Erytype S ABD+Rev. A_1,B

Blood Grouping Reagent

Package size

REF 806127100 FDA Lic. 1702

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

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® System.

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

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® Automated Blood Bank Analyzer 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® Automated Blood Bank Analyzer.
- Opened foil packets that are not loaded on the TANGO® 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 Reverse-Cyte® Reagent Red Blood Cells and insert cell mixers before loading on the TANGO®.

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 2-8°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.

Procedure

Materials Supplied:

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

Materials and Equipment Not Supplied

- TANGO® Automated Blood Bank Analyzer
- Reverse-Cyte® Group A_1 and B Cells for TANGO® System
- Bromelin for Erytype
- Isotonic saline
- Centrifuge
- Cell Mixers

Test Method

1. TANGO® prepares a 1% suspension of patient/donor red blood cells with Bromelin for Erytype .
2. TANGO® dispenses 50uL of a 1% suspension of patient/donor red blood cells into the first 6 wells of test strip.
3. TANGO® dispenses 50uL of patient/donor plasma and 50uL of reagent red blood cells into the last two wells.
4. TANGO® 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®.
7. The Erytype S ABD+Rev. A_1,B strip is resuspended by TANGO®.
8. Reaction is evaluated by TANGO®.

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 the TANGO® Automated Blood Bank Analyzer 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®.

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® Automated Blood Bank Analyzer Software evaluate, and provide an interpretation (positive or negative) for the well. The operator performs validation 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® 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®. (Please see Precautions section in this package insert regarding preparation of Reverse-Cyte® A_1 and B Cells for TANGO® System).
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.

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. Vengelen-Tyler, Virginia. Technical Manual-12th edition. Bethesda, Maryland: American Association of Blood Banks, 1996.
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.

Please contact OLYMPUS Immunohematology Technical Services (Tel: 800-447-5852) if controls repeatedly fail to give expected results.

Biotest

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for

Olympus® America Inc.
Two Corporate Center Drive
Melville, NY 11747, USA

Erytype S AB0 Donor

Blood Grouping Reagent

Package size
REF 806130100 FDA Lic. 1702

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
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® System. 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
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® Automated Blood Bank Analyzer.
- Opened foil packets that are not loaded on the TANGO® 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® User Guide.

Procedure
Materials Supplied
- Erytype S AB0 Donor Microplates

Materials and Equipment Not Supplied
- TANGO® Automated Blood Bank Analyzer
- Bromelin for Erytype
- Isotonic Saline
- Centrifuge
- 12X75mm sample tubes

Test Method
1. The TANGO® Automated Blood Bank Analyzer prepares a 1% suspension of donor red blood cells with Bromelin for Erytype.
2. TANGO® dispenses 50uL 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®.
4. Room temperature incubation for 10 minutes.
5. The Erytype S AB0 Donor Strip is centrifuged by TANGO®.
6. The Erytype S AB0 Donor Strip is resuspended by TANGO®.
7. The reaction is evaluated by TANGO®.

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® Automated Blood Bank Analyzer 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. 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® Automated Blood Bank Analyzer Software evaluate, and provide an interpretation (positive or negative) for the well. The operator performs validation 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® 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® 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.

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. Vengelen-Tyler, Virginia et al.Technical Manual-12th edition. Bethesda, Maryland: American Association of Blood Banks, 1996.
2. Pittiglio, D. Harmening. Modern Blood Banking and Transfusion Practices. Philadelphia, PA: F.A. Davis Company, 1983.

Please contact OLYMPUS Immunohematology Technical Services (Tel: 800-447-5852) if controls repeatedly fail to give expected results.

Biotest

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for

Olympus® America Inc.
Two Corporate Center Drive
Melville, NY 11747, USA

Erytype S Rh Donor

Blood Grouping Reagent

Package size

REF 806190100 FDA Lic. 1702

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

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® System. 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® Automated Blood Bank Analyzer.
- Opened foil packets that are not loaded on the TANGO® 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® User Guide.

Procedure

Materials Supplied

- Erytype S Rh Donor Microplate

Materials and Equipment Not Supplied

- TANGO® Automated Blood Bank Analyzer
- Bromelin for Erytype
- Isotonic Saline
- Centrifuge
- 12x75mm sample tubes

Test Method

1. The TANGO® Automated Blood Bank Analyzer prepares a 1% suspension of donor red blood cells with Bromelin for Erytype.
2. TANGO® 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®.
4. Room temperature incubation for 10 minutes.
5. The Erytype S Rh Donor test strip is centrifuged by TANGO®.
6. The Erytype S Rh Donor test strip is resuspended by TANGO®.
7. The reaction is evaluated by TANGO®.

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® Automated Blood Bank Analyzer 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® Automated Blood Bank Analyzer Software evaluate, and provide an interpretation (positive or negative) for the well. The operator performs validation 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® 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.

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
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References

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

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