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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/partial D antigen (DVI and DVIll)
- TANGO® infinity*: antibody screening, antibody identification, crossmatch, auto control, DAT, antigen typing of weak D/partial D antigen (DVI and DVIll)

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.

Principle of the Test
The test principle is a solid phase assay for anti-D using Erytype®. 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 washing processes to remove unbound proteins, 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

<table>
<thead>
<tr>
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<tr>
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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 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 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.

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- 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.
- 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 cells 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 the TANGO infinity User Manual for more information on verification of results.

<table>
<thead>
<tr>
<th>Test</th>
<th>Results from Clinical Trials</th>
<th>Results from In-House Study with well-characterized samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negative Agreement</td>
<td>Positive Agreement</td>
</tr>
<tr>
<td>IAT Crossmatch</td>
<td>N Point Estimate (one-sided Exact 95% LCL)</td>
<td>N Point Estimate (one-sided Exact 95% LCL)</td>
</tr>
<tr>
<td></td>
<td>538  98.70% (97.57%)</td>
<td>449  99.33% (98.28%)</td>
</tr>
<tr>
<td>IAT Crossmatch</td>
<td>344 100% (99.13%)</td>
<td>320 100% (99.07%)</td>
</tr>
</tbody>
</table>

All discrepancies in positive and negative percent agreement were at one clinical site. During resolution testing (antiglobulin crossmatch/hube 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

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
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<th>Definition</th>
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<tbody>
<tr>
<td>LSTC</td>
<td>Batch Code</td>
<td>[IVD]</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>⚖</td>
<td>Caution, consulting accompanying documents</td>
<td>[TH]</td>
<td>Consult instructions for use.</td>
</tr>
<tr>
<td>Man</td>
<td>Manufacturer</td>
<td>[YYYY-MM-DD]</td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td>🔄</td>
<td>Contains sufficient quantity for &lt;x&gt; tests.</td>
<td>[REF]</td>
<td>Catalog number</td>
</tr>
<tr>
<td>🚨</td>
<td>Temperature limitation</td>
<td>[VOL]</td>
<td>Volume</td>
</tr>
</tbody>
</table>

Bibliography

5. KJ Reis et al. Journal of Immunology 1984