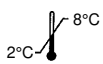
QUOTIENT

# ALBAclone®
# Anti-Lu$^b$

**BLOOD GROUPING REAGENT**
**Mouse Monoclonal / Direct Agglutinin**

REF **Z223**




IVD

CE

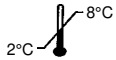
## INTRODUCTION

Since the description of the antigen Lu$^a$ in 1945 by Callender *et al* and its allele Lu$^b$ in 1956 by Cutbush *et al*, the Lutheran blood group system has been shown to be increasingly complex. Over 10 antigens are now known to be associated with the system and 4 sets of alleles have been identified ie Lu$^a$, Lu$^b$; Lu6, Lu9; Lu8, Lu14; Lu18 and Lu19. These are probably controlled from a series of closely linked loci so that Lutheran antigens, like CDE in the Rh system are inherited as a haplotype.
The antigens of the Lutheran blood group system are not completely developed at birth, show variable strength and are destroyed by trypsin. The low frequency phenotype Lu(a-b-) arises from at least 3 different genetical backgrounds.

## INTERPRETATION OF LABEL SYMBOLS

LOT Batch code


Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)

IVD *In vitro* diagnostic medical device

Consult instructions for use


Manufacturer

REF Product Code

## INTENDED PURPOSE

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

## REAGENT DESCRIPTION

The main component of this reagent is derived from the *in-vitro* culture of the mouse hybridoma LU2 which secretes IgG anti-Lu$^b$.
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.
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°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% sodium azide.
Sodium azide 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 build-up.

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.

This reagent is for *in vitro* professional 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 seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

## TEST PROCEDURES

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

## ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells suitable for the control of Anti-Lu$^b$
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

## RECOMMENDED TECHNIQUES

**Tube Technique - NIS/LISS, 37ºC, 15 Minutes/Spin**

- Add 1 volume of blood grouping reagent to a 12 x 75mm glass test tube.
- Add 1 volume of red cells suspended to 2-3% in PBS pH 7.0 ± 0.2 or 1.5 - 2% in LISS.
- Mix thoroughly and incubate for 15 minutes at 37ºC.
- Following incubation, centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and 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 and with single groups. As a minimum a positive and a negative control should be used.

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

**PERFORMANCE LIMITATIONS**

The antigens of the Lutheran blood group system are not completely developed at birth, show variable strength and are destroyed by trypsin.

Tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

It is important to use the recommended g force during centrifugation as 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 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.

UK frequencies: Lu(a+b-) 0.15%; Lu(a+b+) 7.5%; Lu(a-b+) 92.35%

**SPECIFIC PERFORMANCE CHARACTERISTICS**

This Anti-Lu$^{b}$ reagent will give significantly weaker reactions with red cells of the phenotypes Lu(a-b+$^{w}$) and Lu(a+b+$^{w}$).

**DATE OF ISSUE**

2024-02

For further information or advice please contact your local distributor.


EC REP

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 Z223PI/07

INSTRUCTIONS FOR USE
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