BLOOD GROUPING REAGENT

Anti-C
ALBAclone®
(Human/Murine Monoclonal)
For Tube Technique

**REF** Z064U

- Meets FDA potency requirements
- Discard if turbid
- Preservative: 0.1% (w/v) sodium azide

**CAUTIONS:** THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

**INTERPRETATION OF LABELING SYMBOLS**

- **LOT** Batch code
- **REF** Product Code
- **IVD** In vitro diagnostic medical device
- **www.quotitmed.com** Consult instructions for use
- **Manufacturer**

**STORAGE CONDITIONS**
The reagent should be stored at 2–8 °C.

**SPECIMEN COLLECTION AND PREPARATION**
Specimens should be collected by a standard collection technique. The specimen should be stored as soon as possible after collection. If testing is delayed, the specimen should be stored at refrigerated temperatures.

Clotted samples, or those collected in EDTA, should be tested within fourteen days from collection. Donor blood collected in ACD, CPD, CPDA-1, CP2D, CP2D with AS-1, and CPD with AS-1 and CPD with AS-5 may be tested until the expiration date of the donation.

Special care should be taken if hemolyzed samples must be tested. Grossly icteric or contaminated blood specimens should not be used.

**MATERIALS**
- Material provided
  - ALBAclone® Anti-C

**MATERIALS required but not provided**
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-C
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Optical aid (optional)
- Centrifuge
- Timer
- Heating block/waterbath

**PROCEDURE**

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

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

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

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

**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.

The bovine material used in the manufacture of this reagent was collected in a USDA approved facility.

Monoclonal antibodies exhibit a high degree of potency, avidity and specificity. When using such antibodies, great care should be taken to avoid cross contamination. This product has components (dropper bulbs) containing dry natural rubber.

This Anti-C reagent is for the in vitro detection and identification of the human C blood group antigen by direct agglutination.

**SUMMARY AND EXPLANATION**

Since the description of the RhD antigen by Levine and Stetson in 1939, more than 40 other Rh antigen complexes have been identified. With the exception of C, c, E and e, and perhaps C*, few of these antigens or their corresponding antibodies are encountered in routine testing. Rh antigens are controlled by a series of closely linked loci on chromosome 1, the genetic contribution from each parent being inherited as a haplotype e.g. Cde, cDE etc. Used separately, anti-Rh blood grouping reagents will indicate whether an individual expresses the corresponding antigen—an essential procedure in the selection of blood for transfusion of patients with Rh antibodies.

Testing red blood cell samples with anti-C, anti-D, anti-E, anti-c and anti-e may disclose the Rh phenotype from which the most probable genotype may be deduced. Knowing the probable paternal genotype can be of value in the management of RhD hemolytic disease of the fetus and newborn where Rh infants are likely to be more severely affected than Rr infants. Probable genotype information can also be useful in establishing antibody specificity and in selecting blood for transfusion of patients with Rh antibodies.

**PRINCIPLE OF THE TEST**

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

**REAGENT DESCRIPTION**

The main component of this reagent is IgM antibody derived from the in vitro culture of the IgM secreting human/mouse heterohybridoma of cell line MS-24:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code</th>
<th>Cell Line</th>
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</thead>
<tbody>
<tr>
<td>Anti-C</td>
<td>Z064U</td>
<td>MS-24</td>
</tr>
</tbody>
</table>

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

The volume delivered by the reagent bottle dropper is approximately 40 µL. Care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

**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.

Do not dilute
Do not use beyond the expiration date.
Do not use if turbid
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STABILITY OF REACTION

7. Record results.

6. After centrifugation, gently shake the tube to dislodge the tube contents and re-suspend the antigen-negative red blood cells.

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.

4. Mix the contents of the test tube and incubate at 37 °C ± 1 °C for 5-15 minutes.

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

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

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.)

STABILITY OF REACTION

Test results should be read and interpreted 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.

C+c+ red blood cells should be used as a positive control. C-c+ red blood cells should be used as a negative control.

False positive test results are rarely seen with low-protein reagents. False positive agglutination may be due to a positive direct antiglobulin test (DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBAclone® Anti-C (Monoclonal) should be substituted for the blood grouping reagent in the testing procedure. A negative result would serve as an appropriate control. If the monoclonal control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

Comparator Study Results

During comparator studies (data on file at Alba Bioscience Limited), blood samples were tested with ALBAclone® Anti-C (Monoclonal) as follows:

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Anti-C</th>
<th>Comparator Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>Positive</td>
<td>703</td>
<td>0</td>
</tr>
<tr>
<td>Negative</td>
<td>0</td>
<td>336</td>
</tr>
<tr>
<td>Total</td>
<td>703</td>
<td>336</td>
</tr>
</tbody>
</table>

Positive Percent Agreement = 100 0.99

Negative Percent Agreement = 100 0.99

In performance evaluation studies, 1039 samples were tested with ALBAclone® Anti-C (Monoclonal). The positive percent agreement at the one-sided 95% exact lower confidence limit was 0.99 for agglutination tests based on a comparison of interpreted results. The negative agreement at the one-sided 95% exact lower confidence limit was 0.99 for agglutination tests based on a comparison of interpreted results.

Results were evaluated against comparable FDA approved products using the appropriate methods for the comparators.

BIBLIOGRAPHY

2. AABB Standards Program Committee: Standards for Blood Banks and Transfusion Services, 29th ed. AABB, 2014

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