ERYCARD™ ABO

Blood Grouping Card for ABO Forward Grouping with Autocontrol

SUMMARY

Human Blood group system comprises of 26 blood group systems. Out of these ABO and Rh are the blood group systems capable of causing severe hemolytic transfusion reactions. Inclusion of bed side ABO testing as pre transfusion testing will help in reducing the ABO incompatible blood transfusions. **ERYCARD™ ABO** can be used as bed side testing for patient and donor's blood unit prior to transfusion. **ERYCARD™ ABO** can also be used for donor's ABO group screening in outdoor camps as well as in blood banks.

REAGENTS

1. **ERYCARD™ ABO** Blood Grouping Card for ABO Forward Grouping with Autocontrol is based on the principle of lateral flow guided by capillary action. The appropriate reagents are pre-dried at the appropriate sample pad beneath the sample well namely Anti-A (IgM) antibodies in sample well A and Anti-B (IgM) antibodies in sample well B. The autocontrol is a negative control that does not contain any antibodies in sample well (Ctrl) and serves to validate the test results.
2. Reagent Buffer (Proprietary Buffer) contains Sodium azide (< 0.1%) as a preservative.

STORAGE AND STABILITY

1. Store the **ERYCARD™ ABO** at 2-30°C .
2. The shelf life of the **ERYCARD™ ABO** is as per the expiry date mentioned on the label.
3. Avoid exposure of **ERYCARD™ ABO** to direct sunlight or any direct heat source.

ADDITIONAL REAGENTS AND MATERIAL REQUIRED

1. Sterile Blood Lancet (when finger prick blood is to be used).
2. 5 µl micropipette (ERYCARD™ Micropipette Cat. No. ECMP00005).
3. Micropipette tips (ERYCARD™ Micropipette tips Cat. No. ECMPT0100).

PRINCIPLE

When 5 µl of the whole blood sample to be tested is placed on to the sample well pad and the test is run using the reagent buffer, the agglutinated red cells adhere onto the sample well pad and are visible as a red patch (positive test result) indicating that the red cells are positive for corresponding blood group antigen. Unagglutinated red cells are washed away by the reagent buffer revealing a white color sample pad (negative test result) indicating that the red cells are negative for the corresponding blood group antigen. The autocontrol must be negative at all times to validate the test results. For each red cell so tested on the card the ABO group of the sample can be determined.

SAMPLE COLLECTION

1. Finger prick blood or venous whole blood can be used for testing.
2. Finger prick blood should be tested immediately without letting the blood to clot.
3. No special preparation of the patient is required prior to sample collection by approved techniques.
4. Sample should be stored at 2-8°C if not tested immediately.
5. Do not use hemolysed samples for testing.
6. Anticoagulated venous blood using various anticoagulants should be tested within the below mentioned time period:

   HEPARIN : 2 Days.
   EDTA : 7 Days.
   ACD : 21 Days
   CPD -A : 35 Days.

TEST PROCEDURE

1. Bring the pouch and reagent buffer bottle to room temperature.
2. Tear open the pouch just prior to testing and remove the **ERYCARD™ ABO** test device.
3. Label the **ERYCARD™ ABO** test device with the patient's ID and date.
4. For finger prick samples, sample collection loop provided in the device pouch should be used and for samples collected in anticoagulant, use of 5µl micropipette is recommended.
5. Using a micropipette/sample collection loop add 5 µl of the patient's whole blood sample to each of the sample wells indicated as 'S'. When using a micropipette, ensure that only the blood drop is in contact with the pre-dried reagent on the sample pad and absorbed by it as shown in figure 1. In case the micropipette tip touches the sample pad, discard the tip and use fresh tip for dispensing the sample into the next sample well. When sample collection loop is used, the loop should be held in vertical position for collecting sample from finger prick as shown in figure 2.

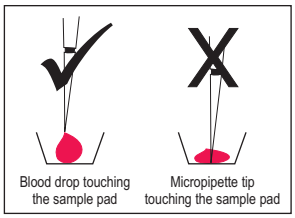

Fig. 1

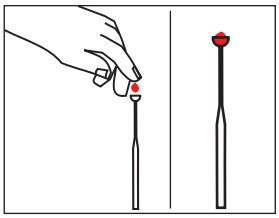

Fig. 2

Once a sample collection loop is used to dispense the sample on a sample pad, the same loop should not be used to dispense sample on any other sample pad. It should be discarded and fresh sample collection loop should be used. 3 sample collection loops are provided with each ERYCARD ABO device for dispensing sample on A, B and Ctrl.

6. After waiting for one minute allowing the sample to react with the reagent on sample pad, add two drops of the reagent buffer to each of the reagent wells indicated as 'R'.
7. After addition of reagent buffer wait for 3 minutes to interpret the test results. The autocontrol should show a colorless patch before the results can be interpreted correctly. If the autocontrol pad has a color (invalid result) then the test results should not be interpreted.

INTERPRETATION OF TEST RESULTS

Reaction in the Sample pad

A	B	Ctrl	Results
			Group A
			Group B
			Group AB
			Group O
			Invalid

The test results may be noted for future reference. Using a marking pen the test results may also be noted on the card. The test results are stable for a period of 1 week provided the storage is done in a sealed cover without contamination in a cool dry place. Do not expose to direct heat and sunlight.

NOTES

1. In vitro diagnostic reagent for laboratory and professional use. Not for medicinal use.
2. **ERYCARD™ ABO** contains <0.1% sodium azide as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantitiy of water.
3. Contamination of reagents or blood samples may cause false positive or negative results.
4. To avoid contamination use separate micropipette tips to dispense in all the circular sample wells, taking care to ensure that micropipette tip does not touch the side walls of the sample wells.
5. **ERYCARD™ ABO** can be used as bed side testing of patient and donor's blood unit prior to transfusion, donor's ABO group screening in outdoor camps and in blood banks.
6. Fresh samples will give more accurate results as compared to aged or old cells.
7. Red cell aggregation or rouleaux formation may interfere with test results and give false positive results. Rouleaux formation can occur in samples collected in heparin and in patients treated with plasma expanders, oncological patients and patients with coagulation dysfunction.
8. Clotted samples or fibrin if present in sample may lead to erroneous results.
9. Due to use of monoclonal antibodies, red cells with weaker A subgroup (like A_x and A_3) may also be detected. Red cells showing weaker reaction with Anti-A and/or Anti-B probably indicate subgroups of A and/or B and results should be correlated with laboratory testing.
10. Use of red blood cell concentration / volumes and reagents other than those described may lead to erroneous results.

LIMITATIONS OF THE TEST

1. **ERYCARD™ ABO** is not a substitute for complete blood grouping or compatibility test (cross match) by tube technique, solid phase or Gel technique.
2. Cold auto antibodies if present in sample may cause a false positive reaction.
3. Blood samples with hematocrit (PCV) less than 15% may give false negative or weak reactions.
4. Red cells with weaker antigenic expression like weaker subgroup of A or B may give a weaker or negative reaction.

REMARKS

1. Known positive and negative control should be tested as per Good Laboratory Practices for each lot of **ERYCARD™ ABO**.

BIBLIOGRAPHY

1. Mollison, P.L. Blood Transfusion in Clinical medicine: - 10th Edition. Oxford: Blackwell Scientific Publications, 1997.
2. Human Blood Groups by Geoff Daniels, Blackwell Science Ltd, 1995.
3. Data on file: Tulip Diagnostics (P) Ltd.

ERY-ABO/0914/VER-1

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