

BLOOD GROUPING REAGENT

Anti-Le^b

ALBAclone®

(Murine Monoclonal IgM)

For Tube Technique

REF Z217U

- 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



Batch code



Use by (YYYY-MM-DD)



Product code



Storage temperature limitation (2-8 °C)



In vitro diagnostic medical device



Consult instructions for use



Manufacturer



Rx only

INTENDED USE

The Anti-Le^b reagent is for the *in vitro* detection and identification of human Le^b positive red blood cells by direct agglutination.

SUMMARY AND EXPLANATION

Monoclonal Anti-Le^a and Anti-Le^b blood grouping reagents enable red blood cells to be classified as one of four phenotypes: Le(a+b-), Le(a-b+), Le(a-b-) Le(a+b+). The latter phenotype, Le(a+b+), is extremely rare.

Agglutination of red blood cells with either of these reagents indicates the presence of the appropriate antigen on the red blood cell surface. Lewis antigens are also present in serum and other body fluids. Cord cells do not express Lewis antigens in sufficient quantity to be agglutinated by these reagents and will therefore group as Le(a-b-). An infant's true Lewis status does not normally become apparent until the age of 2 years (approx).

PRINCIPLE OF THE TEST

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

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgM immunoglobulin-secreting mouse hybridoma, LEB2.

Product Name	Product Code	Cell Line
ALBAclone® Anti-Le ^b	Z217U	LEB2

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

NOTE: 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.

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 FOR INFECTIOUS AGENTS WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS.

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-Le^b

Materials required but not provided

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-Le^b
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Optical aid (optional)
- Centrifuge
- Timer
- Heating block/waterbath

PROCEDURE

NOTE: This reagent has been standardized for use by the technique 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.

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 tested as provided (preservative suspended).
3. Mix the contents of the test tube well and incubate at 20–25 °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 re-suspension 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.

Le(a-b+) red blood cells should be used as a positive control
Le(a-b-) red blood cells should be used as a negative control

LIMITATIONS

Cord cells do not express Lewis antigens in sufficient quantity to be agglutinated and will therefore group as Le(a-b-).

Direct antiglobulin test positive samples may exhibit false positive reactions due to the potentiators used in the formulation of this reagent. Unexpected weak positive reactions (1+ or less) obtained with this reagent should be interpreted with caution. Spontaneous agglutination can be eliminated as the cause of the weak reaction if the sample produces a negative result in direct antiglobulin tests. Samples that type as Le(a+b+) should be evaluated further by performing a direct antiglobulin test to ensure the typing results are not due to spontaneous agglutination.

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. The LEB2 cell line from which this reagent is derived produces an Anti-LebH which has been formulated to optimize detection of the Le^b antigen on red blood cells of all ABO types. However, on rare occasions there is the potential of false positive reactions occurring with group O Le(b-) red blood cells due to cross reactivity between the antibody and the H antigen. Weakened reactions with group AB Le(b+) red blood cells may also be encountered.

Suppressed or weak expression of blood group antigens may give rise to false negative reactions.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

BIBLIOGRAPHY

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3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012.
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