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Blood Grouping Reagent

Erytype S ABD+Rev. A_1,B

FOR IN-VITRO DIAGNOSTIC USE
Microplate for Tango® optimo
MEETS FDA POTENCY REQUIREMENTS

Package size
REF 806127100 VOL 10 plates Erytype S ABD+Rev. A_1,B

Intended Use
Each microplate is used for the determination of the presence or absence of A, B and D antigens on human red blood cells, and Anti-A or Anti-B in human plasma on anticoagulated specimens with the TANGO® optimo.

Summary
In 1900, Karl Landsteiner discovered the first 3 blood groups (A, B and 0) by mixing the serum and red blood cells from several of his colleagues.[1] He found that serum from Group B individuals agglutinated red blood cells from Group A individuals, serum from Group A individuals agglutinated red blood cells from Group B individuals and serum from Group O individuals agglutinated red blood cells from both Group A and Group B individuals. In 1902, Landsteiner's associates discovered the fourth AB0 blood group, AB.[2] Unlike most other blood group systems, the AB0 system contains "naturally occurring" antibodies. Individuals possess the antibody or antibodies to antigens that aren't expressed on their red cell.

By testing the serum and cells of individuals with appropriate antisera and reagent red blood cells, an accurate interpretation of a person's blood group can be obtained.

Landsteiner and Wiener first described the Rhesus blood group system in 1940.[3] They immunized rabbits and guinea pigs with the red blood cells of Rhesus monkeys. They found that sera from the rabbits and guinea pigs agglutinated not only Rhesus monkey cells, but also red blood cells from approximately 85% of humans. The antigen discovered by Landsteiner and Wiener is now known as the "D" antigen.

The D antigen is probably the most important antigen outside of the AB0 blood group system. Most D negative and D category (e.g. D^{VI}) individuals will make anti-D when sensitized by the D antigen.
Additionally, D negative females can become sensitized during pregnancy as a result of a fetal-maternal hemorrhage.

Principle of the Test
The test method of Erytype S is hemagglutination. A "forward" and "reverse" AB0 grouping is performed as well as a "D" typing. Specimen cells or plasma are added to the strip containing appropriate antisera. The TANGO® optimo pipettes Reagent Red Blood Cells into the last two wells for the reverse AB0 grouping. Agglutinates form if the well contains the antigen and the corresponding antibody.

Reagents
Each strip on the Erytype S ABD+Rev.A_1,B microplate contains the following configuration for the performance of a single AB0 grouping and D typing. The reagents are dried on the strips in the order depicted below:

Well No.	Reagent	Source	Antibody Class	Clone	Manuf.
A	Anti-A	Murine monoclonal	IgM	A003	Biotest/ Sifin
B	Anti-B	Murine monoclonal	IgM	B005	Biotest/ Sifin
C	Anti-AB	Murine monoclonal blend	IgM/IgM	BS63/ BS85	Biotest/ Sifin
D	Anti-D	Human monoclonal	IgM	BS226	Biotest/ Sifin
E	Anti-D	Human monoclonal	IgM	BS232	Biotest/ Sifin
F	Negative Control	Casein diluent + preservative			Biotest
G	None				
H	None				

Additional Reagent Information
- The A003 clone can detect the A_x subgroup.
- Category^{VI} will not be detected with the anti-D reagents on this strip. Category^{VII} and very weak expressions of the D antigen (D weak with very few receptors) will give weakened or negative reactions with the anti-D reagents on this strip.

Preservative: 0.1% Sodium Azide

Meets FDA minimum potency requirements.

Precautions
- For in vitro diagnostic use
- Store between 2-8°C
- Do not freeze
- Do not use beyond the expiration date printed on the package. Do not use beyond seven days when loaded on the TANGO® optimo.
- Opened foil packets that are not loaded on the TANGO® optimo can be used up to 24 hours if stored in a dry area at room temperature.
- Do not attempt to reuse test strips.
- Do not use samples collected with gel separators of any kind.
- **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.**
- Let plate come to room temperature before opening the foil packet to limit condensation.
- Resuspend Reagent Red Blood Cell A_1 and B and insert cell mixers before loading on the TANGO® optimo.

Specimen Collection
Collect specimens using a standard accepted aseptic collection method. EDTA whole blood is suitable for testing. Fresh samples are preferred for AB0 and D (Rh_o) testing. If the samples are not tested within 24 hours of collection, store samples at 2 to 8°C. Allow the sample to reach room temperature before testing. Samples may be tested up to seven days after collection.

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

Materials
Materials Supplied
- Erytype S (ABD+Rev. A_1,B) Microplate

Materials and Equipment Not Supplied
- TANGO® optimo
- Erytypecell A_1 & B REF 816056100*
- Reverse-Cyte® Group A_1 and B Cells for TANGO® optimo
- Bromelin for Erytype REF 806210100
- Isotonic saline
- Centrifuge
- Cell Mixers

Test Procedure
Test Method
1. TANGO® optimo prepares a 1% suspension of patient/donor red blood cells with Bromelin for Erytype .
2. TANGO® optimo dispenses 50uL of a 1% suspension of patient/donor Red Blood Cells into the first 6 wells of test strip.
3. TANGO® optimo dispenses 50uL of patient/donor plasma and 50uL of Reagent Red Blood Cells into the last two wells.
4. TANGO® optimo mixes the contents of the strip.
5. Room temperature incubation for 10 minutes.
6. The Erytype S ABD+Rev.A_1,B strip is centrifuged by TANGO® optimo.
7. The Erytype S ABD+Rev. A_1,B strip is resuspended by TANGO® optimo.
8. Reaction is evaluated by TANGO® optimo.

Stability of the Reactions
For the TANGO® optimo 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) of the well. The operator performs verification the final results.

For Reference USA Only

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

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 and the TANGO® optimo are functioning properly.

Additionally, controls should be run whenever:
1. A lot number changes (plate, reagent).
2. A new bottle or preparation is placed on the system.
3. Following service or repair of the TANGO® optimo.

Controls may be selected from previously tested blood samples. Controls should be selected from samples that are less than 7 days old. Clotted, grossly hemolyzed, or grossly lipemic samples should not be used for quality control samples.

Control samples should be selected to verify positive and negative reactions with every reagent.

The following example may be used for AB0/Rh quality control testing. Other configurations of AB0 and Rh types are possible and acceptable as long as there is a positive and negative control for each reagent.

Group 0 Neg
Group AB Pos
Group A Neg
Group 0 Pos

Interpretation
The tests are considered valid if a valid positive and negative result exists for each antisera/ reagent tested. A positive result is not required for the Negative Control. If the controls do not give 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.

Results
The results are read immediately and a digital image is stored for review by the operator. Image algorithms contained in the TANGO® optimo Software evaluate, and provide an interpretation (positive or negative) for the well. The operator performs verification of the final results.

Negative Result: A diffuse suspension of cells throughout the well.

Positive Result: An aggregate of cell clumps at the bottom of the well.

Limitations
Category^{VI} will not be detected with the anti-D reagents on this strip. Category VII and very weak expressions of the D antigen (D weak with very few receptors) will give weakened or negative reactions with the anti-D reagents on this strip.

Contaminated materials, sample condition (excessive lipemia or hemolysis), improper centrifugation or pipetting may produce false test results.

False positive reactions may occur if:

1. The TANGO® optimo is stopped during processing for too long a period of time. The orbital shaker on the analyzer keeps cells in suspension while the CCD camera is reading strips. Stopping this process may allow cells to settle in the center of the well on the strip, thus leading to a false positive interpretation of the well.
2. Reverse grouping cells are not adequately mixed prior to loading on the TANGO® optimo. (Please see Precautions section in this package insert regarding preparation of Reagent Red Blood Cells A_1 and B for TANGO® optimo).
3. Samples contain antibodies that react at room temperature (Le,M,N).
4. Samples contain Anti-A_1 from individuals who are a subgroup of A.

False negative reactions may occur if:

1. Neonatal plasma is used since isoagglutinins are not usually present in infants until three months of age.
2. Samples from immunocompromised, elderly, or patients that have received multiple transfusions are tested.

Specific Performance Characteristics
- Meets FDA minimum potency requirements.

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
Σ	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation		

References

1. Mark E. Brecher, MD et al Technical Manual 15th Edition, Bethesda, MA: AABB, 2005.
2. Pittiglio, D. Harmening. Modern Blood Banking and Transfusion Practices. Philadelphia, PA: F.A. Davis Company, 1983.
3. Issitt, Peter D., and Issitt, Charla H. Applied Blood Group Serology. Oxnard, CA: Spectra Biologicals, 1979.

* product not available for Canada

Key: Underline = Addition of changes ◄ = Deletion of text

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