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 immunohaematological 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 antigens (DVI and DVIIL)
- TANGO® infinity™: antibody screening, antibody identification, crossmatch, auto control, DAT, antigen typing of weak D/partial D antigens (DVI and DVIIL)
- Crossmatch on TANGO® infinity is not approved by the FDA

Summary

Moersch 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

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 DVIIL) of samples which have tested negative with IgM Anti-D using Erytype™ II.

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 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

عبور علاميات

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 bind to IgA or IgM sensitized red blood cells. There is no activity with complement sensitized 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.

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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 and Solidscreen® II Anti-D (RH1) Blend instructions for use and the instrument User Manual for sample collection and handling guidelines.

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
- 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
- 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, antiserum 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 image. Therefore, negative reactions must be confirmed by a positive reaction. A compact button of cells in the middle of the well is indicative of a negative reaction.

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® optimo 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.
- 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
  - 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.
  
  • Sample hemolysis prior testing 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.

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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<tr>
<th>Symbol</th>
<th>Definition</th>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch Code</td>
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<tr>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
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<td>!</td>
<td>Caution, consult accompanying documents</td>
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<tr>
<td>H</td>
<td>Consult instructions for use</td>
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<tr>
<td>M</td>
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<td>e</td>
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<td>s</td>
<td>Contains sufficient quantity for &lt;n&gt; tests</td>
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<td>VOL</td>
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<tr>
<td>t</td>
<td>Temperature limitation</td>
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Bibliography

1. Moreschi C. Neue Tatsache über die Blutkörperchen Agglutinationen, Zbl Bakl 1908; 46:49,456
5. KJ Reis et al. Journal of Immunology 1984

Key: **Underline** = Addition of changes  ➯ = Deletion of text