BLOOD GROUPING REAGENT

Anti-C\textsuperscript{w}
ALBAclone\textsuperscript{®}
(Human/Murine Monoclonal)
For Tube Technique

REF Z106U

- 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

<table>
<thead>
<tr>
<th>LOT</th>
<th>Batch code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</table>

USE BY (YYYY-MM-DD)

<table>
<thead>
<tr>
<th>REF</th>
<th>Product code</th>
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<tbody>
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</table>

Storage temperature limitation (2–8 °C)

<table>
<thead>
<tr>
<th>IVD</th>
<th>In vitro diagnostic medical device</th>
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<tbody>
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</table>

Consult instructions for use

www.quotenbdf.com

Manufacturer

INTENDED USE
This Anti-C\textsuperscript{w} reagent is for the in vitro detection and identification of the human C\textsuperscript{w} 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\textsuperscript{w}, 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 will 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 R\textsuperscript{D}r infants are likely to be more severely affected than R\textsuperscript{d}r 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\textsuperscript{w} antigen. Lack of agglutination demonstrates the absence of the C\textsuperscript{w} 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-110:

<table>
<thead>
<tr>
<th>Product Name</th>
<th>Product Code</th>
<th>Cell Line</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-C\textsuperscript{w}</td>
<td>Z106U</td>
<td>MS-110</td>
</tr>
</tbody>
</table>

The formulation contains bovine material 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.

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.

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 tested 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-3, 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
Materials provided
- ALBAclone\textsuperscript{®} Anti-C\textsuperscript{w}

Materials required but not provided
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-C\textsuperscript{w}
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Optical aid
- 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.

RECOMMENDED TECHNIQUE
Tube Technique – 5-15 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 cell suspension. Steps 2 and 3 may be performed in either order.
4. Mix the contents of the test tube and incubate at 37 °C ± 1 °C for 5-15 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.

**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**

<table>
<thead>
<tr>
<th>Agglutination</th>
<th>Comparator Reagent</th>
<th>Anti-Cw</th>
<th>Comparator Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>Positive</td>
<td>157</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>8</td>
<td>894</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>165</td>
<td>905</td>
</tr>
</tbody>
</table>

**SPECIFIC PERFORMANCE CHARACTERISTICS**
Prior to release, each lot of ALBAclone® Anti-Cw is tested by macroscopically for agglutination. Negative reactions may be examined with an optical aid. 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.

**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.

**FALSE POSITIVE AND FALSE NEGATIVE RESULTS**

**INTERPRETATION OF RESULTS**

<table>
<thead>
<tr>
<th>Trial Reagent</th>
<th>Anti-Cw</th>
<th>Comparator Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Negative</td>
<td></td>
<td></td>
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<tr>
<td>Total</td>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>Classification</th>
<th>Number of Discrepancies</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>DAT Positive</td>
<td>7</td>
<td>The comparator reagent utilizes an enzyme addition method which may give false positive results with DAT positive samples.</td>
</tr>
<tr>
<td>Unresolved</td>
<td>2</td>
<td>ALBAclone® Anti-Cw reagent and comparator reagent continued to show a different result following repeat testing. Resolver reagent was concordant with the Trial reagent result.</td>
</tr>
</tbody>
</table>

In performance evaluation studies, 1060 samples were tested with ALBAclone® Anti-Cw (Monoclonal). Test results were evaluated against a comparable approved product using the appropriate method for the comparator. The positive percent agreement at the one-sided 95% exact lower confidence limit was 0.91 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.

The comparator reagent utilizes an enzyme addition method which may give false positive results with DAT positive samples which may have had an impact on the outcome of the testing and the discrepancies observed.

The low positive percent agreement at the one-sided 95% lower confidence limit (i.e. less than the acceptance criteria of 0.99) is partly due to the discrepancies observed with DAT positive red blood cells but is also influenced by the low frequency of positive samples encountered during the study.

**PREDICTIVE VALUE**

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

**DATE OF ISSUE**
YYYY-MM-DD

**US Distributor**

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**Customer Service Fax:** 1-888-694-5208
**E-mail:** customer.serviceUS@quotientbd.com
**Web:** www.quotientbd.com

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