QUOTIENT

ALBAsera®
Anti-Kp^a

BLOOD GROUPING REAGENT
Human Polyclonal / Indirect Agglutinin

REF Z139

2°C 8°C

IVD

INTRODUCTION

Since the description of the antigen K in 1946 by Coombs *et al* and its allele k in 1949 by Levine *et al*, the Kell blood group system has been shown to be increasingly complex. Over 20 antigens are now known to be associated with the system and 4 sets of alleles have been identified ie K, k; Kp^a, Kp^b, Kp^c; Js^a, Js^b; K11 (C) and K17 (Wk^a). These are probably controlled from a series of closely linked loci so that Kell antigens, like CDE in the Rh system, are inherited as a haplotype.
The antigens of the Kell blood group system are of further interest in that they tend to occur either very frequently (eg k 99.8%) or relatively infrequently (eg K 8%) and show considerable ethnic variation e.g. the antigen Js^a is extremely rare in whites but is expressed by 20% of black Americans. The antigens require the presence of disulphide bonds for full expression and are destroyed by treatment with trypsin and chymotrypsin either separately or in combination.
Kell system antibodies are capable of causing haemolytic transfusion reactions and haemolytic disease of the newborn and are optimally detected by the indirect antiglobulin technique.

INTERPRETATION OF LABEL SYMBOLS

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

INTENDED PURPOSE

The Anti-Kp^a reagent is for the *in vitro* detection and identification of human Kp^a positive red blood cells.

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

General Information

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-Kp^a
- 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 $\pm$ 0.2 (eg 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.

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.

Kp(a+b+) red cells should be used as a positive control.
Kp(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.

Kell system antigen expression may be dramatically weakened in some cases of Chronic Granulomatous Disease.

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

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.

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: Kp(a+b-) 0.1%; Kp(a+b+) 2%; Kp(a-b+) 98%

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For further information or advice please contact your local distributor.

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