US

Blood Grouping Reagent

Erytype S Rh Donor

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

Package size
REF 806190100 VOL 10 plates Erytype S Rh Donor

Intended Use
The Erytype S Rh Donor microplate is used to **confirm** the Rh labeling of a unit of whole blood or packed red blood cells with the TANGO® optimo. The Erytype S Rh Donor microplate 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 Rh Type of a donor.

Summary
Landsteiner and Wiener first described the Rhesus blood group system in 1940.[1] 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 ABO blood group system. Most D negative 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. The sensitization can lead to destruction of fetal red blood cells and possibly death of the fetus.

Principle of the Test
The principle of the test is hemagglutination. Donor red blood cells are added to the wells containing Anti-D. 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.
A separate well containing dried casein diluent and preservative is tested in conjunction with each Anti-D well. This well serves as an agglutination control.

Reagent
Each Erytype S Rh Donor microplate contains eight wells. Each well is coated alternately with dried Anti-D and Control. Therefore, a total of four Rh confirmations can be performed with each test strip on the microplate. The strip configuration is as follows:

Well No.	Reagent	Source	Antibody Class	Clone	Manuf.
A	Anti-D	Human monoclonal	IgM	BS226	Biotest/ Sifin
B	Negative Control	Casein diluent + preservative			Biotest
C	Anti-D	Human monoclonal	IgM	BS226	Biotest/ Sifin
D	Negative Control	Casein diluent + preservative			Biotest
E	Anti-D	Human monoclonal	IgM	BS226	Biotest/ Sifin
F	Negative Control	Casein diluent + preservative			Biotest
G	Anti-D	Human monoclonal	IgM	BS226	Biotest/ Sifin
H	Negative Control	Casein diluent + preservative			Biotest

Additional Reagent Information:
- 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 Rh Donor Microplate

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 50uL of a 1% suspension of donor red blood cells into 2 wells of the Erytype S Rh Donor test strip.
3. The contents of the strip is mixed by TANGO® optimo.
4. Room temperature incubation for 10 minutes.
5. The Erytype S Rh Donor test strip is centrifuged by TANGO® optimo.
6. The Erytype S Rh Donor test 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 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
- Leukoreduced status of the donor unit can affect the NTD (No Type Determined) rate of this assay. Higher NTD rates have been associated with non-leukoreduced donor units.
- The Rh Donor Test Strip is used to **confirm** the labeling of blood donor units. This strip should **never** be used to identify the Rh type 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 test results.
- Category^{VI} and some examples of Weak D can not be detected with the monoclonal Anti-D on this test strip. Category^{VII} and very weak expressions of the D antigen (D weak with very few receptors) react weakly or not at all with the monoclonal Anti-D on this test strip.
- 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
Σ	Contains sufficient quantity for <n> tests.	REF	Catalog number
	Temperature limitation		

References

1. Issitt, Peter D. and Issitt, Charla H. Applied Blood Group Serology. Oxnard, CA: Spectra Biologicals, 1979.

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