BLOOD GROUPING REAGENT

Anti-E

ALBAclone®

(Human/Murine Monoclonal IgM)

For Tube Technique

REF **Z073U**

- **FOR *IN VITRO* DIAGNOSTIC USE**
- **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.quotientbd.com	Consult instructions for use
	Manufacturer

INTENDED USE

This Anti-E reagent is for the *in vitro* detection and identification of the human E 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 determination of antibody specificity and 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 are 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 E antigen. Lack of agglutination demonstrates the absence of the E antigen.

REAGENT DESCRIPTION

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

Product Name	Product Code	Cell Line
ALBAclone® Anti-E	Z073U	DEM1

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

NOTE: The volume delivered by the reagent bottle dropper is approximately 40µL. Bearing this in mind, care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

STORAGE

The reagent should be stored at 2-8 °C.

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 buildup. This reagent is of animal origin; therefore care must be taken during use and disposal as there is a potential infection risk.

CAUTION: 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. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

The bovine material which was used has been collected in a USDA approved facility.
Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.
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.

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. Blood collected into other anticoagulants may be used (ACD, CPD and ACD A1). Donor blood 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-E

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

PROCEDURE

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.
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 - 5 Minute Incubation/Spin

1. Add 1 drop of blood grouping reagent to a glass test tube.
2. Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Reagent red cells may be used as provided (preservative suspended).
3. Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 5 minutes.
4. 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 resuspension 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. Add 1 drop of blood grouping reagent to a glass test tube.
2. Add 1 drop of red blood cells suspended to 2-4% in isotonic saline. Reagent red cells may be used as provided (preservative suspended).
3. Mix the contents of the test tube well and incubate at 37 °C ± 1 °C for 15 minutes.
4. 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 resuspension 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.

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 each day of use and in accordance with local, state and federal regulations.

E+e+ red blood cells should be used as a positive control
E-e+ 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

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 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-E is tested using 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-E (Monoclonal) as follows*:

Anti-E		Comparator Reagent			One-sided 95% Exact lower confidence limit
		Positive	Negative	Total	
Trial Reagent	Positive	166	0	166	
	Negative	0	92	92	
	Total	166	92	258	
Positive Percent Agreement*				100	98.21
Negative Percent Agreement*				100	96.80

** The data presented in this table was generated during field trials executed in support of the original US licensing of this reagent.*

BIBLIOGRAPHY

1. Roback, JD, Grossman BJ, Harris T, *et al*. AABB Technical Manual, 18th ed. AABB, 2014.
2. AABB Standards Program Committee. Standards for Blood Banks and Transfusion Services. 29th ed. AABB 2014.
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012.

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