

## Alsevers Solution

Suspension medium and stabilizer for red cells

FOR IN-VITRO DIAGNOSTIC USE

For Suspending and Preserving Red Blood Cells and for the use on TANGO<sup>®</sup> optimo

### Package size

[REF] 806510100 [VOL] 50 mL Alsevers Solution

### Intended Use

Alsevers Solution is used as suspension medium and stabilizer for red blood cells. Red blood cell suspensions prepared with Alsevers Solution are suitable for the use in immunohematology methods.

Alsevers Solution is used for the TANGO<sup>®</sup> optimo, as suspension medium and stabilizer for red blood cells applied in the indirect antiglobulin (IAT) test for crossmatch, direct antiglobulin test (DAT) and for the determination of weak D and partial D antigens (DVI and DVII) with the Soliscreen II solid phase antiglobulin test.

### 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 as well as the detection of weak D and partial D antigens (DVI and DVII) in donors. 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.

Routine pretransfusion testings always include the detection of unexpected antibodies directed against human red blood cells

### Principle

- Alsevers Solution is a preservative medium to stabilize red blood cell suspensions. It enables the preparation and storage of red blood cell suspensions for several days under refrigeration.
- Red blood cells are suspended in MLB2/Alsevers Solution to be tested in the solid phase antiglobulin test Soliscreen II (please also refer to instructions for use of Soliscreen II).

Soliscreen II is a solid phase assay for

- a) the detection of red blood cell alloantibodies or autoantibodies in human plasma or serum.
- b) the determination of weak D and partial D antigens (DVI and DVII) of donor samples which have been tested negative with IgM anti-D using Erytype S and the TANGO<sup>®</sup> optimo.

### Reagent

Alsevers Solution is a suspension medium for red blood cells and contains stabilizing and preserving substances in an citrate buffered environment. ◀

Preservative: Chloramphenicol 0.033%, Neomycinsulfat 0.01%, Amphotericin B 5ppm

### Precautions

- For in vitro diagnostic use.
- Store at 2 to 8°C.
- Store in the dark.
- ▶
- Do not use beyond 6 weeks after opening.
- Do not use beyond the expiration date.
- Do not freeze.
- Do not use damaged vials.
- Do not use if turbid
- Bring to room temperature before use
- Do not use if color changed
- Do not use specimens collected with gel separators.
- Do not use past seven days on the TANGO<sup>®</sup> optimo
- 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
- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions

### Specimen Collection

#### For use in immunohematology methods

Fresh samples of EDTA, CPD, ACD or heparin anticoagulated whole blood samples can be stored and used for several days when stored under refrigeration. Samples collected following standard blood sampling guidelines are acceptable.

The actual viable storage time of red blood cells may vary based on several factors such as the initial condition of the red blood cells, storage conditions and adherence to aseptic technique. Storage of red blood cells prior to preparation of a red blood cell suspension may result in weaker-than-normal reactions.

### TANGO<sup>®</sup> optimo

#### For crossmatch (Indirect Antiglobulin Test)

Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the crossmatch. Samples collected following standard blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA specimens should be stored at 2 to 8°C, citrated specimens (donor segments) at 1 to 6°C. Use of EDTA anticoagulated samples older than seven days should be avoided unless there is no other alternative since antibody reactivity has been shown to decrease in older samples. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. These red blood cells to be tested must be prepared prior to testing. Refer to instructions in the TANGO<sup>®</sup> optimo Users Guide <sup>2</sup>. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used. There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

#### For Direct Antiglobulin Test (DAT)

Fresh samples of EDTA anticoagulated whole blood samples or cord blood samples must be used for the Direct Antiglobulin Test. Samples collected following standard blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA anticoagulated whole blood samples should be stored at 2 to 8°C. Use of samples older than seven days should be avoided unless there is no other alternative since antibody reactivity has been shown to decrease in older samples. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used.

There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

#### For weak D and partial D antigen typing (Indirect Antiglobulin Test IAT)

Fresh samples of EDTA or citrate anticoagulated whole blood samples must be used for the weak D test. Samples collected following standard blood sampling guidelines are acceptable. The specimen should be tested as soon as possible after collection. If testing is delayed the EDTA anticoagulated samples should be stored at 2 to 8°C. EDTA anticoagulated whole blood samples may be tested for up to seven days following collection. Donor blood stored in citrate anticoagulant at 1 to 6°C may be tested until the expiration date of the donor unit. The red blood cells to be tested must be prepared prior to testing. Refer to instructions in the TANGO<sup>®</sup> optimo Users Guide. <sup>4</sup> Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used. There must be a distinct separation between the cellular and the plasma layer in the sample tube. Samples can be centrifuged or allowed to settle.

### Materials

#### Materials Provided

Alsevers Solution

Materials and Equipment required but not provided (as regards the use with the TANGO<sup>®</sup> optimo system)

- TANGO<sup>®</sup> optimo [REF] 848900010
- Soliscreen II [REF] 806521100
- MLB 2 (Modified LISS Biotest) [REF] 805200100
- Anti-D Blend Soliscreen II [REF] 806530100
- Donor or patient red blood cells
- Anti-Human Globulin Anti-IgG Soliscreen II [REF] 806516100
- Soliscreen II Control [REF] 806514100
- Soliscreen II Control B [REF] 806519100
- Soliscreen II Negative control 806509100
- Phosphate Buffered Saline pH 7.3 ± 0.2
- Cell Mixers

### 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<sup>®</sup> optimo evaluate, and provide an interpretation (positive or negative) for the well. The operator performs validation of the final results

### Test procedure

- In case of using Alsevers Solution to prepare red blood cell suspensions and to retain them for several days blood samples should be washed at least one time in Alsevers Solution before preparing a suspension of red cells in a desired concentration.
- Prepare a suspension of red cells in a desired concentration in Alsevers Solution. Store the suspension at 2 to 8°C.
- The TANGO<sup>®</sup> optimo prepares the suspension of patient or donor red blood cells 1% in MLB 2/Alsevers Solution. Detailed test procedure instructions as well as details for the evaluation of test results are given in the instructions for use of Soliscreen II and TANGO<sup>®</sup> optimo User's Guide

**FOR REFERENCE USE ONLY: DO NOT USE in place of package inserts provided with each product.**

#### Quality Control (as regards the use with the TANGO<sup>®</sup> optimo system)

A series of quality control samples must be run each day before testing or according to local requirements to ensure that the reagents, Blood Grouping Reagents and TANGO<sup>®</sup> optimo 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.

Two positive controls, Solidscreen II Control and Solidscreen II Control B are available for testing on the TANGO<sup>®</sup> optimo. The Solidscreen II Control contains diluted anti-D and Solidscreen II Control B contains diluted anti-c.

A negative control, Solidscreen II Negative Control is available for testing on the TANGO<sup>®</sup> optimo.

A minimum of one positive and one negative plasma/serum should be run for the Solidscreen II assay. The Solidscreen II Control or Solidscreen II Control B can be used as positive control.

#### Interpretation QC (as regards the use with the TANGO<sup>®</sup> optimo system)

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 (as regards the use with the TANGO<sup>®</sup> optimo system)

The results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO<sup>®</sup> 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 red blood cells across the bottom of the well.

**Negative Result:** A compact red blood cell button at the center of the well

#### Limitations

- AIservers Solution is light-sensitive and should be stored dark
- Turbidity or other visible changes may indicate a bacterial contamination. In this case the reagent must be discarded. The cause for turbidity must be examined by the manufacture
- Blood specimens exhibiting gross hemolysis, contamination or discoloration should not be used
- Red blood cell suspensions exhibiting gross hemolysis, contamination or discoloration should not be used

In case of questionable results of unknown origin, contact Biotest at 800-522-0090.

#### 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

Used tests must be discarded as hazardous material. Manage waste according to local, state and national regulations

#### Glossary of Symbols

Symbol	Definition	Symbol	Definition
	Batch Code		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.		Catalog number
	Temperature limitation		

#### Bibliography

1. KJ Reis et al. Journal of Immunology 1984
2. TANGO<sup>®</sup> optimo User's Guide, Dreieich Germany Biotest 2006

Key: Underline = Addition or significant change ◀ = Deletion of text