Reagent Red Blood Cells

Biotestcell® A₁ & B
Biotestcell® A₂

3.0 to 3.4%
Pooled cells for Reverse Grouping by tube test

FOR IN-VITRO DIAGNOSTIC USE
NO U.S. STANDARD OF POTENCY
U.S. License Number: 1845
Rx only

Package size

<table>
<thead>
<tr>
<th>REF</th>
<th>VOL</th>
<th>Biotestcell® A₁ &amp; B</th>
</tr>
</thead>
<tbody>
<tr>
<td>816057100</td>
<td>2 x 10 mL</td>
<td></td>
</tr>
<tr>
<td>816047100</td>
<td>1 x 10 mL</td>
<td></td>
</tr>
</tbody>
</table>

Intended Use
Biotestcell® A₁ & B and Biotestcell® A₂ are used for the detection of antibodies to A and B antigens in test serum or plasma.

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 grouping for the ABO system. Routine pretransfusion studies always include tests for the ABO antigens and reverse grouping.

Bio-Rad Reagent Red Blood Cells A₁ & B and A₂ are 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.

<table>
<thead>
<tr>
<th>Phenotype Frequency (%)</th>
<th>Caucasians</th>
<th>Blacks</th>
<th>Asians</th>
<th>Mexican</th>
</tr>
</thead>
<tbody>
<tr>
<td>A₁</td>
<td>33</td>
<td>19</td>
<td>27</td>
<td>22</td>
</tr>
<tr>
<td>A₂</td>
<td>10</td>
<td>8</td>
<td>Rare</td>
<td>6</td>
</tr>
<tr>
<td>B</td>
<td>9</td>
<td>20</td>
<td>25</td>
<td>13</td>
</tr>
<tr>
<td>0</td>
<td>44</td>
<td>49</td>
<td>43</td>
<td>55</td>
</tr>
<tr>
<td>A₁B</td>
<td>3</td>
<td>3</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>A₂B</td>
<td>1</td>
<td>1</td>
<td>Rare</td>
<td>Rare</td>
</tr>
</tbody>
</table>

Principle of the Test
The test principle is a hemagglutination test. The antigens of the Reagent Red Blood Cells react with the respective antibodies in the serum or plasma to be tested. The existence or lack of Anti-A and/or Anti-B antibodies must correspond with the existence or lack of A and/or B antigens on the Reagent Red Blood Cells.

Reagent
Human Reagent Red Blood Cells, ready-to-use, for plasma or serum grouping. Biotestcell® A₁ & B and Biotestcell® A₂ are available suspended 3.0 to 3.4% in modified Alsever solution and can be used immediately following careful resuspension. Biotestcell® A₁ & B and Biotestcell® A₂ are produced every 4 weeks.

Biotestcell® A₁ & B and Biotestcell® A₂ have the following antigen combinations:

- Biotestcell® A₁: A₁ Rh negative (D negative) (Ccddee)
- Biotestcell® B: B Rh negative (D negative) (Ccddee)
- Biotestcell® A₂: A₂ Rh negative (D negative) (Ccddee)

Preservative:
0.01% Neomycin, 0.033% Chloramphenicol, 5 ppm Amphotericin 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 DERIVED 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.

Specimen Collection
Fresh samples of clotted or 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, specimens should be stored at 2 to 8°C or the plasma or serum can be separated from red blood cells and frozen. Stored samples should be allowed to reach room temperature prior to testing. Blood specimens exhibiting gross hemolysis or contamination should not be used. Clotted or EDTA samples older than ten days can be tested, however antibody reactivity has been shown to decrease in older samples.

Materials

- Material provided
  - Biotestcell® A₁ & B and Biotestcell® A₂

- Material required but not provided
  - Pipettes
  - Glass tubes 10 x 75mm or 12 x 75mm
  - Serological centrifuge
  - Interval timer
  - Markers
  - Agglutination viewer (optional).

Test procedure

Tube Test
Resuspend Reagent Red Blood Cells prior to use and allow to reach room temperature. The procedures below intended as guidelines. It may be desirable to modify these procedures based on in-house requirements or standard operating procedures.

1. Place two drops (approx. 40 to 50 µL each) of sample serum/plasma to be tested into each properly labelled tube (A₁, B and/or A₂).
2. Add one drop of corresponding Reagent Red Blood Cells to the appropriate tube and mix.
3. Centrifuge for:
   - a. 20 seconds at 800 to 1000 x g or
   - b. at a time and speed appropriate for the centrifuge calibration.
4. Gently dislodge the red blood cell button and observe for macroscopic agglutination. Negative reactions may be examined with an agglutination viewer, however, microscopic examination is not recommended.
5. Record results

Stability of the Reaction
Following centrifugation, all tube tests should be read immediately and results interpreted without delay. Time delays may cause a dissociation of the antigen-antibody complexes resulting in false negative or more often weak positive reactions.

Quality Control
To confirm the reactivity or specificity of Bio-Rad Reagent Red Blood Cells A₁ & B and A₂, each should be tested with Anti-A and Anti-B, preferably from normal blood donors, of known ABO blood group or with a quality control product specifically designed for the quality evaluation of A₁ & B and/or A₂ Reagent Red Blood Cells. Each Reagent Red Blood Cells is satisfactory for use if it reacts only with the corresponding antibody.
Interpretation of Results
Agglutination of the red blood cells is a positive result and indicates the presence of the corresponding antibody. No agglutination is a negative result and indicates the absence of the corresponding antibody.

An agglutination viewer may facilitate the reading of tube tests (as recommended by the AABB Technical Manual)\(^1\).

### Reaction patterns, red blood cell antigens and isoagglutinins

<table>
<thead>
<tr>
<th>Reagent sera with red blood cells</th>
<th>Reagent Red Blood Cells with serum/plasma</th>
<th>Blood</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-A</td>
<td>Anti-B</td>
<td>Anti-AB</td>
</tr>
<tr>
<td>+</td>
<td>0</td>
<td>+</td>
</tr>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

* = agglutination  
0 = no agglutination

\*Testing with A\(_2\) Reagent Red Blood Cells is not required, but most commonly used to identify anti-A\(_1\) in the sera of group A people.

\**A positive reaction may indicate an unexpected anti-A\(_1\) in a person with A\(_2\) blood group.

\***A positive reaction may indicate an unexpected anti-H in a person with A\(_1\) blood group.

### Limitations
- In very rare cases weak reactions (reaction strength under 3+) or hemolysis may occur.
- Since serum characteristics may react at different strengths, incubation for 15 to 30 minutes at room temperature may be performed.
- 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.
- Not for use in detection or identification of unexpected antibodies.
- Not recommended to be used instead of antiglobulin crossmatch 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. As part of the release process, each lot of Bio-Rad Reagent Red Blood Cells is tested according to the 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 Bio-Rad Laboratories, Inc., at 800-224-6723.

### Note
Manual techniques are to be performed according to the manufacturer’s instructions. Each deviation from these instructions is the sole responsibility of the user. Used test material must be discarded as hazardous material. Manage waste according to local, state and national regulations.

### Glossary of Symbols

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition</th>
<th>Symbol</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="lot.png" alt="LOT" /></td>
<td>Batch Code</td>
<td><img src="ivd.png" alt="IVD" /></td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td><img src="caution.png" alt="Caution" /></td>
<td>Caution, consult accompanying documents</td>
<td><img src="i.png" alt="I" /></td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td><img src="manufacturer.png" alt="Manufacturer" /></td>
<td>Manufacturer</td>
<td><img src="use_by.png" alt="Use by" /></td>
<td>Use by YYYY-MM-DD</td>
</tr>
<tr>
<td><img src="contains_quantity.png" alt="Contains sufficient quantity for &lt;n&gt; tests." /></td>
<td>Contains sufficient quantity for &lt;n&gt; tests.</td>
<td><img src="ref.png" alt="REF" /></td>
<td>Catalog number</td>
</tr>
<tr>
<td><img src="temperature_limitation.png" alt="Temperature limitation" /></td>
<td>Temperature limitation</td>
<td><img src="vol.png" alt="VOL" /></td>
<td>Volume</td>
</tr>
</tbody>
</table>

---

**Bibliography**