ERYCLONE®

ANTI-K (KELL)

MONOCLONAL ANTI-K (KELL) ANTIBODIES FOR SLIDE AND TUBE TESTS

SUMMARY

Kell system antigens are expressed on the red cell membrane in low density and are weakened or destroyed by treatment with reducing agents and with acid. The K antigen was first identified in 1946 because of an antibody that caused HDFN. The allele responsible for the K antigen is present in 9% of Whites and approximately 2% of Blacks. The Kell system antibodies are capable of causing hemolytic transfusion reactions and hemolytic disease of the newborn and are optimally detected by the indirect antiglobulin technique. Because the K antigen is strongly immunogenic, Anti-K is frequently found in sera from transfused patients.
ERYCLONE® Anti-K (KELL) sera can be used to detect the presence of K antigen on red blood cells for phenotyping and blood transfusion purpose.

REAGENTS

ERYCLONE® Anti-K (KELL) contains monoclonal IgM antibodies (Clone MS-56).
Each batch of reagent undergoes rigorous quality control at various stages of its manufacture for its specificity, avidity, titre and performance.

REAGENT STORAGE AND STABILITY

1. Store the reagent at 2-8°C. DO NOT FREEZE.
2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

PRINCIPLE

Human red blood cells possessing K antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with ERYCLONE® Anti-K (KELL) reagents is a positive test result and indicates the presence of the corresponding antigen on red blood cells. Absence of agglutination of red blood cells with ERYCLONE® Anti-K (KELL) reagents is a negative test result and indicates the absence of the corresponding antigen on red blood cells.

PRECAUTIONS

1. In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. MSDS available on request.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source; hence contamination due to HBsAg, HIV and HCV is practically excluded.
5. It is necessary to use the dropper provided in the reagent vial to dispense a reagent drop.
6. It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution.
7. Do not use damaged or leaking reagents.
8. Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8° C if not tested immediately.
Do not use haemolysed samples.
Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

EDTAor HEPARIN :	2 days
Sodium citrate or sodium oxalate :	14 days
ACD or CPD :	28 days

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Glass Test tubes (12 x 75 mm), Micropipettes, Isotonic saline (0.9% NaCl), Centrifuge, Timer, Mixing sticks, test tube rack.

TEST PROCEDURE

Bring reagent and samples to room temperature before testing.

Slide test

1. Place one drop of ERYCLONE® Anti-K (KELL) reagent using the reagent vial dropper separately on a clean glass slide.
2. To each reagent drop, add 50µl of whole blood.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm .
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at two minutes.

Tube test

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of ERYCLONE® Anti-K (KELL) reagent using the reagent vial dropper into corresponding labeled test tube.
3. Pipette into each of the test tubes, 50µl of the test red cell suspension and mix well.
4. Incubate at room temperature for 5 mins.
5. Centrifuge for 1 minute at 1000 rpm (125g) or 20 seconds at 3400 rpm (1000 g).
6. Gently suspend the cell button, observing for agglutination macroscopically.

INTERPRETATION OF RESULTS

Slide and Tube Tests

Agglutination is a positive test result and indicates the presence of K antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative test result and indicates the absence of K antigen.

REMARKS

1. As undercentrifugation or over centrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and time required for achieving the desired results.
2. In the tube test procedure, it is recommended that tubes with negative reactions should be centrifuged and results read again after 5 minutes so that weak antigens are not overlooked.
3. A positive control known to possess K antigen and a negative control (known red blood cells lacking the K antigen) should be tested preferably on a daily basis so as to check reagent performance and validation of test results.
4. After usage the reagents must be immediately recapped and replaced at 2-8° C storage.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty and sale for any other purpose.

BIBLIOGRAPHY

1. Daniels G. (1995) Human Blood groups, Blackwell Science Publications.
2. Mollison P.L. and Engelfriet C.P. (1997), 10th edition, Blackwell Scientific Publication.
3. AABB Technical Manual, 15th edition.
4. HMSO, Guidelines for the Blood Transfusion Service, 2nd Edition.
5. Data on File: Tulip Diagnostics (P) Ltd.

0175/0920/VER-2

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

GITANJALI, TULIP BLOCK, DR. ANTONIO DO REGO BAGH, ALTO SANTACRUZ, BAMBOLIM COMPLEX P.O., GOA-403 202, INDIA. Website: www.tulipgroup.com

PLOT NOS. 92/96, PHASE II C, VERNA IND. EST., VERNA, GOA-403 722, INDIA.

In vitro Diagnostic Reagent
NOT FOR MEDICINAL USE.
Store at 2-8°C. DO NOT FREEZE.
Preservative: 0.1% NaN_3
An ISO 13485 Certified Company