ANTI-K (Kell)

I. PRINCIPLE

The presence of the K antigen is determined by testing with Anti-K reagent. Agglutination of the test red blood cells constitutes a positive test result and indicates the presence of the K antigen. No agglutination constitutes a negative test result and indicates that the K antigen is not present.

The K antigen itself (which is present on the red blood cells of approximately 9% of whites and 2% of blacks) is strongly immunogenic. Anti-K has been reported to cause hemolytic disease of the newborn and transfusion reactions. Examples of anti-K may be found in transfused patients, necessitating the selection of K-negative donors for future transfusions. In this situation, an anti-K reagent capable of being used by the slide test procedure enables donors to be screened for their K antigen status with minimal delay.

II. CLINICAL SIGNIFICANCE

UPH-Pekin laboratory personnel will utilize this procedure to test red cells for the presence or absence of Kell (K) antigen.

III. SPECIMEN

A. Blood should be drawn by an aseptic technique in an EDTA pink top tube or a citrated specimen (donor segments).
B. The specimen should be tested as soon as possible after collection. If delay in testing should occur, the specimen must be stored at 2°C to 8°C. (Donor segments may be stored at temperatures as low as 1°C.)
C. Blood specimens exhibiting gross hemolysis or contamination should not be used.
D. Blood drawn into EDTA should not be stored for longer than 10 days.
E. Donor blood may be tested up to the expiration date. Note, however, that storage may result in weaker than normal reactions.

IV. REAGENT

A. As the reactive component Seraclone® Anti-K (KEL1) contains a human monoclonal antibody of the immunoglobulin class IgM. It is derived from cell culture supernatant and demonstrates the consistent specificity and reproducibility characteristic for monoclonal antibodies.
B. Antibodies are diluted in a buffered protein solution containing bovine albumin and macromolecular potentiators.
C. Sodium azide (0.1% has been added as a preservative to this reagent).
    1. For In-vitro diagnostic use.
    2. Store at 2-8°C.

3. Do not use beyond the expiration.
4. Do not use if turbid.
5. Handle and dispose of reagents as potentially infectious.
6. Caution: Do not pipette by mouth. The absence of all viruses has not been determined.
7. Caution: This product contains natural rubber latex which may cause allergic reactions.
8. Warning: Contains sodium azide (NaN_3) which may react with lead or copper plumbing to form explosive azides. If discarded in the sink, flush with large amounts of water to prevent the build-up of explosive metal azides.
9. The bovine albumin used for the production of this reagent is sourced from animals of U.S. origin that have been inspected and certified by U.S. Veterinary Service inspectors to be disease free.

V. QUALITY CONTROL

A. The reactivity of all blood typing reagents should be confirmed by testing with known positive and negative red blood cells on each day of use.
B. To confirm the reactivity or specificity of Bio-Rad Monoclonal Anti-K Blood Grouping Reagent, it should be tested with antigen-positive (preferably from heterozygous individuals) and antigen-negative red blood cells, respectively. The reagent is satisfactory for use if it reacts only with antigen-positive red blood cells.

VI. PROCEDURE:

A. Label one 12 x 75 mm test tube for each red blood cell sample to be tested. Label additional tubes for known K+ and K- controls. (Screen cells or panel cells may be used.)
B. Label each tube with first and last initial of patient being tested. (Lengthen the minimum letters to differentiate patients with the same initials, if necessary.)
C. Prepare a 3-5% suspension of the red blood cells in saline. (Red blood cells may be washed prior to their suspension in saline).
D. Add 1 drop of Bio-Rad Anti-K Blood Grouping Reagent to each tube.
E. Using a transfer pipette, add 1 drop of each test red blood cell suspension to the appropriate tubes. Add 1 drop each of a 2-5% suspension of known K+ and K- control red blood cells to the appropriate tubes.
F. Mix the contents of the tubes thoroughly.
G. Incubate the tubes 5-10 minutes at 15-30 C (room temperature).
H. Centrifuge the tubes (at time and speed appropriate for the centrifuge calibration).
I. Gently agitate each tube to suspend each red blood cell button. Examine the resultant reactions macroscopically for agglutination. Negative reactions may be examined with an agglutination viewer, however, microscopic examination is not recommended. Record results.

Stability of the final reaction: Test results must be interpreted immediately upon completion of the test. Time delays may cause a dissociation of the antigen-antibody complexes resulting to false negative or more often weak positive reactions.

VII. REPORTING RESULTS/INTERPRETATION OF RESULTS:

A. Positive Test: Agglutination of the red blood cells. Note: Hemolysis, if obtained should not be interpreted as a positive test. Hemolysis may indicate the reagent is contaminated with bacteria.
B. Negative Test: No agglutination of red blood cells.

VIII. PROCEDURAL NOTES/PROBLEM-SOLVING TIPS

A. Samples with a positive direct antiglobulin test, cold agglutinins, or rouleaux formation may show false positive results in testing with monoclonal antibodies. Results on these samples must be interpreted with caution. False positive results or reaction suspected to be due to cold agglutinins should be resolved according to in-house procedures.
B. Kell antigen expression may be dramatically weakened in some cases of Chronic Granulomatous Disease.
C. Stored red blood cells may exhibit weaker reactions.
D. Some conditions that may cause false positive results are:
    1. Contamination of sample or reagents
    2. Autoantibodies
    3. Improper storage or preparation of cells
    4. Antibodies to antibiotics or other reagents
    5. Cold antibodies

IX. REFERENCES

A. Blood Grouping Reagent, Anti-K (KEL1), Seraclone® Human Monoclonal, Bio-Rad Medical Diagnostics GmbH, Dreieich Germany, 186255/08, Rev. 08/2014.

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