

# Reagent Red Blood Cells

## Erytypecell A<sub>1</sub> & B

1.0 to 1.3%

Pooled cells for reverse grouping with TANGO<sup>®</sup> optimo

FOR IN-VITRO DIAGNOSTIC USE  
NO FDA STANDARD OF POTENCY  
U.S. License Number: 1798

### Package size

**[REF]** 816056100 **[VOL]** 2 x 10 mL Erytypecell A<sub>1</sub> & B

### Intended Use

Erytypecell A<sub>1</sub> & B is used for the detection of antibodies to A and B antigens on red blood cells using Erytype S and the TANGO<sup>®</sup> optimo.

### Summary

Between 1900 and 1902, Landsteiner and associates discovered the ABO system of red blood cell antigens. The importance of this discovery is the recognition that antibodies are present when the corresponding antigens are lacking. The ABO system is the only blood group system in which the reciprocal antibodies are consistently and predictably present in most people. Due to this reciprocity, a blood type determination is considered valid if serum isoagglutinins correspond with red blood cell antigens<sup>1</sup>.

Erytypecell A<sub>1</sub> & B is used to test for the presence or absence of the corresponding antibodies in reverse grouping for the ABO system. Routine pretransfusion studies always include tests for the ABO antigens and reverse grouping.

**Phenotype Frequency (%)<sup>3</sup>**

	Caucasians	Blacks	Asians	Mexican
A <sub>1</sub>	33	19	27	22
A <sub>2</sub>	10	8	Rare	6
B	9	20	25	13
O	44	49	43	55
A <sub>1</sub> B	3	3	5	4
A <sub>2</sub> B	1	1	Rare	Rare

### Principle of the Test

The test principle is hemagglutination. The antigens of the Reagent Red Blood Cells react with the respective antibodies in the serum or plasma to be tested. Agglutinates form if the antibody is present.

### Reagent

Erytypecell A<sub>1</sub> & B is available ready for use suspended 1.0 to 1.3% in modified Alsevers solution and can be used immediately after careful resuspension. Erytypecell A<sub>1</sub> & B is produced every 4 weeks.

Erytypecell A<sub>1</sub> & B has the following antigen combinations:

Erytypecell-A<sub>1</sub> A<sub>1</sub> Rh negative (D negative) (c̄c̄ddee)  
Erytypecell-B B Rh negative (D negative) (cc̄ddee)

Preservative: 0.01% Neomycin, 0.033% Chloramphenicol, 5 ppm Amphothericin B

### Precautions

- For In-vitro diagnostic use.
- Store at 2 to 8°C.
- Do not use beyond the expiration date.
- Do not use damaged vials.
- Do not use if markedly hemolyzed or discolored
- Handle and dispose of reagents as potentially infectious
- Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
- Caution: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DEFIVED WAS FOUND NEGATIVE WHEN TESTED WITH FDA LICENSED EIA/ELISA TESTS. NAT TESTING WAS NOT PERFORMED. NO KNOWN TEST METHOD CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

- Caution: This product contains Natural Rubber Latex Which May Cause Allergic Reactions.
- Do not use beyond seven days when loaded on the TANGO<sup>®</sup> optimo
- Do not use samples collected with gel separators of any kind.
- Erytypecell A<sub>1</sub> & B, shows maximum reactivity on Erytype S and the TANGO<sup>®</sup> optimo and is to be used in these test systems only.

### Specimen Collection

EDTA anticoagulated whole blood collected following general 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.

Blood specimens exhibiting gross hemolysis or contamination should not be used. Do not use samples collected with gel separators of any kind:

Samples older than seven days can be tested, however antibody reactivity has been shown to decrease in older samples. A distinct separation between plasma and red blood cells must be visible for testing. Samples may be centrifuged or allowed to settle. Stored samples should be allowed to reach room temperature (18 to 26°C) prior to testing.

### Materials

#### Material provided

- Erytypecell A<sub>1</sub> & B

#### Material required but not provided

- TANGO<sup>®</sup> optimo (Biotest **[REF]** 848900010)
- Erytype S Rev.A<sub>1</sub>B plates (Biotest **[REF]** 806127100)
- Bromelin for Erytype (Biotest **[REF]** 806210100)
- Cell mixers

### Test procedure

#### TANGO<sup>®</sup> optimo (Erytype S)

Please refer to the instructions for use of the TANGO<sup>®</sup> optimo in the TANGO<sup>®</sup> optimo User's Guide.

### Stability of the Reactions

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

### 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 analyzer are functioning properly.

Refer to TANGO<sup>®</sup> optimo instructions for recommended instrument quality control.

Controls should be run whenever:

- Lot numbers change (plate, reagent).
- A new bottle or preparation is placed on the system.
- After service/repair of the analyzer.

To confirm the reactivity or specificity of Erytypecell A<sub>1</sub> & B each should be tested with Anti-A and Anti-B, preferably from normal blood donors, of known ABO blood group. Each Reagent Red Blood Cell is satisfactory for use if it reacts only with the corresponding antibodies.

### Interpretation of QC

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.

Please contact Biotest (800-522-0090) if controls repeatedly fail to give expected results.

### Interpretation of results

Negative result: a diffuse suspension of red blood cells throughout the well.

Positive result: an aggregate of red blood cell clumps at the bottom of the well.

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 of the final results.

### Reaction patterns, red cell characteristics and isoagglutinins

Reagent sera with Patient red blood cells			Reagent Red Blood Cells with Patient serum/plasma		Blood Group
Anti-A	Anti-B	Anti-AB	A <sub>1</sub>	B	
+	0	+	0*	+	A
0	+	+	+	0	B
0	0	0	+	+	O
+	+	+	0	0	AB

+ = agglutination

0 = no agglutination

\*A positive reaction may indicate an unexpected anti-A<sub>1</sub> in a person with A<sub>2</sub> blood group.

### Limitations

- In very rare cases weak reactions (reaction strength under 3+) or hemolysis may occur.
- Generally, newborns and young babies do not show test reaction due to missing isoagglutinins. Isoagglutinins may also be absent in elderly patients.
- The reactivity of the product may decrease during the dating period and therefore should not be used after the expiration date.
- Do not use if markedly hemolyzed.
- Not for use in detection or identification of unexpected antibodies.
- Product is not recommended to be used instead of major cross-match for the detection of unexpected antibodies.

### 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 Red Blood Cell is tested in the Quality control by package insert method against a panel of Blood Grouping Reagents to insure suitable reactivity. The result must react appropriately positive or negative.

No FDA Standard of potency. 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 Diagnostics Corporation at 800-522-0090.

### Note

Erytypecell A<sub>1</sub> & B is suited for use in the TANGO® optimo. Used test material must be discarded as hazardous material. Manage waste according to local, state and national regulations.

### Glossary of Symbols

Symbol	Definition	Symbol	Definition
	Batch Code		<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.		Catalog number
	Temperature limitation		Volume

### Bibliography

1. Mark E. Brecher, MD et al. Technical Manual 15th Edition, Bethesda, MA: AABB, 2005.
2. Marion E. Reid, Christine Lomas-Francis, The Blood Group Antigen FactsBook, New York, NY: Academic Press, 2004.