BLOOD GROUPING REAGENT

Anti-K

ALBAsera®

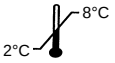
REF Z131U

For Indirect Antiglobulin Test by Tube Technique

- **Meets FDA potency requirements**
- **Discard if turbid**
- **Preservative: 0.1% sodium azide**

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER

INTERPRETATION OF LABEL SYMBOLS

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

INTENDED USE

The Anti-K reagent is for the *in vitro* detection and identification of human K positive red blood cells by the indirect antiglobulin test.

SUMMARY AND EXPLANATION

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 and over 20 antigens are now known to be associated with the system. 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 Caucasians but is expressed by 20% of African 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 hemolytic disease of the newborn and are optimally detected by the indirect antiglobulin technique.

PRINCIPLE OF THE TEST

When used by the recommended technique, this reagent will cause agglutination (clumping) of red blood cells carrying the K antigen. Lack of agglutination of the red blood cells demonstrates the absence of the K antigen.

REAGENT DESCRIPTION

This reagent has been prepared from plasma collected from blood donors. ABO hemagglutinins 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.

PRECAUTIONS

Store at 2°C - 8°C.
Do not use if turbid.
Do not dilute.
Do not use beyond the notified expiry date.
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.
Handle and dispose of reagents as potentially infectious.
CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
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 hemolysis or contamination should not be used. Do not use collection tubes that contain serum or plasma/cell separation media. 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.

MATERIALS

Materials provided

- ALBAsera® Anti-K

Materials required but not provided

- Isotonic saline
- Reagent red blood cells suitable for the control of Anti-K
- Polyspecific Anti-Human Globulin / Monospecific Anti-Human IgG
- IgG sensitized red blood cells
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Heating block / waterbath @ 37°C
- Optical aid

TEST PROCEDURE

General Information

This reagent has been standardized 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 period of time, a timer should be used.

RECOMMENDED TECHNIQUES

37°C Indirect Antiglobulin

- Add 2 drops of blood grouping reagent to a test tube.
- Add 1 drop of red blood cells suspended to 2-4% in isotonic saline.
- Mix the test well and incubate for 15-45 minutes at 36-38°C.
- Wash the test at least 3 times with a large excess isotonic saline. e.g. 4ml of saline per 12 (or 10) x 75mm glass tube)

NOTE: (i) allow adequate spin time to sediment the red blood cells.
(ii) make sure that most of the residual saline is removed at the end of each wash.

- Add Anti-Human Globulin to each test tube in the amount specified in the manufacturer's product insert.
- Mix the contents of the test tube well and centrifuge. Suggested centrifugation: 900-1000g for 10-20 seconds or a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive cells, yet allows easy resuspension of antigen-negative cells.
- Gently shake the test tube to dislodge the cell button from the bottom and observe macroscopically for agglutination. Negative reactions may be examined with an optical aid.
- Record results.
- Add IgG sensitized antiglobulin control cells to confirm the validity of negative test results.

STABILITY OF REACTION
Test results should be read and interpreted 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

Frequency (%):

Phenotype	Caucasians	African Americans
K+k-	0.2	Rare
K+k+	8.8	2
K-k+	91.0	98

QUALITY CONTROL
Quality control of reagents is essential and should be performed on each day of use 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.

Kk red blood cells should be used as a positive control.
kk red blood 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 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 K 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.

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.

Suppressed or weak expression of blood group antigens may give rise to false-negative reactions.

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 ALBAsera® Anti-K is tested by FDA recommended methods against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

For additional information or technical support, contact Product Technical Support at 1-888-228-1990.

BIBLIOGRAPHY

1. Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.

2. Standards for Blood Banks and Transfusion Services. 25th ed. Bethesda, MD: American Association of Blood Banks, 2008.

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