

BIBLIOGRAPHY

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2. HMSO, Guidelines for the Blood Transfusion Services, 2nd Edition, 1993.
3. M.C.Z. Novaretti et. al. Comparison of Tube and Gel Techniques for Antibody Identification, Immunohaematology 2000;16: 138-141.
4. D. Voak, New Developments in Blood Group Serology, Infusion Therapy Transfusion Medicine 1999; 26: 258-260.
5. Blood Transfusion in Clinical Medicine, P.L. Mollison; 10th Edition.
6. H. Malyska & D. Weiland, The Gel Test. Laboratory Medicine Vol. 25, No. 2 February 1994, pg. 81-85.
7. Data on file: Tulip Diagnostics (P) Ltd.



+4°C Store at 4-25°C	Manufacturer	LOT Batch Number/ Lot Number	Contains sufficient for <n> tests
Use by (Last day of stated month)	Consult Instructions for use	IVD <i>In vitro</i> Diagnostic Medical Device	EC REP Authorised Representative in the European Community
Date of Manufacture	REF Catalogue Number	This side up	Keep Away from Sunlight

Manufactured by:

TULIP DIAGNOSTICS (P) LTD.

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EC REP

CMC Medical Devices & Drugs S.L., C/ Horacio Lengo No. 18, CP 29006, Malaga, Spain

matrixTM
—GEL•SYSTEM

MatrixTM Forward Grouping and Cross Match Card

SUMMARY

Human blood groups can be divided into four groups A, B, AB and O depending on the presence or absence of A and B antigens on red blood cells. Also human red 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 cross check the ABO and Rho (D) status of recipient and donor in compatibility testing while detecting clinically significant antibodies. The MatrixTM Forward Grouping and Cross Match Card facilitates ABO and Rho (D) determination of both patient and donor along with compatibility testing.

PRESENTATION

REF	102140024	102140048
Pack Size	24 Cards	48 Cards

REAGENTS

MatrixTM Forward Grouping and Cross Match 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 + NaTH119) from microtube 1 to 3. Microtube 4 (ENZ) contains neutral gel for enzyme phase test and microtube 5 & 6 contains Anti-Human Globulin reagent which is a blend of polyclonal Anti-Human IgG and Monoclonal Anti-C₃d (Clone BRIC-8).

STORAGE AND STABILITY

Store MatrixTM gel cards in an upright position at 4-25°C. Do not freeze.

Avoid exposure of MatrixTM gel cards to direct sunlight or any heat source. The shelf life of MatrixTM 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

MatrixTM Diluent -2 LISS for preparation of red cell suspension. Papain solution suitable for serological applications (Refer package insert before use). Gel card centrifuge (85g), Incubator (37°C), Work station, Micropipette capable of delivering 5-50µl of specimen and Bottle top dispenser.

PRINCIPLE

As the MatrixTM 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 venous whole blood sample should be used. Anticoagulants like EDTA, CPD-A and Citrate can be used. Serum or plasma sample can be used.

Samples should be centrifuged at 1500g for 10 minutes to avoid fibrin residue which may interfere with results.

SAMPLE PREPARATION

Prepare a 0.8% red blood cell suspension from donor's and patient's sample in MatrixTM Diluent- 2 LISS as follows:

1. Bring the MatrixTM Diluent- 2 LISS to room temperature before testing.
2. Dispense 1.0 ml of MatrixTM Diluent- 2 LISS into a clean test tube.
3. Add 10 µl of packed red cells and mix gently.
4. Red blood cell suspension so obtained should be used for testing.

TEST PROCEDURE

A. ABO & Rho (D) typing of both patient and donor with compatibility testing.

1. Label the MatrixTM Forward Grouping and Cross Match Card with donor's and patient's name or identification number. Remove the aluminium foil carefully by pulling it backwards.
2. Add 50µl of 0.8% patient's red cell suspension to microtubes 1, 2, 3 and 6 (A-B-D-AHG), taking care to ensure that the micropipette tip does not touch the microtube.
3. Add 50µl of 0.8% donor's red cell suspension to microtubes 1, 2, 3, 4 and 5 (A-B-D-ENZ-AHG)

- Add 25µl patient's serum or plasma to microtubes 4, 5 and 6 (Cross Match and autocontrol). The interval between cell and serum / plasma transfer should not exceed 10 minutes.
- Add 25µl Enzyme (Papain) in microtube 4 (ENZ).
- Incubate the Matrix™ gel card for 15 minutes at 37°C in an incubator.
- After incubation centrifuge the Matrix™ gel card for 10 min in gel card centrifuge.
- Retrieve the card from centrifuge, read and record the results.

B. ABO & Rho (D) typing of patient only with compatibility testing.

- Label the Matrix™ Forward Grouping and Cross Match Card with donor's and patient's name or identification number. Remove the aluminium foil carefully by pulling it backwards.
- Add 50µl of 0.8% patient's red cell suspension to microtubes 1, 2, 3 and 6 (A-B-D-AHG), taking care to ensure that the micropipette tip does not touch the microtube.
- Add 50µl of the donor's red cell suspension to microtubes 4 and 5 (ENZ-AHG)
- Add 25µl patient's serum or plasma to microtubes 4, 5 and 6 (Cross Match and autocontrol). The interval between cell and serum/plasma transfer should not exceed 10 minutes.
- Add 25µl Enzyme (Papain) in microtube 4 (ENZ).
- Incubate the Matrix™ gel card for 15 minutes at 37°C in an incubator.
- After incubation centrifuge the Matrix™ gel card for 10 min in gel card centrifuge.
- 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 the gel column or agglutinates dispersed in the gel column.

Negative reaction: Non agglutinated red blood cells settle at the bottom of the microtube forming a compact 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

A. ABO/Rho(D) confirmation of donor and patient

- ABO/Rho (D) compatibility is proven when the reaction gives only one cell population (positive/negative).
- ABO incompatibility has to be considered when the reaction with Anti-A and /or Anti-B shows two distinct cell populations (Mixed Field Agglutination) observed.
- Rho (D) incompatibility has to be considered when the reaction with Anti-D shows two distinct cell populations observed.
- When there is incompatibility, ABO and Rho (D) blood groups of both donor and patient's should be retested.

B. Expected reactivity pattern for ABO grouping with Matrix™ gel card

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 with Matrix™ gel card:

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.

C. Compatibility Test

- Positive reaction (± to 4+) in microtube 4 and/or 5 (ENZ & AHG) and negative in microtube 6 (AHG) indicates incompatibility due to clinically significant antibodies.
- Negative reaction in microtube 4 and 5 (ENZ & AHG) and negative in microtube 6 (AHG) indicates compatibility and absence of clinically significant antibodies.
- Positive reaction (± to 4+) in microtube 6 (AHG) indicates auto antibodies and further tests are required.

NOTES AND LIMITATIONS

- In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The Matrix™ gel card contains sodium azide < 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantity of water.
- All Matrix™ gel cards should be centrifuged for one complete cycle (10 minutes) in gel card centrifuge before use.
- Visually inspect the Matrix™ gel cards before use.
- 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 bubble(s) are not removed the card should not be used.
- Matrix™ gel cards that exhibits 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.
- Matrix™ gel cards with damaged aluminium foil seal should not be used.
- Freezing of Matrix™ gel cards or evaporation of gel or reagent buffer due to exposure to heat may lead to erroneous results.
- Fibrin or particulate matter if present in the sample may lead to erroneous results.
- Fibrin if present in the sample may trap red blood cells on top of gel column presenting a pink line. To avoid, samples should be well centrifuged at 1500g for 10 minutes before taking serum or plasma and RBCs should be washed if not collected properly in anticoagulant.
- Use of red blood cells concentration/volume other than those described may lead to erroneous results. Follow the instructions carefully.
- Aged or stored red blood cells may exhibit weaker reactivity than freshly collected cells.
- Old cell panels may give an unclear background with Matrix™ gel cards.
- Do not use hemolysed, lipemic, icteric and hyperproteic samples.
- Extreme turbidity or discoloration may indicate microbial contamination or denaturation of protein due to thermal damage. Such Matrix™ gel cards should be discarded.
- Contamination of reagents during usage may cause false positive or negative results.
- Red cell aggregation in the red cell suspension may interfere the passage.
- 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.
- To avoid contamination always use fresh tips before dispensing into each microtube.
- Some pathological conditions are reported as causing non-specific reactions in AHG procedures.

REMARKS

- Known positive and negative control should be tested as per Good Laboratory Practices.
- ERYWELL (Catalogue no. 10253020) can be used as red blood cell preservative solution for preservation of known cells.
- Agtrol™ (Cat. No. 10252010) can be used for quality control procedures related to AHG.
- The Anti-D does not detect the D VI variant.

PERFORMANCE

The performance study has been evaluated on 3275 blood samples (from donors, clinical and neonates) drawn in the recommended anticoagulants. The evaluation demonstrated 100% specificity of Anti-A, Anti-B and Anti-D reagents and 100% sensitivity of Anti-A and Anti-B reagents, 99.4% sensitivity of Anti-D reagent versus the expected results with common known phenotypes A₁, A₂, A₃, B, A₂B, B and O and with common known Rhesus phenotypes. Blood sample with weak D expression showed different reaction strength.