



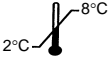




BLOOD GROUPING REAGENT
Anti-E
ALBAclone®
(Human/Murine Monoclonal IgM)
For Tube Technique

This insert refers to product Z073U

- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% 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

	Batch code
	Use by (YYYY-MM-DD)
	Storage temperature limitation (2°C-8°C)
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Harmful
	Manufacturer

SUMMARY

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.

INTENDED USE

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

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 DEM1.

The formulation also contains potentiators, EDTA and 1g/l sodium azide.

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

STORAGE CONDITIONS

The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

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 sink, flush with a large volume of water to prevent azide buildup.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

This product has components (dropper bulbs) containing dry natural rubber. This reagent is for *in vitro* diagnostic use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C - 8°C. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

General Information

This reagent has been standardised 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.

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.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-E
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath @ 37°C
- Timer

RECOMMENDED TECHNIQUES

Tube Technique - 5 Minute Incubation / Spin

- . Add 1 volume of blood grouping reagent to a test tube.
- . Add 1 volume of red blood cells suspended to 2-4% in isotonic saline.
- . Mix the contents of the test tube well and incubate at 37°C ± 1°C for 5 minutes.
- . Centrifuge the test tube.
Suggested centrifugation: 1000g 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.
- . After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

Tube Technique – 15 Minute Incubation / Spin

- . Add 1 volume of blood grouping reagent to a test tube.
- . Add 1 volume of red blood cells suspended to 2-4% in isotonic saline.
- . Mix the contents of the test tube well and incubate at 37°C ± 1°C for 15 minutes.
- . Centrifuge the test tube.
Suggested centrifugation: 1000g 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.
- . After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each series of groups, single groups and in accordance with local, state and federal regulations. A red blood cell sample showing heterozygous expression of the E antigen should be used as a positive control. E antigen negative red blood cells should be used as a negative control.

PERFORMANCE LIMITATIONS

Driblocks 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.

Direct antiglobulin test positive samples may exhibit false positive reactions due to the potentiators used in the formulation of this reagent. A satisfactory reagent control may be achieved 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.

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

Excessive centrifugation can lead to difficulty in resuspending 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

BIBLIOGRAPHY

1. Technical Manual. 15th ed. Bethesda, MD: American Association of Blood Banks, 2005.
2. Standards for Blood Banks and Transfusion Services. 24th ed. Bethesda, MD: American Association of Blood Banks, 2006.

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