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1434

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

 Manufactured by:

 **TULIP DIAGNOSTICS (P) LTD.**

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matrixTM
—GEL•SYSTEM

MatrixTM Rh Phenotype Card with Anti-K

SUMMARY


The Rh D determination is done by detecting the presence or absence of the D antigen on the red blood cells. The Rh blood group system consists of forty nine antigens out of which five principle antigens i.e., D, C, c, E, e, and their corresponding antibodies account for the vast majority of clinical issues related to the Rh system. The determination of Rh phenotypes is very important because C, c, E, e antigens may stimulate antibody production in corresponding antigen negative individuals, and antibodies thus formed are capable of RBC destruction.

Antibodies to Kell blood group system are also capable of producing transfusion reactions and HDFN. The incidences of Anti-K are much higher than Anti-k.

Therefore Rh phenotype determination along with K is important for patients with multiple transfusions, patients with irregular antibodies and during pregnancy.

MatrixTM Rh Phenotype Card with Anti-K facilitates the determination of Rh Phenotypes along with K antigen of Kell system.

PRESENTATION

| | | |
|---|-----------|-----------|
|  REF | 102190012 | 102190024 |
| Pack Size | 12 Cards | 24 Cards |

REAGENTS

The MatrixTM Rh Phenotype Card with Anti-K contains six microtubes, prefilled with a gel in a suitable buffer containing Monoclonal Anti-C (Clone MS-24), Anti-c (Clone MS-33), Anti-E (Clone MS-80 + MS-258), Anti-e (Clone MS-16 + MS-21 + MS-63), Anti -K (Clone MS-56) and neutral gel in appropriate microtubes.

STORAGE AND STABILITY

Store the 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 (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 MatrixTM gel card containing red blood cells is centrifuged under specific conditions, 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.

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

SAMPLE PREPARATION

Prepare a 5% red blood cell suspension in MatrixTM Diluent- 2 LISS as follows:

1. Bring the MatrixTM Diluent- 2 LISS to room temperature before testing.
2. Dispense 0.5 ml of MatrixTM Diluent- 2 LISS into a clean test tube.
3. Add 50µl of whole blood or 25µl of packed red cells and mix gently.
4. Red blood cell suspension so obtained should be used for testing.

TEST PROCEDURE

1. Label the "MatrixTM Rh Phenotype Card with Anti-K" with patient's/ donor's name or identification number. Remove the aluminium foil carefully by pulling it backwards.
2. Pipette 10µl of 5% patient's/ donor's red blood cell suspension to all the microtubes, 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

The control microtube (Ctrl) must be negative to validate the test results. If it is not negative then repeat the test after washing the patient's/ donor's red blood cells with warm saline.

Positive reaction: Agglutinated red blood cells forming a clear line at 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.

Note: A positive reaction indicates presence of the corresponding antigen. Weaker reactions may indicate weaker antigen expressions or antigen variants.

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 |

NOTES AND LIMITATIONS

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. 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.
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 bubbles, 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 or 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. To avoid, samples should be well centrifuged at 1500g for 10 minutes before testing and RBCs should be washed if not collected properly in an anticoagulant.
11. Use of red blood cell 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. Do not use hemolysed, lipemic or icteric samples.
14. Extreme turbidity or discoloration may indicate microbial contamination or denaturation of protein due to thermal damage. Such Matrix™ gel cards should be discarded.
15. Contamination of reagents during usage may cause false positive or negative results.
16. Red cell aggregation in the red blood cell suspension may interfere the passage.
17. Aluminium foil seal of Matrix™ gel cards should be removed gently and carefully by pulling the aluminium foil seal backwards to avoid contamination of reagents from one microtube to another.

18. To avoid contamination always use fresh tips before dispensing into each microtube.
19. Matrix™ ContaVoid can be used to avoid contamination of reagents in microtubes while usage. For details refer package insert of Matrix™ ContaVoid (Catalogue no. 102770100).

REMARKS

1. Known positive and negative controls should be tested as per Good Laboratory Practices.
2. ERYWELL (Catalogue no. 10253020) can be used as red cell preservative solution for preservation of known cells.

PERFORMANCE

The performance study has been evaluated on 1081 blood samples (from donors,clinical,newborns and weak D blood samples) Each Rh and Kell (KEL1) test result showed complete concordance with the reference method.The evaluation demonstrated 100% specificity and100% sensitivity of Anti-C,Anti-E,Anti-c,Anti-e and Anti-K reagents.

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