BLOOD GROUPING REAGENT

Anti-C^{w}

ALBAclone®
(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

LOT	Batch code
	Use by (YYYY-MM-DD)
REF	Product code
8°C 2°C	Storage temperature limitation (2– 8 °C)
IVD	*In vitro* diagnostic medical device
www.alivedx.com	Consult instructions for use
	Manufacturer
Rx only	Rx only

INTENDED USE
This Anti-C^{w} reagent is for the *in vitro* detection and identification of the human C^{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^{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_2r infants are likely to be more severely affected than R_1r 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^{w} antigen. Lack of agglutination demonstrates the absence of the C^{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:

Product Name	Product Code	Cell Line
Anti-C^{w}	Z106U	MS-110

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.
Contains material of murine origin; therefore, handle appropriately as the absence of murine 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 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® Anti-C^{w}

Materials required but not provided
- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-C^{w}
- 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.

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
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^w+ red blood cells should be used as a positive control.
C^w- 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, ALBAcheck® - BGS Monoclonal Control (Z271U) or 6-10% albumin in saline may 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.

PERFORMANCE LIMITATIONS
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 the 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.

Care should be taken when testing red blood cells that have been treated with proteolytic enzymes, as these may produce false positive or false negative results.

SPECIFIC PERFORMANCE CHARACTERISTICS
Prior to release, each lot of ALBAclone® Anti-C^w 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^w (Monoclonal) as follows:

Anti-C^w		Comparator Reagent			One-sided 95% Exact lower confidence limit
		Positive	Negative	Total	
Trial Reagent	Positive	157	1	158	
	Negative	8	894	902	
	Total	165	895	1060	
Positive Percent Agreement				95.2	0.91
Negative Percent Agreement				99.9	0.99

Classification	Number of Discrepancies	Comment
DAT Positive	7	The comparator reagent utilizes an enzyme addition method which may give false positive results with DAT positive samples
Unresolved	2	ALBAclone® Anti-C^w reagent and comparator reagent continued to show a different result following repeat testing. Resolver reagent was concordant with the Trial reagent result

In performance evaluation studies, 1060 samples were tested with ALBAclone® Anti-C^w (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.

Precision Study Results
As part of the performance evaluation, precision and lot to lot studies were performed using multiple operators, days and runs to confirm repeatability and reproducibility of test results in the same run, day and with the same operator and between runs, days and operators. The study took into account variables such as days of the week, times of day and supplementary reagents used in testing.

There were no discordant results; all antigen positive test outcomes generated unequivocal positive reactions and antigen negative test outcomes generated unequivocal negative reactions.

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DATE OF ISSUE
2025-08

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 Z106UPI/05

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