QUOTIENT

BLOOD GROUPING REAGENT

Anti-Le^b

ALBAclone®
(Murine Monoclonal)
For Tube Techniques

REF **Z217** CE

INTERPRETATION OF LABELLING 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
	Consult instructions for use
	Harmful
	Manufacturer

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 two years (approximately).

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause the 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 secreting mouse hybridoma, LEB2.

Product Name	Product Code	Cell Line
Anti-Le^b	Z217	LEB2

The formulation also contains bovine serum albumin, potentiator, and 0.1 % (w/v) sodium azide.

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

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

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 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.

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. Donor blood collected in ACD, CPD, CPDA-1, CP2D, CP2D with AS-3, 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 hemolysed 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
- PBS pH 7.0 ± 0.2
- 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
- Centrifuge
- Timer

PROCEDURE

NOTE: This reagent has been standardised 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.

It is recommended to allow reagents to reach 18-24 °C prior to use.

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 – NIS 15 Minute Incubation/Spin
1. Prepare a 2-3% suspension of red blood cells in cells in PBS pH 7.0 ± 0.2. (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 18-24 °C for 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.
7. 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 the day of use.

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

LIMITATIONS

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

The LEB2 cell line from which this reagent is derived produces an Anti-Le^{bH} which has been formulated to optimise 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.

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

When using this reagent do not use any optical aid to interpret results.

SPECIFIC PERFORMANCE CHARACTERISTICS

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

The ALBAclone® Anti-Le^{b} reagent reacts with cells expressing the Le^{b} antigen.

BIBLIOGRAPHY

1. British Committee for Standards in Haematology: Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories, *Trans Med* 2013; 23: 3-35
2. National Blood Service: Guidelines for the Blood Transfusion Services in the United Kingdom, ed 8. TSO, 2013
3. Reid ME, Lomas-Francis C, Olsson ML: The Blood Group Antigen FactsBook, ed 3. Academic Press, 2012

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