**SUMMARY**

ABO blood grouping is generally performed by testing red cells with anti-A and anti-B (many laboratories also test with anti-A,B). Confirmation of the red cell group can be provided by simultaneously performing a reverse or serum group i.e testing the donor or recipients serum/plasma with reagent red blood cells of group A, B and A & B to detect anti-A and anti-B. Group A, reagent red blood cells can be used to identify anti-A, in the serum of group A people. Group O cells can be used to identify agglutination due to non-ABO antigens.

**PRINCIPLE OF THE TEST**

When mixed with human serum/plasma, group A, A1 and B reagent red blood cells will be agglutinated (clumping of red blood cells) if the corresponding antibody is present. Agglutination of group O reagent red blood cells shows the presence of a cold-reactive antibody other than anti-A and anti-B. This can indicate that the reactions with group A and B reagent red blood cells may not be due to the presence of anti-A or anti-B.

**REAGENT DESCRIPTION**

These reagent red blood cells are presented as a 2-3% suspension of washed red blood cells (pooled red blood cells for groups A, B and AB). In Modified Alsever's Solution. The Rh phenotype of the group A, A1, B and O reagent red blood cells is coded. The preservative solution has been specially formulated to preserve red cell integrity and antigenically and contains the following components - trisodium citrate, citric acid, dextrose, sodium metabisulfite, neomycin sulfate, thimerosal, benzyl alcohol and chloramphenicol (0.349g/l). The volume delivered by the reagent dropper contains the following components - Modified Alsever’s Solution. The Rh phenotype of the group A reagent red blood cells can be used to identify anti-A1 and anti-B1. The reactivity of the product may decrease during the dating period and the expected reaction patterns for serum/plasma of a patient/donor may cause unexpected agglutination of these reagent red blood cells.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The reagent red blood cells have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 complement components are detectable on the cell surface. Prior to release, each lot of ALBAcyte® Reagent Red Blood Cells for ABO SERUM Grouping are tested by FDA recommended methods to confirm specificity.

**BIBLIOGRAPHY**


**DATE OF ISSUE**

15 September 2013

**US Distributor**

Quotient

301 S. State Street

S-204

Newtown

PA 18940

USA

Customer Service Tel: 1-888-284-1301

Product Technical Support Tel: 1-888-228-1900

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E-Mail: customerservice@quotientbd.com

Web: www.quotientbd.com

**CAUTION:** The absence of all viruses has not been determined. This product has components (dropper bulbs) containing dry natural rubber.

**INTERPRETATION OF LABEL SYMBOLS**

**LOT**

Batch code

Use by (YYYY-MM-DD)

**IN VITRO DIAGNOSTIC MEDICAL DEVICE**

Storage temperature limitation (2-8°C)

**PRODUCT CODE**

In vitro diagnostic medical device

**CONSULT INSTRUCTIONS FOR USE**

Manufacturer

**INTENDED PURPOSE**

These reagent red blood cells are for the ABO reverse grouping of patient or donor serum/plasma.

**SPECIMEN COLLECTION AND PREPARATION**

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, EDTA and clotted specimens should be used. However, antibody reactivity may decrease over time. Blood specimens exhibiting gross hemolysis or contamination should not be used.

**TEST PROCEDURE**

**Tube Technique**

- Label 1 test tube for each of the ALBAcyte® reagent red blood cells to be tested.
- Add 2 drops of serum or plasma to each test tube.
- Add 1 drop of reagent red blood cell suspension to the test tube. Mix the contents of the test tube well and centrifuge.*

**Suggested centrifugation: 100g for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen positive red blood cells, yet allows easy resuspension of antigen-negative red blood cells.

* After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

**Interpretation of Results**

Agglutination = positive test result

No agglutination = negative test result

The expected reaction patterns for serum/plasma are shown below.

<table>
<thead>
<tr>
<th>Blood Group</th>
<th>A</th>
<th>B</th>
<th>O</th>
<th>A with anti-A</th>
<th>B with anti-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B</td>
<td>0</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A1</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>O</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A with anti-A1</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**QUALITY CONTROL**

Quality control of reagents is essential and should be performed on the day of use and in accordance with local and federal regulations. For ABO reagent red blood cells, appropriate ABO antibodies should be used.

**PERFORMANCE LIMITATIONS**

The presence of unexpected antibodies in the serum/plasma of a patient/donor may cause unexpected agglutination of these reagent red blood cells.

**ALBAcyte® group O reagent red blood cells do not meet the FDA requirements for reagent red blood cells intended for antibody screening of unexpected antibodies.

**ADDITIONAL MATERIALS REQUIRED**

- Isotonic saline
- 15 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Timer
- Agglutination viewer

**REAGENT RED BLOOD CELLS**

<table>
<thead>
<tr>
<th>Blood Group</th>
<th>A</th>
<th>B</th>
<th>O</th>
<th>A with anti-A</th>
<th>B with anti-B</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>B</td>
<td>0</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A1</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>O</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>A with anti-A1</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

**STABILITY OF REACTION**

Suggested centrifugation: 100g for 10 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen positive red blood cells, yet allows easy resuspension of antigen-negative red blood cells.

**QUICK TEST**

Prior to release, each lot of ALBAcyte® Reagent Red Blood Cells for ABO SERUM Grouping are tested by FDA recommended methods to confirm specificity.

**No U.S. standard of potency.**

**False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.**

**A and B pooled red blood cells are not recommended for pre-transfusion tests performed in lieu of a major crossmatch, to detect unexpected antibodies in patients samples.**

**SPECIFIC PERFORMANCE CHARACTERISTICS**

The reagent red blood cells have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 complement components are detectable on the cell surface. Prior to release, each lot of ALBAcyte® Reagent Red Blood Cells for ABO SERUM Grouping are tested by FDA recommended methods to confirm specificity.

**No U.S. standard of potency.**