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 and over 20 antigens are now known to be associated with the system. The antigens require treatment with trypsin and chymotrypsin in combination. The antigens of the Kell blood group system are of further interest in that they tend to occur either very frequently (eg k 98.8%) or relatively infrequently (eg K 8%) and show considerable ethnic variation eg the antigen Jk

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.

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INTENDED PURPOSE

The Anti-k reagent is for the in vitro detection and identification of human k (cellano) positive red blood cells by direct agglutination.

REAGENT DESCRIPTION

The main component of this reagent is derived from the in vitro culture of the immunoglobulin secreting mouse hybridoma Lk1. The formulation consists of culture supernatant in MES buffer pH 5.2 containing 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. 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

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

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

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

RECOMMENDED TECHNIQUES

Tube Technique - NIS 5 Min 20°C Spin
- Add 2 volumes of blood grouping reagent to a 12 x 75mm glass test tube.
- Add 2 volumes of red cells suspended to 2-3% in PBS pH 7.0 ± 0.2.
- Mix thoroughly and incubate for 5 minutes at 20°C.
- 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.

Kk red cells should be used as a positive control.
KK red cells should be used as a negative control.

PERFORMANCE LIMITATIONS

Red cells from individuals of the Kell phenotype KkKp (a+b+) show a substantially weakened expression of k antigen.

This monoclonal antibody may not detect weak genetic variants of the k antigen.

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

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: KK 0.2%; Kk 7.8%; kk 92%

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