANGO® optimo is used for the direct antiglobulin test to demonstrate the in-vivo coating of red blood cells with antibodies (such as autoanti-bodies, maternal antibodies in hemolytic disease of the newborn and stillbirth, alloanti-bodies against red blood cells in transfusion reactions).

**Summary**
Moreschi 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.

Biotest Anti-IgG Solidscreen II reagent is used to test for the presence or absence of unexpected red blood cell antibodies. Furthermore, blood group weak D and partial D (DV1 and DVII) antigen typing (with the corresponding reagent for the indirect antiglobulin test) can be carried out. Routine pretransfusion studies always include tests for antibody screening, crossmatch and antibody identification.

**Principle of the Test**
The test principle is a solid phase assay for:

- a. the detection of red blood cell allo-antibodies or auto-antibodies in human plasma or serum.
- b. the determination of weak D and partial D antigens (DV1 and DVII) of samples which have tested negative with IgM anti-D using Erytype S and the TANGO® optimo.

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.

Sensitization of the red blood cell occurs if the corresponding antibody is present on the red blood cell. Following incubation, and two wash processes 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 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**
Anti-Human Globulin Anti-IgG Solidscreen II is prepared by immunizing rabbits with human IgG. The anti-IgG component contains antibody reactivity against light chain (IgG) and thus may also bind to IgM or IgG sensitized red blood cells. There is no activity with complement coated red blood cells. The reagent is supplied in a 55 mL glass bottle.

Antibodies are diluted in a isotonic saline solution containing bovine albumin and as colorant Patent Blue and Tartrazine.

**Preservative**
0.1% sodium azide.

**Precautions**
- For in vitro diagnostic use
- Resuspend Reagent Red Blood Cells prior to use and insert red blood cell mixers before loading on TANGO® optimo.
- Store between 2 to 8°C.
- Do not use if turbid.
- Handle and dispose of reagents as potentially infectious
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic 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.
- Do not use beyond seven days when opened and loaded on the TANGO® optimo.
- Do not freeze.
- Do not use samples collected in gel separator tubes.
- The bovine albumin used for the production of this reagent is purchased from BSE-free US sources, Boval Company L.P. in Cleburne, TX, USA and Millipore in Kankakee, IL, USA.

**Specimen Collection**

**TANGO® optimo**
For antibody detection and identification (Indirect Antiglobulin Test IAT)

Fresh samples of EDTA or EDTA anticoagulated whole blood samples can 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 specimens should be used.

**For crossmatch (Indirect Antiglobulin Test)**

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 specimens should be used.

**For Direct Antiglobulin Test (DAT)**

Fresh samples of EDTA or citrate anticoagulated whole blood samples 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 specimens should be used.

**Materials**

**Materials Supplied**
- Anti-Human Globulin Anti-IgG Solidscreen II

**Material required but not provided**
- TANGO® optimo
- Solidscreen II microplates
- Biotestcell® Pool
- Biotestcell® 1 & 2
- Biotestcell® 3
- Biotestcell® 3
- Biotestcell® 1
- Biotestcell® 1
- Donor or patient red blood cells
- LDL B2 (Modified LISS Biotest)
- Solidscreen II Anti-D Blend
- Solidscreen II Control
- Alsevers Solution
- Centrifuge
- Isotonic Saline
- PBS pH 7.3 ± 0.2
- Cell mixers

**Do not use beyond seven days when opened and loaded on the TANGO® optimo.**
**Do not freeze.**
**Do not use samples collected in gel separator tubes.**
**The bovine albumin used for the production of this reagent is purchased from BSE-free US sources, Boval Company L.P. in Cleburne, TX, USA and Millipore in Kankakee, IL, USA.**
7. The mixture is incubated for 20 minutes at 37°C.
8. The mixture is centrifuged following incubation.
9. The supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
10. 100 μL of Anti-Human Globulin Anti-IgG Solidscreen II is added to the well and mixed.
11. Centrifugation by TANGO® optimo

Reaction is evaluated and interpreted by TANGO® optimo.

Interpretation of Results
The results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® optimo evaluate, and provide an interpretation (positive or negative) for the well. The operator performs verification of the final results.

Positive Result: A layer of red blood cells across the bottom of the well.

Negative Result: A compact red blood cell button at the center of the well.

Limitations
- 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.
- 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 Anti-IgG Solidscreen II.
- There is no anti-complement activity with this product. Red blood cells coated with complement should 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 red blood cells
  - Antibodies to antibodies or other reagents
  - Cold Antibodies

Stability of the Reaction
Weak D and partial D antigen (DVI and DVII) testing
1. The TANGO® optimo dispenses 50 μL of Serum/Plasma or control reagents into the Solidsscreen II microplate well.
2. TANGO® optimo dispenses 50 μL of the donor red blood cells prepared in (2.) into the Solidsscreen II microplate well.
3. Following centrifugation, the supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
4. 100 μL of Anti-Human Globulin Anti-IgG Solidscreen II is added to the well and mixed.
5. Centrifugation by TANGO® optimo

Reaction is evaluated and interpreted by TANGO® optimo.

Stability of the Reaction
The results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® optimo evaluate, and provide an interpretation (positive or negative) for the well. The operator performs verification of the final results.

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.
- A new bottle or preparation is placed on the system.
- Service/repair of the TANGO® optimo
- After service/repair of the TANGO® optimo
- 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-Human Globulin, Anti-IgG Solidsscreen II, MLB 2).

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.

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