BLOOD GROUPING REAGENT

**Anti-D delta**

ALBAclone®

(Human/Murine Monoclonal IgM/IgM)

For Slide and Tube Techniques

**REF** Z039U

**RECOMMENDED FOR DONOR TESTING**

- FOR IN VITRO DIAGNOSTIC USE
- Meets FDA potency requirements
- Discard if turbid
- Preservative: 0.1% (w/v) sodium azide

**INTERPRETATION OF LABELING SYMBOLS**

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
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<tbody>
<tr>
<td>LOT</td>
<td>Batch code</td>
</tr>
<tr>
<td>☑️</td>
<td>Use by (YYYY-MM-DD)</td>
</tr>
<tr>
<td>REF</td>
<td>Product Code</td>
</tr>
<tr>
<td>0°C</td>
<td>Storage temperature limitation (2-8 °C)</td>
</tr>
<tr>
<td>IVD</td>
<td>In vitro diagnostic medical device</td>
</tr>
<tr>
<td>📄</td>
<td>Consult instructions for use</td>
</tr>
<tr>
<td>🌐</td>
<td>Manufacturer</td>
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**CAUTIONS: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.**

**INTENDED USE**

This Anti-D reagent is for the in vitro detection and identification of human RhD blood group status in donor samples by direct agglutination.

**SUMMARY AND EXPLANATION**

First described in 1939, the RhD antigen is surpassed in importance only by the antigens of the ABO blood group system. Transfusion of RhD positive blood to an RhD negative recipient or failure to administer prophylactic anti-D to an RhD negative woman can result in the production of anti-D. Consequently, establishing the correct RhD group is fundamental to safe transfusion practice. Certain individuals exhibit a quantitative reduction in the expression of their RhD antigen and are categorized as weak D (Dw). Others display a qualitative variation in RhD antigen expression and are referred to as partial RhD. Weak D individuals may also be partial RhD.

This monoclonal Anti-D reagent will directly agglutinate red blood cells from all known D categories including DVI and, therefore, is ideally suited for RhD grouping of donor samples. This reagent is not recommended for the RhD grouping of patient samples for the purpose of transfusion. This reagent will also directly agglutinate most weak D and unclassified partial RhD samples.

**PRINCIPLE OF THE TEST**

When used by the recommended techniques, this reagent will cause agglutination (clumping) of red blood cells carrying the RhD antigen. Lack of agglutination demonstrates the absence of the RhD antigen.

**REAGENT DESCRIPTION**

The main component of this reagent is derived from the in vitro culture of the IgM/IgM secreting human/mouse heterohybridomas:

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<tr>
<th>Product Name</th>
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<tr>
<td>Anti-D delta</td>
<td>Z039U</td>
<td>LDM1/ESD1M</td>
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</table>

The formulation also contains bovine material, potentiators, EDTA and 0.1% (w/v) sodium azide.

**WARNINGS AND PRECAUTIONS**

For in vitro diagnostic use only
- Products should be used by qualified personnel
- Do not use beyond the expiration date
- Do not use if turbid
- Do not dilute
- The format of the expiration date is expressed as YYYY-MM-DD (Year-Month-Day)

This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into a sink, flush with a large volume of water to prevent azide build-up.

This reagent is of animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

**MATERIALS**

- ALBAclone® Anti-D delta

**Materials required but not provided**

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-D
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipets
- Optical aid (optional)
- Centrifuge
- Glass slides (optional)
- Timer
- Heating block/waterbath

**PROCEDURES**

**General Information**

**NOTE:** This reagent has been standardized for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

When a test is required to be incubated for a specific time period, a timer should be used.

It is recommended to allow reagents to reach 20-24 °C prior to use.

When using supplemental testing equipment (i.e. centrifuge), follow the procedures that are contained in the operator’s manual provided by the device manufacturer.

Two tube techniques offering different incubation times are described below. Both are equal and will give comparable results. The user can choose the incubation time within the range that is most compatible with their current laboratory procedures.

**Tube Technique - Immediate Spin**

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent red blood cells may be used directly from the vial or according to the manufacturer’s instructions).
2. Add 1 drop of blood grouping reagent to a glass test tube.
3. Add 1 drop of red blood cell suspension. Steps 2 and 3 may be performed in either order.

4. Mix the contents of the test tube and centrifuge.
   NOTE: Suggested centrifugation: 900-1000 g (approx. 3400 rpm) 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 re-suspension of antigen-negative red blood cells.

5. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.

6. Record results.

**Tube Technique – 15 Minute Incubation/Spin**

1. Prepare a 2-4% suspension of red blood cells in isotonic saline solution (Reagent Red Blood Cells may be used directly from the vial or according to the manufacturer’s instructions).

2. Add 1 drop of blood grouping reagent to a glass test tube.

3. Add 1 drop of red blood cells suspension. Steps 2 and 3 may be performed in either order.

4. Mix the contents of the test tube and incubate at 37 ± 1 °C for 15 minutes.

5. Centrifuge the test tube.
   NOTE: Suggested centrifugation: 900-1000 g (approx. 3400 rpm) 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 re-suspension of antigen-negative red blood cells.

6. After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.

7. Record results.

**Slide Technique**

1. Add 1 drop of blood grouping reagent to an appropriately prepared area of a glass slide e.g. a wax pencil oval.

2. Add 1 drop of whole blood or 1 drop of red blood cells suspended to approximately 30-45% in group homologous plasma/serum.

3. Mix by rocking the slide for approximately 30 seconds and incubate the test at 18-24 °C for 5 minutes with occasional mixing.

4. After incubation, immediately observe macroscopically for agglutination. This may be facilitated by reading over a diffuse light source.

5. Record results.

Refer to Performance Limitations section for additional guidance on the use of this product.

**STABILITY OF REACTION**

Test results should be read, interpreted and recorded immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

**INTERPRETATION OF RESULTS**

- Agglutination = positive test result
- No agglutination = negative test result

**QUALITY CONTROL**

Quality control of reagents is essential and should be performed on the day of use and in accordance with local, state and federal regulations.

**RhD(+) red blood cells should be used as a positive control.**

Suggested phenotype, Rh.

**RhD(+) red blood cells should be used as a negative control.**

Suggested phenotype, rr.

**PERFORMANCE LIMITATIONS**

Some very weak D and/or partial D samples may not react with monoclonal Anti-D reagents.

This reagent is potentiated to aid in the detection of weak D and partial D. Very weak agglutination detected at immediate spin (< 1+) should be tested using an alternative reagent by the Indirect Anti-human Globulin Test technique (preferably) prior to the final determination of the RhD type.

Certain tests performed on unwashed samples (e.g. cord), direct antiglobulin test positive samples, or samples stored and tested at below 20 °C, may exhibit false positive reactions due to the potentiators used in the formulation of this reagent. AlbaCheck Reagent Control for Anti-D (Z271U) may be used as a control reagent or alternatively by substituting 6-10% BSA in saline for the blood grouping reagent in the procedure chosen for use. If the control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made. A control test should always be used if a sample groups as AB RhD positive.

Slide techniques are not recommended for the detection of weakened antigen expression. If the detection of antigens exhibiting weakened or modified expression is required, negative slide tests should be confirmed by tube testing.

Heating blocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

The expression of certain red blood cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Gently re-suspend tube tests before reading. Excessive agitation may disrupt weak agglutination and produce false negative results.

Excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

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.

Suppressed or weak expression of blood group antigens may give rise to false negative reactions.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

Prior to release, each lot of ALBAclone® Anti-D delta is tested using FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

This Anti-D reagent will directly agglutinate red blood cells from all known RhD categories including DVI.

This reagent will also directly agglutinate most weak D and unclassified partial D samples.

**TECHNICAL NOTE**

- It is important to note that monoclonal Anti-D reagents vary widely in their ability to detect both partial D and weak D.

- Reagents used to test donors for the RhD antigen should detect category DVI.

**BIBLIOGRAPHY**

2. AABB Standards Program Committee: Standards for Blood Banks and Transfusion Services, ed 30 AABB, 2016

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