

Solidscreen II Control

FOR IN-VITRO DIAGNOSTIC USE
Positive Control Reagent for TANGO[®] optimo

Package size

[REF] 806514100 [VOL] 4 mL Solidscreen II Control

Intended Use

Solidscreen II Control is intended for use as a positive 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 Control is supplied as a ready-to-use internal positive control for the Solidscreen II assay. The Solidscreen II Control is supplied in a 4mL glass vial and consists of a monoclonal anti-D.

Solidscreen II 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 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 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
- Search-Cyte[®] Pool, or Search-Cyte Duo, or Search-Cyte[®] Trio for TANGO[®] optimo.
- Donor or patient red blood cells
- MLB2 (Modified LISS Biotest) [REF] 805200100
- Solidscreen II Control B [REF] 806519100
- Solidscreen II Negative Control [REF] 806509100
- 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 Rh (D) positive Reagent Red Blood Cells should give a positive reaction with Solidscreen II Control. When the Solidscreen II Control repeatedly fails to perform as expected, contact Biotest at 800-522-0090.

False negatives can occur if Solidscreen II 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 REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each product.

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	<i>In vitro</i> 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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