



ALBAsera[®] Anti-Fy^b BLOOD GROUPING REAGENT indirect agglutinin

REF Z153



Consult instructions for use



Harmful



Manufacturer



Product Code

INTENDED PURPOSE

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

REAGENT DESCRIPTION

This reagent has been prepared from plasma collected from blood donors. ABO haemagglutinins were removed by adsorption. Conversion to serum was achieved by the addition of calcium chloride and where necessary, thrombin. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 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.

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 (EC No.247-852-1) and is classified as harmful. R22 Harmful if swallowed.

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.

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 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. Users are advised to carefully confirm reagent suitability before using alternative techniques.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells suitable for the control of Anti-Fy^b
- Polyspecific Anti-Human Globulin / Anti-Human IgG
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES

LISS, 37°C Indirect Antiglobulin

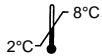
- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass tube.
- Add 2 volumes of 1.5-2% LISS suspended cells.
- Mix the test well and incubate for 15 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0 ± 0.2 (e.g. 4ml of PBS per 12 x 75mm tube).

- NOTE:** (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.
- Add two drops of anti-human globulin reagent to each tube.
 - Mix thoroughly.
 - 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.

NIS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass tube.
- Add 1 volume of 2-3% NIS suspended red cells.
- Mix the test well and incubate for 45 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0 ± 0.2 (eg 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.



IVD

CE
0843

INTRODUCTION

Anti-Fy^a and anti-Fy^b were described in 1950 and 1951 respectively and define a pair of alleles on the long arm of chromosome 1.

In whites the phenotype Fy(a-b-) is exceptionally rare. In blacks, the incidence of Fy(a-b-) is 68% and it is perhaps not insignificant that Fy(a-b-) red cells are resistant to invasion by the malarial parasite Plasmodium vivax. This is thought to be due to balanced polymorphism.

Fy^a and Fy^b antigens are destroyed when red cells are treated with appropriate concentrations of the proteolytic enzymes ficin, papain and bromelain.

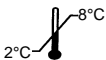
INTERPRETATION OF LABEL SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)



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

IVD

In vitro diagnostic medical device

- (ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.
- . Add two drops of anti-human globulin reagent to each tube.
- . Mix thoroughly.
- . 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.

DATE OF ISSUE

15 September 2013

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.

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

PERFORMANCE LIMITATIONS

Since the antibodies from which this product has been prepared were stimulated by red blood cells, extensive tests have been undertaken to exclude the presence of additional contaminating blood group antibodies. However, it is impossible to state categorically that reagents of this nature will only contain antibodies of the required specificity.

Driblocks and waterbaths promote better heat transfer and are recommended for 37°C tests, particularly where the incubation period is 30 minutes or less.

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

In tube tests 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.

Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their Fy^b status.

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: Fy (a+b-) 17%; Fy (a+b+) 47%;
Fy (a-b+) 34%

For further information or advice please contact your local distributor.



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Z153PI/05