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

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/D partial D antigen (DVI and DVI). **TANGO® infinity**: antibody screening, antibody identification, crossmatch, auto control, DAT, antigen typing of weak D/D partial D antigen (DVI and DVI). “Crossmatch on TANGO infinity” is not approved by the FDA.

Principle of the Test
The 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 DVI). samples which have tested negative with IgM unbound protein, Anti-Human Globulin is added to the well and acts as a link to the unbound protein, Anti-Human Globulin Anti-IgG Solidscreen®. Sensitization of the red blood cell occurs if the corresponding antibody is present on the red blood cell. Following incubation, and two wash processes to remove unbound protein. Anti-Human Globulin is added to the well and acts as a linking 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
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) Erysitype®. 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 to remove unbound protein. Anti-Human Globulin is added to the well and acts as a linking 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.

Precautions
- For in vitro diagnostic use.
- 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.
- 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® 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.
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.

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

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<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
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<tr>
<td>!</td>
<td>Caution, consult accompanying documents</td>
<td>I</td>
<td>Consult instructions for use</td>
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<tr>
<td>M</td>
<td>Manufacturer</td>
<td>REF</td>
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<td></td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
<td>VOL</td>
<td>Volume</td>
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<tr>
<td></td>
<td>Temperature limitation</td>
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Bibliography
1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Baktr 1908; 46:49,456
5. KJ Reis et al. Journal of Immunology 1984

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