ERYGEN-ABO

A panel of 3% Reagent Red Blood Cells for ABO Grouping

SUMMARY

In the ABO system, human red blood cell antigens can be divided into four groups A, B, AB and O depending on the presence or absence of the corresponding antigens on the red blood cells. Agglutination tests of red blood cells using the Anti-A, Anti-B and Anti-A, B reagents, is known as forward grouping. Forward grouping can be confirmed by testing the patient's serum using red cells of known ABO phenotypes to demonstrate the presence of Anti-A or Anti-B. This is called reverse grouping.

ERYGEN-ABO reagent red blood cells are prepared from selected donor's blood and are suitable for reverse grouping, detection of hemolysins, immune A and B antibodies and for control of ABO Test sera in conventional techniques.

REAGENT

ERYGEN-ABO is a reagent set for laboratory use only.

ERYGEN-ABO panel of 3% reagent red blood cells comprise of:

1. Red Blood Cells of Group A,.
2. Red Blood Cells of Group B.
3. Red Blood Cells of Group O.

The reagent red blood cells are suspended in isotonic medium to which a Red Cell Preserving solution is added to preserve the red cell integrity and antigenicity.

ADDITIONAL MATERIAL REQUIRED

Test tubes (12x75 mm or 10x75 mm), Physiological saline, Optical aid, Centrifuge (calibrated for 1000 RPM and/or 3400 RPM) and pipettes.

PRINCIPLE

Every individual is assigned to four ABO blood groups A, B, AB or O depending upon the reaction of his/her red blood cells with the blood grouping sera namely Anti-A, Anti-B and Anti-A,B. This is known as forward grouping. The results of forward grouping can be confirmed by performing the reverse grouping technique wherein the serum of an individual is tested for agglutination reaction with known red blood cells of group A, B and O. **ERYGEN-ABO** panel of 3% reagent red blood cells provides for detection of subgroups of A antigen, B antigen as well as the H antigen for faster reverse grouping.

STORAGE AND STABILITY

1. Store the **ERYGEN-ABO** at 2-8º C. Do Not Freeze.
2. Stability of the **ERYGEN-ABO** kit is as per the expiry date mentioned on the label.

NOTE

1. *In vitro* diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. Indications of deterioration are notable hemolysis (which may be caused by microbial contamination or improper handling), darkening of cells or spontaneous clumping. Such reagents should be discarded.
3. The reactivity of the product may diminish slightly during the dating period.
4. Interpret both serum and cell ABO grouping results. Resolve discrepancies if any.
5. Ensure that the centrifuge used for testing is properly calibrated for specific test procedures.
6. Ensure that the cells are firmly packed and the negative control cells can be resuspended easily.
7. Known relatively weak positive serum samples may be tested with **ERYGEN-ABO** panel of 3% reagent red blood cells, each day the cells are in use.
8. Discrepant results in reverse grouping due to the presence of unexpected antibodies or other factors can be confirmed by parallel testing with group 'O' screening cells.

Caution: All blood related products should be treated as potentially infectious. **ERYGEN-ABO** reagents are derived from donors found negative for HIV, HBsAg, HCV and Syphilis. However, absence of infectious agents in products derived from human blood cannot be guaranteed by any test method.

SAMPLE COLLECTION AND PREPARATION

No special preparation of the patient is required prior to sample collection by approved techniques. Serum collected from freshly clotted blood may be used for optimum results. Fresh plasma can also be used, but care should be taken as false positives may occur due to fibrin clot formation. For plasma collected from donor: blood collected in anticoagulants such as CPDA-1 or CPD may be tested upto the expiry date of the unit. Serum or plasma samples, if not tested immediately may be frozen at - 20º to - 70º C or stored at 2-8ºC for not more than 48 hours.

TEST PROCEDURE

Tube Test

1. Bring the kit to room temperature before testing.
2. Place 100 µl of test serum/plasma in test tubes appropriately labeled.
3. Add 50 µl of **ERYGEN-ABO** panel of 3% reagent red blood cells to the labeled tubes. Shake to mix well.
4. Centrifuge for 20 seconds at 3400 RPM (1000g).
5. Gently resuspend the cells completely and examine macroscopically for agglutination.
6. Grade the reaction and record results accordingly.

INTERPRETATION OF RESULTS

Agglutination indicates a positive result. No agglutination indicates a negative result.

The seven possible group combinations are shown in the following table:

Reaction with Test Serum / Plasma			
Reagent Cell Group A_1	**Reagent Cell Group B**	**Reagent Cell Group O**	**Blood Group**
+	+	–	O
+	+	+	Oh
–	+	–	A
+	–	–	B
–	–	–	AB

+ = agglutination
- = no agglutination

LIMITATIONS

In all serological tests, factors such as contaminated materials, improper incubation time / temperature, improper centrifugation or improper interpretation of agglutination pattern may be the cause of false test results.

False negative results may occur if:

1. An expected isoagglutinin reacts poorly at room temperature.
   Very weak isoagglutinins are frequently demonstrated on incubation of the serum-cell mixtures for 15 minutes at a temperature of 5-15º C before centrifugation.
2. Neonatal serum is used for testing.
   False negative results can occur when neonatal serum is used for testing because isoagglutinins are not visible in infants till the age of 6 months.
3. Serum of an aged individual is used for testing.
   False negative results can occur when serum of an aged individual is used for testing as isoagglutinin activity is reduced in such individuals.
4. Serum used for testing is obtained from patients with hypo-agammaglobulinemia.
   False negative results can occur when serum used for testing is obtained from patients with hypo-agammaglobulinemia; as such samples may not contain detectable levels of ABO antibodies.

Other discrepancies in results may occur if:

1. The unexpected antibody Anti-A_1 may be present in a blood group A_2 or A_2B individual (Frequency of such an occurrence: A_2 bloods 1-2%, A_2B bloods - 22-25%). To resolve such a problem, test the serum sample with group A_1 erythrocytes.
2. The serum contains cold agglutinins (such as Anti-I or Anti-H) having sufficient activity at room temperature to produce an agglutination reaction. Such reactions can be clarified by:
   a) Testing the serum with autologous cells.
   b) Testing the serum with groups A, B and O cord cells.
3. Neonatal serum used for testing contains IgG, anti-A and/or anti-B antibodies passively acquired from maternal serum.
4. In rare cases, the test serum contains an antibody directed at one of the components of the reagent diluent.

SPECIFIC PERFORMANCE CHARACTERISTICS

1. Each lot of **ERYGEN-ABO** panel of 3% reagent red blood cells is carefully prepared to permit detection of ABO isoagglutinins when used according to the above procedures.
2. Direct antiglobulin tests are negative on all cells.
3. As with all red blood cells, the reactivity of the product may decrease before the expiry date mentioned. The rate at which the antigen reactivity is lost is partially dependent upon the individual donor characteristics that are neither controlled nor predictable by the manufacturer. However, if properly stored when not in use, the reagent can be expected to perform as described upto its expiry date.

WARRANTY

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

BIBLIOGRAPHY

1. Mollison P.L., Blood Transfusion in Clinical Medicine, 10th Edition, Oxford: Blackwell Scientific Publications 1997: Chapter 4.
2. Technical Manual of the American Association of Blood Banks, 12th Edition, 1996, Chapter 12.
3. UK Blood Transfusion and Tissue Transplantation Guidelines.
4. Data on file: Tulip Diagnostics (P) Ltd.

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Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

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