US

Solidscreen II Negative Control

FOR IN-VITRO DIAGNOSTIC USE
Negative Control Reagent for Tango® optimo

Package size
REF 806509100 VOL 4 mL Solidscreen II Negative Control

Intended Use
Solidscreen II Negative Control is intended for use as a negative control for the Solidscreen II assay with the TANGO® optimo.

Summary
The ability to detect alloantibodies or autoantibodies directed against human red blood cells, in human plasma or serum, is a necessary part of routine laboratory testing. There are two very important applications for antibody detection:

1. The detection of red blood cell antibodies prior to red blood cell or whole blood transfusion to prevent the possibility of a transfusion reaction with accompanying red cell destruction.
2. To detect the presence of red blood cell antibodies in maternal or newborn serum that may result in Hemolytic Disease of the Newborn.

Principle
Solidscreen II is a solid phase assay for the detection of red cells sensitized with alloantibodies or autoantibodies in human plasma or serum.

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.[1]

The plasma or serum and Reagent Red Blood Cells are added to the Protein A coated well.
Sensitization of the Reagent Red Blood Cells occurs if the corresponding antibody is present for the antigen on the red cell. Following incubation, and two wash processes to remove unbound protein, Anti-Human Globulin, Anti-IgG Solidscreen II is added to the well. Following centrifugation, the well is evaluated. A smooth monolayer of 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
Solidscreen II Negative Control is supplied as a ready-to-use internal negative control for the Solidscreen II assay. The Solidscreen II Negative Control is supplied in a 4mL glass vial and consists of antibody-free human serum blood type AB.

Solidscreen II Negative Control

Preservative: 0.1% sodium azide.

Precautions
- For in vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not freeze.
- 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.
- Bring to room temperature before use.
- CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
- 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.
- 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 and Preparation:
Solidscreen II Negative Control is supplied ready-to-use.
To test the control on the TANGO® optimo:

1. Aliquot a portion of the control material into a clean properly labeled test tube.
2. Place the control into a sample rack for the TANGO® optimo. Follow instructions in the TANGO® optimo User Guide for identifying a sample as a control.
3. When the control is not in use, stopper the aliquot and store at 2 to 8°C. The aliquot can be used until the expiration date or until exhausted, whichever comes first.

Materials
Materials Supplied
- Solidscreen II Negative Control

Materials and Equipment Not Supplied
- TANGO® optimo REF 848900010
- Solidscreen II 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)
- Donor or patient red blood cells
- MLB2 (Modified LISS Biotest) REF 805200100
- Solidscreen II Control REF 806514100
- Solidscreen II Control B REF 806519100
- Alsevers Solution REF 806510100
- Anti- Human Globulin, Anti-IgG Solidscreen II REF 806516100
- Centrifuge
- Isotonic Saline
- PBS pH 7.3
- Cell mixers
- 12x75mm test tube.

Test Procedure
Indirect Antiglobulin Test (IAT)
1. TANGO® optimo dispenses 50µL of patient serum/plasma or control reagents into the Solidscreen II microplate well.
2. TANGO® optimo prepares a 1% suspension of antibody screen red blood cells or donor red blood cells (Crossmatch) with MLB 2.
3. TANGO® optimo dispenses 50µL of the antibody screen cells or donor red blood cells prepared in (2.) into the well with patient serum/plasma or control reagents.
4. The mixture is incubated for 20 minutes at 37°C.
5. The mixture is centrifuged following incubation.
6. The supernatant is aspirated and the strip is washed twice. Centrifugation follows each wash process.
7. 100µL of Anti-Human Globulin, Anti-IgG Solidscreen II is added to the well and mixed.
8. Centrifugation by TANGO® optimo
9. 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 validation 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 (plate, reagent).
- A new bottle or preparation is placed on the system (red blood cells, AHG, MLB 2).
- After service/repair of the analyzer.

Interpretation
Quality Control
All Reagent Red Blood Cells should give a negative reaction with Solidscreen II Negative Control. When the Solidscreen II Negative Control repeatedly fails to perform as expected, contact Biotest at 800-522-0090.
False positive can occur if Solidscreen II Negative Control is contaminated or if the TANGO® optimo fails to pipette, wash, centrifuge or evaluate reactions appropriately.

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 validation of the final results.

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

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

Limitations

- 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.
- Some conditions that may cause false positive results are:
  - Contamination of reagents
  - Improper storage or preparation of 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.
Each lot of Biotest Reagent is tested in the Quality control by package insert method to insure suitable reactivity.
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 Biotest at 800-522-0090.

Note
All techniques are to be performed according to the manufacturers instructions. Each deviation from these instructions is the sole responsibility of the user and needs to be validated by the user. Used test material must be discarded as hazardous material. Waste management according to national guidelines.

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		

Bibliography

1. KJ Reis et al. Journal of Immunology 1984

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