US

# Blood Grouping Reagent

## Erytype S AB0 Donor

FOR IN-VITRO DIAGNOSTIC USE
Microplate for Tango® optimo
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1798

**Package size**
REF 806130100 VOL 10 plates Erytype AB0 Donor

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**Intended Use**
The AB0 Donor Strip is used to **confirm** the blood group labeling of a unit of whole blood or packed red blood cells with the TANGO® optimo. The AB0 Donor Strip is to be used only for the purpose of confirming the **labeling** of a donor unit and is not intended as a test to determine the blood group of a donor unit.

**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 0 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]

Confirmation of the labeling of a unit of packed red blood cells or whole blood involves performing a "forward" AB0 grouping. The red blood cells from the unit of blood are tested with Anti-A and Anti-B to confirm the presence or absence of A or B antigens on the red blood cell.

**Principle of the Test**
The principle of the test is hemagglutination. Donor red blood cells are added to the wells containing Anti-A and Anti-B. The antibody binds to the corresponding antigen (if present). Following centrifugation, the mixture is resuspended. Agglutinates form if the sample contains the corresponding antigen to the antibody contained in the reagent test well.

**Reagent**
Each Erytype S AB0 Donor Strip contains eight wells. Each well is coated alternately with dried Anti-A and Anti-B. Therefore, a total of four AB0 confirmations can be performed with each strip. The strip configuration is as follows:

| 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-A | Murine monoclonal | IgM | A003 | Biotest/ Sifin |
| D | Anti-B | Murine monoclonal | IgM | B005 | Biotest/ Sifin |
| E | Anti-A | Murine monoclonal | IgM | A003 | Biotest/ Sifin |
| F | Anti-B | Murine monoclonal | IgM | B005 | Biotest/ Sifin |
| G | Anti-A | Murine monoclonal | IgM | A003 | Biotest/ Sifin |
| H | Anti-B | Murine monoclonal | IgM | B005 | Biotest/ Sifin |

**Additional Reagent Information**
- The A003 clone can detect the $A_x$ subgroup.

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.
- **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.

**Specimen Collection**
Donor segments taken from the original unit of whole blood or packed red blood cells are suitable for testing. Donor segments are suitable for testing through the expiration date of the original unit as long as they have been stored at 1-6°C. The red blood cells from the segment must be prepared for testing per the requirements in the TANGO® optimo User Guide.

**Materials**
**Materials Supplied**
- Erytype S AB0 Donor Microplates

**Materials and Equipment Not Supplied**
- TANGO® optimo
- Bromelin for Erytype
- Isotonic Saline
- Centrifuge
- 12X75mm sample tubes

**Test Procedure**
**Test Method**
1. The TANGO® optimo prepares a 1% suspension of donor red blood cells with Bromelin for Erytype.
2. TANGO® optimo dispenses 50µL of a 1% suspension of donor red blood cells into 2 wells of the Erytype S AB0 Donor Strip.
3. The contents of the strip is mixed by TANGO® optimo.
4. Room temperature incubation for 10 minutes.
5. The Erytype S AB0 Donor Strip is centrifuged by TANGO® optimo.
6. The Erytype S AB0 Donor Strip is resuspended by TANGO® optimo.
7. The 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 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 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 analyzer.

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. 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 suspension of cells throughout the well.

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

**Limitations**
- Variable No Type Determined (NTD) rates were experienced with this assay during the field trials. The sample used for this assay is a segment from the donor unit. The average initial NTD rate for ABO Donor testing was 14.0% with a range of 2.4% to 24.6%. This NTD rate reflects unedited test results. Editing of the TANGO® optimo test results based on visual review by a qualified operator would reduce the average initial NTD rate to 3.3%. Investigation into the cause of the NTD determined that the leukoreduced status of the donor unit could affect the NTD rate. Higher NTD rates were associated with non-leukoreduced donor units.
- The ABO Donor Test Strip is used to **confirm** the labeling of blood donor units. This strip should **never** be used to identify the blood group of an individual for pretransfusion testing purposes.
- Contamination of reagents can cause false positive or negative test results.
- Antibodies, medication and certain disease states can cause false positive or negative reactions.
- Clotted, grossly hemolyzed or grossly lipemic samples may result in inaccurate typing or increased “No Type Determined” results.
- False positive reactions may occur if 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.

**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 |
| | 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.

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