US

# Anti-Human Globulin

## Anti-IgG Solidscreen® II

(Rabbit)

FOR IN-VITRO DIAGNOSTIC USE
Anti-Human Globulin For Use With Solidscreen® II with TANGO® Instruments
U.S. License Number: 1845

### Package size

REF 806516100 VOL 55 mL Anti-Human Globulin Anti-IgG Solidscreen® II

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**Intended Use**

Anti-Human Globulin Anti-IgG Solidscreen® II 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® 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 D/partial D antigen (DVI and DVII). ◄

**Summary**

Moreschi first described the use of Anti-Human 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 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.

**Principle of the Test**

The test principle is a solid phase assay for
a) The detection of red blood cell antibodies in human plasma or serum.
b) The determination of weak D and partial D antigens (DVI and DVII) of samples which have tested negative with IgM anti-D using Erytype® S.

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.[5]
Sensitization of the red blood cell occurs if the corresponding antibody is present on the red blood cell. Following incubation, and ◄ wash processes to remove unbound protein, Anti-Human Globulin is added to the well and acts as a link between the antibody coated red blood cells. 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**

IVD

**OBSERVABLE INDICATIONS**

Do not use if turbid.
Do not use damaged vials

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 binds to IgA or IgM 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.

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

Preservative: 0.1% Sodium azide

**Precautions**

- For *in vitro* diagnostic use.
- Store between 2 to 8°C.
- Do not use if turbid.
- Do not use damaged vials.
- Handle and dispose of reagents as potentially infectious.
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- **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.
- Anti-IgG Solidscreen® II contains Tartrazine which may cause allergic reaction
- Do not use beyond seven days when opened and loaded on the TANGO® instruments.
- Do not freeze.
- Do not use samples collected in gel separator tubes.
- The bovine albumin used for the production of this reagent is sourced from donor animals of U.S. origin that have been inspected and certified by U.S. Veterinary Service inspectors to be disease free.

**Specimen Collection**

Refer to the Solidscreen II instructions for use for specimen collection when performing antibody screening, antibody identification, crossmatch, auto control, and DAT testing and the Solidscreen Anti-D (RH1) Blend instructions for use for specimen collection when performing weak D and partial testing.

**Materials**

**Materials Supplied**

- Anti-Human Globulin Anti-IgG Solidscreen® II

**Material required but not provided**

- TANGO® optimo REF 848900010
- TANGO infinity™ REF 850000010
- Solidscreen® II microplates REF 806521100
- Biotestcell® Pool REF 816065100, Biotestcell® 1 & 2 REF 816014100, Biotestcell® 3 REF 816085100, Biotestcell®-I 8 REF 816020100, Biotestcell®-I 11 REF 816021100, Biotestcell®-I 11 Plus REF 816022100
- Donor or patient red blood cells
- MLB 2 (Modified LISS Bio-Rad) REF 805200100
- Solidscreen II Anti-D Blend REF 806530100
- Solidscreen® II Control REF 806514100
- Solidscreen® II Control B REF 806519100
- Solidscreen® II Negative Control REF 806509100
- Alsevers Solution REF 806510100
- Centrifuge
- Deionized water
- Isotonic saline
- Washing Solution Concentrate REF 848000091
- 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 must be run each day before testing or according to local requirements to ensure that the reagents, antisera and automated system components are functioning properly. Solidscreen® II Control (containing diluted Anti-D) or Solidscreen® II Control B (containing diluted Anti-c) can be used as the positive control. 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 TANGO® instruments 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) for the well. The operator performs validation 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**

- 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.
- Contamination of Anti-Human Globulin by extraneous protein can neutralize the entire bottle of Anti-IgG Solidscreen II.
- Low frequency antigens may not always be present on Red Blood Cells and a double dose of antigen may be required to detect very weakly reacting antibodies. Therefore, negative reactions 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.

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- 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 antibiotics or other reagents
  - Drug therapy with monoclonal antibodies
  - Cold antibodies
  - Reagent Red Blood Cells not being mixed prior to loading on the TANGO® instruments.
- Positive reactions may be seen from individuals who have received Rh Immunoglobulin.
- Hemolyzed samples may lead to false negative results
- 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.
- The performance characteristics have not been established with frozen/deglycerolized or enzyme treated red blood cells.

**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 lot release process each lot of Bio-Rad Anti-Human Globulin Anti-IgG Solidscreen II reagent is tested according to the package insert method against IgG red blood cell antibodies to insure suitable reactivity. In addition the reactivity of the reagent is confirmed with IgG coated red blood cells. The products meet FDA potency requirements. The specificity testing for the presence of contaminating antibodies is performed according to the product specific SOPs.

For the product performance it is necessary to adhere to the recommended method in the instructions for use.

**Performance Characteristics for crossmatch (Indirect Antiglobulin Test) on the TANGO infinity**
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 infinity. 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 infinity.

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 theTANGO infinity User Manual for more information on verification of results.

**Results from Clinical Trials**

| Test | Negative Agreement N | Negative Agreement one-sided Exact 95% LCL | Positive Agreement N | Positive Agreement one-sided Exact 95% LCL |
|---|---|---|---|---|
| IAT Crossmatch | 539 | 98.70% (97.57%) | 449 | 99.33% (98.28%) |

**Results from In-House Study with well-characterized samples**

| Test | Negative Agreement N | Negative Agreement one-sided Exact 95% LCL | Positive Agreement N | Positive Agreement one-sided Exact 95% LCL |
|---|---|---|---|---|
| IAT Crossmatch | 344 | 100% (99.13%) | 320 | 100% (99.07%) |

All discrepancies in positive and negative percent agreement were at one clinical site. During resolution testing (antiglobulin crossmatch/tube method) at a referee laboratory, four initially discrepant results were in agreement, and six remained discordant (including 4 resulted by the TANGO infinity as equivocal).
Agreement between the methods does not imply which method obtained the correct result.
The results in the above tables do not reflect any discrepancy resolution between the methods.

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

**Note**
Techniques are to be performed according to the manufacturer's instructions. Each deviation from these instructions is the sole responsibility of the user. Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations.

**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 |
| | Contains sufficient quantity for <n> tests. | REF | Catalog number |
| | Temperature limitation | VOL | Volume |

**Bibliography**

1. Moreschi C. Neue Tatsache über die Blutkörperchen 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.
5. KJ Reis et al. Journal of Immunology 1984


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


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