CE
1293

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

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

EC REP
Qarad b.v.b.a. Cipalstraat 3, B-2440 Geel, Belgium

10255/0814/VER-03

matrix™
GEL•SYSTEM

REF	10255024	10255048
Pack Size	24 Cards	48 Cards

Matrix™ ABO/Rho (D) Forward Grouping Confirmation Card

SUMMARY
According to ABO blood group system human red blood cell antigen can be divided into four groups A, B, AB and O depending on the presence or absence of corresponding antigens on the red blood cells. Also human red blood cells are classified as Rho (D) positive or Rho (D) negative depending upon the presence or absence of Rho (D) antigen.
It is important to examine previous transfusion and testing records in pre transfusion compatibility testing. Similarly current ABO and Rho (D) testing results should be compared with previous testing records. Concurrence between both the results gives confirmation of testing results.

REAGENTS
Matrix™ Forward Grouping Confirmation Card contains six microtubes prefilled with a gel in a suitable buffer containing Monoclonal Anti-A (Clone 11H5), Anti-B (Clone 6F9) and Anti-D (IgM) (VI-) (Clone P3x61 + TH-28) from microtube 1 to 3 and microtube 4 to 6 respectively. Matrix™ Forward Grouping Confirmation Card is used for the ABO grouping and Rho (D) typing.

STORAGE AND STABILITY
Store Matrix™ gel cards in an upright position at 4-25°C. Do not freeze.
Avoid exposure of Matrix™ gel cards to direct sunlight or any heat source. The shelf life of Matrix™ gel cards is as per the expiry date mentioned on the label. Do not use beyond expiry date. Once the aluminium foil is removed from the microtube, it should be used immediately.

ADDITIONAL REAGENTS AND MATERIALS REQUIRED
Matrix™ Diluent -2 LISS for preparation of red cell suspension. (Refer package insert before use). Gel card centrifuge (85g), Work station, Micropipette capable of delivering 5-50µl of specimen and Bottle top dispenser.

PRINCIPLE
As the Matrix™ gel card containing red blood cells is centrifuged under specific conditions, the red blood cells possessing the corresponding antigen will agglutinate in presence of the specific antibody and will be trapped in the gel column. The red blood cells, which do not react are not trapped in the gel column and get settled at the bottom of the microtube. The reactions are then read and graded according to their reactivity pattern.

SAMPLE COLLECTION
No special preparation of the patient is required prior to sample collection by approved techniques. For optimal results, freshly collected sample should be used. Anticoagulants like EDTA, CPD-A and Citrate can be used.

SAMPLE PREPARATION
Prepare a 5% red blood cell suspension in Matrix™ Diluent- 2 LISS as follows:
1. Bring the Matrix™ Diluent- 2 LISS to room temperature before testing.
2. Dispense 0.5 ml of Matrix™ Diluent- 2 LISS into a clean test tube.
3. Add 50µl of whole blood or 25µl of packed red cells to Matrix™ Diluent- 2 LISS collected in test tube and mix gently.
4. Red blood cell suspension so obtained should be used for forward grouping.

TEST PROCEDURE
1. Label the "Matrix™ Forward Grouping Confirmation Card" with patient's name or identification number. Remove the aluminium foil of required number of microtubes carefully by pulling it backwards.
2. Pipette 10µl of 5% patient's red blood cell suspension to the microtubes labeled as A-B-D, taking care to ensure that micropipette tip does not touches the microtube.
3. Centrifuge the cards for 10 minutes in the gel card centrifuge.
4. Retrieve the card from centrifuge, read and record the results.

INTERPRETATION OF RESULTS

Positive reaction: Agglutinated red blood cells forming a clear line at the top of gel column or agglutinates dispersed in the gel column.

Negative reaction: Non agglutinated red cells settle at the bottom of the microtube forming a button.

The reaction strength may be recorded as follows:

Strength of reaction	Comments
4+	Agglutinated red blood cells form a line at the top of the gel microtube.
3+	Most agglutinated red blood cells remain in the upper half of the gel microtube.
2+	Agglutinated red blood cells are observed throughout the length of the microtube. A small button of red blood cells may also be visible at the bottom of the gel microtube.
1+	Most agglutinated red blood cells remain in the lower half of the microtube. A button of cells may also be visible at the bottom of the gel microtube.
±	Most agglutinated red blood cells are in the lower third part of the gel microtube.
Negative	All the red blood cells pass through and form a compact button at the bottom of the gel microtube.
Mixed field agglutination	Agglutinated red blood cells form a line at the top of the gel and non-agglutinated red blood cells form a compact button at the bottom of the gel microtube.
H	Hemolysis of red blood cells

Expected reactivity pattern for ABO grouping:

Anti-A	Anti-B	Blood Group
± to 4+	Negative	A
Negative	± to 4+	B
± to 4+	± to 4+	AB
Negative	Negative	O

NOTE: Human red blood cells that show weak reaction with Anti-A and/or Anti-B probably indicate subgroups of A and/or B and further testing is recommended.

Expected reactivity pattern for Rho (D) typing:

Anti-D	Rho (D) Type
± to 4+	Rho (D) Positive
Negative	Rho (D) Negative

NOTE: Weak D/ Partial D type human red blood cells may give a weaker or negative reaction. Such cells should be retested for weak D confirmation with Matrix™ Coombs Anti-IgG card.

NOTE:

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The Matrix™ gel cards contains sodium azide <0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.
3. All Matrix™ gel cards should be centrifuged for one complete cycle (10 minutes) in gel card centrifuge before use.
4. Visually inspect the Matrix™ gel cards before use.
5. Matrix™ gel cards having bubble(s) entrapped within the gel can be centrifuged for two complete cycles in gel card centrifuge to remove the bubble, if bubbles are not removed the card should not be used.
6. Matrix™ gel cards that exhibit any signs of drying (i.e. absence or reduced level of reagent buffer above the gel column), decreased volume of gel, cracked gel should not be used.
7. Matrix™ gel cards with damaged aluminium foil seal should not be used.
8. Freezing of Matrix™ gel cards or evaporation of gel or reagent buffer due to exposure to heat may lead to erroneous results.
9. Fibrin or particulate matter if present in the sample may lead to erroneous results.
10. Fibrin if present in the sample may trap red blood cells on top of gel column presenting a pink line. RBCs should be washed with normal saline if not collected properly in an anticoagulant.
11. Use of red blood cells concentration/ volume and reagents other than those described may lead to erroneous results. Follow the instructions carefully.
12. Aged or stored red blood cells may exhibit weaker reactivity than freshly collected cells.
13. Old cell panels may give an unclear background with Matrix™ gel cards.
14. Do not use hemolysed, lipemic and icteric samples.
15. Exterme turbidity or discoloration may indicate microbial contamination or denaturation of protein due to thermal damage. Such Matrix™ gel cards should be discarded.
16. Contamination of reagents during usage may cause false positive or negative results.
17. Red cell aggregation in the red cell suspension may interfere the passage.
18. Aluminium foil seal of Matrix™ gel cards should be removed gently and carefully by pulling the foil seal backwards to avoid contamination of reagents from one microtube to another.
19. To avoid contamination always use fresh tips before dispensing into each microtube.
20. Matrix™ ContaVoid can be used to avoid contamination of reagents in microtubes while usage. For details refer pack insert of Matrix™ ContaVoid (Catalogue no. 102770100)

REMARKS

1. Known positive and negative control should be tested as per Good Laboratory Practices.
2. ERYWELL (Catalogue no. 10253020) can be used as red blood cell preservative solution for preservation of known cells.
3. The Anti-D does not detect the D VI variant.

PERFORMANCE

The performance study has been evaluated on 3183 blood samples from 2734 donors, 331 patients, 65 newborns and 53 weak D blood samples. Each ABO/D test result showed complete agreement with the analysis method of the reference laboratory in a university blood bank. Blood samples with weak D expression showed different reaction strength.

BIBLIOGRAPHY

1. Human Blood Groups by Geoff Daniels, 2nd Edition, Blackwell Science, Oxford 2002.
2. HMSO, Guidelines for the Blood Transfusion Services, 2nd Edition, 1993.
3. H. Malyska & D. Weiland, The Gel Test. Laboratory Medicine Vol. 25, No.2 February 1994, pg. 81-85.
4. M.C.Z. Novaretti et al. Comparison Of Tube And Gel Techniques For Antibody Identification. Immunohematology 2000;16:138-141.
5. D. Voak, New Developments in Blood Group Serology, Infusion Therapy Transfusion Medicine 1999;26:258-260.
6. Data on file: Tulip Diagnostics (P) Ltd.