Blood Grouping Reagent
Erytype S ABD+Rev. A1,B

FOR IN-VITRO DIAGNOSTIC USE
Microplate for Tango® optimo
MEETS FDA POTENCY REQUIREMENTS
U.S. License Number: 1845

Package size
REF 806127100 VOL 10 plates Erytype S ABD+Rev. A1,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 O) 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 agglomerated red blood cells from both Group A and Group B individuals. In 1902, Landsteiner’s associates discovered the fourth ABO blood group, AB.2 Unlike most other blood group systems, the ABO 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 Rh group 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 ABO blood group system. Most D negative and D category (e.g. DVI) individuals will make reagent red blood cells, an accurate interpretation of a person’s blood group can be obtained.

Principle of the Test
The test method of Erytype S is hemagglutination. A “forward” and “reverse” ABO 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 ABO grouping. Agglutinates form if the well contains the antigen and the corresponding antibody.

Reagents
Each strip on the Erytype S ABD+Rev. A1,B microplate contains the following configuration for the performance of a single ABO grouping and D typing. The reagents are dried on the strips in the order depicted below:

<table>
<thead>
<tr>
<th>Well No.</th>
<th>Reagent</th>
<th>Source</th>
<th>Antibody Class</th>
<th>Clone</th>
<th>Manuf.</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Anti-A</td>
<td>Murine monoclonal</td>
<td>IgM</td>
<td>A003</td>
<td>Bio-Rad/Sifin</td>
</tr>
<tr>
<td>B</td>
<td>Anti-B</td>
<td>Murine monoclonal</td>
<td>IgM</td>
<td>B005</td>
<td>Bio-Rad/Sifin</td>
</tr>
<tr>
<td>C</td>
<td>Anti-AB</td>
<td>Murine monoclonal blend</td>
<td>IgM/BS226</td>
<td>BS63/BS85</td>
<td>Bio-Rad/Sifin</td>
</tr>
<tr>
<td>D</td>
<td>Anti-D</td>
<td>Human monoclonal</td>
<td>IgM</td>
<td>BS226</td>
<td>Bio-Rad/Sifin</td>
</tr>
<tr>
<td>E</td>
<td>Anti-D</td>
<td>Human monoclonal</td>
<td>IgM</td>
<td>BS232</td>
<td>Bio-Rad/Sifin</td>
</tr>
<tr>
<td>F</td>
<td>Negative Control</td>
<td>Casein diluent + preservative</td>
<td>IgM</td>
<td>Bio-Rad</td>
<td></td>
</tr>
<tr>
<td>G</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>H</td>
<td>None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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.
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 ABO/Rh quality control testing. Other configurations of ABO and Rh types are possible and acceptable as long as there is a positive and negative control for each reagent.

<table>
<thead>
<tr>
<th>Group 0</th>
<th>Neg</th>
<th>Group AB</th>
<th>Pos</th>
<th>Group A</th>
<th>Neg</th>
<th>Group 0</th>
<th>Pos</th>
</tr>
</thead>
</table>

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
The A003 clone can detect in the Erytype S ABD+Rev. A, B, the A_x subgroup, but very weak expressions of A_x especially in combination with A_x B may not always be detected.

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, and B for TANGO® optimo).
3. Samples contain antibodies that react at room temperature (Le,M,N).
4. Samples contain Anti-A_x 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 Bio-Rad Diagnostics Corporation at 800-224-6723.