

MLB 2

Modified LISS Solution

Package size

[REF] 805200100

Please note: The use of symbols was implemented for product labeling associated with the TANGO® System. A glossary of symbols and their definitions is available in this package insert.

Intended Use

Biotest MLB 2 is intended for use with the TANGO® Automated Blood Bank Analyzer, in conjunction with the Solidscreen II Microplate, as a potentiator for the qualitative detection of Red Blood Cell alloantibodies.

Summary

Low Ionic Strength Salt Solutions (LISS) increase the rate of antigen-antibody complex formation.¹ Additionally, since antibody uptake is increased, incubation times of antigen-antibody reactions can be shortened. Excessive amounts of ions can interfere with binding of antibody to antigen.² Enhancement is achieved by decreasing the amount of ions in solution.

Principle

MLB 2 is used in conjunction with the Biotest Solidscreen II Microplate and the TANGO® System. One volume of patient plasma/sera is incubated with an equal volume of one percent antibody screening cells diluted with MLB 2. The mixture is incubated for 20 minutes at 37° C. The MLB 2 allows for the rapid uptake of alloantibody contained in the sample sera/plasma.

Reagent

MLB 2 is a low ionic strength salt solution containing 0.1% sodium azide. It is supplied in a 50mL glass bottle for use with the TANGO® System. The reagent is stable for seven days when opened and loaded on the TANGO® Automated Blood Bank Analyzer.

Precautions

- For in vitro diagnostic use.
- Store at 2-8°C.
- 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.**
- Resuspend Search-Cyte® Reagent Red Blood Cells for and insert cell mixers before loading on TANGO®.
- Do not use if markedly turbid. Turbidity may be an indication of reagent contamination.
- Do not use past seven days on the TANGO® Automated Blood Bank Analyzer.
- Do not use past the expiration date printed on the bottle.
- Do not use specimens collected with gel separators.

Specimen Collection

Serum or plasma can be used for the indirect antiglobulin test on the TANGO® Automated Blood Bank Analyzer. Samples should be collected using standard, accepted aseptic phlebotomy techniques. If the samples are not tested within 24 hours of collection, store samples between at 2-8°C. For transfusion purposes, the sample can be used no longer than dictated by state and federal regulatory agencies. Samples may be tested for up to seven days following collection.

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.

Procedure

Materials Provided

- MLB 2 in a 50mL glass bottle

Additional Materials Required but not provided

- Centrifuge
- TANGO® Automated Blood Bank Analyzer
- Solidscreen II Microplates
- Search-Cyte® Pool, or Search-Cyte® Duo, or Search-Cyte® Trio for the TANGO
- TANGO® System
- Anti-IgG Solidscreen II
- Cell Mixers
- PBS pH 7.3

Preparation

- MLB 2 is manufactured as ready to use for the TANGO® Automated Blood Bank Analyzer.
- Please see the TANGO® User Guide for loading instructions on the TANGO® Automated Blood Bank Analyzer.

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.

A positive control, Solidscreen II Control is available for testing on the TANGO® Automated Blood Bank Analyzer. The Solidscreen II Control contains diluted anti-D. The negative control may be selected from previously tested blood samples. Controls should be selected from samples that are less than 7 days old. Clotted, hemolyzed, or grossly lipemic samples should not be used for Quality Control samples.

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

Interpretation

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.

Limitations

- Low frequency antigens may not always be present on Search-Cyte® cells, and a double dose of antigen may be required to detect very weakly reacting antibodies. Therefore, negative reactions with the screening cells do not always indicate the absence of unexpected antibodies. Such antibodies are usually directed against the known antigens present on the screening cells, but may be directed against an antigen not indicated on the antigenic constitution matrix.
- 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.
- There is no anti-complement activity with this product. Cells coated with complement will not give a positive reaction.
- False test results may occur, but are not limited to:
 - Contamination of sample or reagents
 - Autoantibodies
 - Improper storage or preparation of cells
 - Antibodies to antibiotics or other reagents in the TANGO® Test System
 - Cold Antibodies
 - Screen cells not being mixed prior to loading on the TANGO®. (Please see **Precautions** section in this package insert regarding preparation of Search-Cyte® Reagent Red Blood Cells for TANGO®.)
- Positive reactions may be seen from individuals who have received Rh Immunoglobulin.

Specific Performance Characteristics

When properly stored and used according to the procedure described in the TANGO® User Guide, MLB 2 may increase the rate of association between antibodies in human plasma/serum and red blood cell antigens.

For Technical Support or further product information, contact Biotest Diagnostics Corporation at 800-522-0090.

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		

References

- Issitt, Peter D., and Issitt, Charla H. *Applied Blood Group Serology* Oxnard, Calif.: Spectra Biologicals, 1979
- Walsh, R.J. "The effect of electrolytes on the Rh agglutination reaction." *Med J Aust* 1948;i:793.



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