BLOOD GROUPING REAGENT

Anti-Le^{a}

ALBAclone®

(Murine Monoclonal IgM)

For Tube Technique

This insert refers to product Z212U

- **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

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

SUMMARY

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).

INTENDED USE

The Anti-Le^{a} reagent is for the *in vitro* detection and identification of human Le^{a} positive red blood cells 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 Le^{a} antigen. Lack of agglutination demonstrates the absence of the Le^{a} antigen.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgM immunoglobulin secreting mouse hybridoma, LEA2.
The formulation also contains 100g/l dextran, 20g/l BSA 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.
As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.
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 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.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-Le^{a}
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Incubator
- Timer

RECOMMENDED TECHNIQUE

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 20° – 25°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. We suggest that the following red blood cell samples are used to control the reactions of this reagent.

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

PERFORMANCE 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.

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.

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.

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-Le^{a} 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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