PERFORMANCE

The performance study has been evaluated on 300 blood samples.The evaluation demonstrated 98.92% sensitivity of Matrix AHG in DAT and IAT testing.The evaluation demonstrated 100% specificity of Matrix AHG with DAT negative samples and with IAT negative samples.The results obtained were similar to those obtained with established products of equivalent use.

BIBLIOGRAPHY

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6. Blood Transfusion in Clinical Medicine, P.L. Mollison, 10th Edition.
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CE
1434

+25°C / +4°C Store at 4-25°C	Manufacturer	LOT Batch Number/ Lot Number	Σ Contains sufficient for <n> tests
Use by (Last day of stated month)	Consult Instructions for use	IVD *In vitro* 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.

Plot Nos. 92/96, Phase II C, Verna Industrial Estate, Verna, Goa - 403 722, INDIA.
Regd. Office: Gitanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Alto Santacruz, Bambolim Complex P.O., Goa - 403 202, INDIA.

EC REP

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

0220/VER-02

matrix™
GEL•SYSTEM

Matrix™ AHG (Coombs) Test Card

SUMMARY

Generally antibodies involved in transfusion reactions are of two types, namely the complete and the incomplete. The complete antibodies agglutinate human red blood cells in saline medium, whereas the incomplete type of antibodies sensitize red blood cells without agglutination. Usually IgM antibodies and IgG antibodies (IgG1 and IgG3 type) fix complement. Cell lysis, in vivo, is mediated through the complement system and the complement C_3b is further acted upon to produce C_3d.
In the direct antiglobulin test, Anti- Human Globulin reagent is used to detect antibodies adsorbed to the red blood cells in vivo.
In the indirect antiglobulin test, Anti- Human Globulin reagent is used to detect antibodies adsorbed to the red blood cells in vitro.

PRESENTATION

REF	102210024	102210048
Pack Size	24 Cards	48 Cards

REAGENTS

The Matrix™ AHG (Coombs) Test Card contains six microtubes, prefilled with a gel in a suitable buffer containing polyclonal Anti- Human IgG and monoclonal Anti-C_3d (BRIC-8).
The Matrix™ AHG (Coombs) Test Card is suitable for Direct Coombs test, Indirect Coombs test including compatibility testing, antibody screening and antibody identification.

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), Incubator (37°C), Work station, Micropipette capable of delivering 5-50µl of specimen, Bottle top dispenser and Reagent red blood cell suspension for antibody screening and identification.

PRINCIPLE

As the Matrix™ gel card containing red blood cells is centrifuged under specific conditions, the red blood cells sensitized with antibody will agglutinate in the presence of the Anti- Human Globulin reagent in the gel matrix and will be trapped in the gel column. The red blood cells, which do not react are not trapped in the gel matrix and are pelleted at the bottom of the column. 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 samples 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 cell suspension in Matrix™ Diluent- 2 LISS as follows:
1. Bring the Matrix™ Diluent -2 LISS to room temperature before use.
2. Dispense 1.0 ml of Matrix™ Diluent -2 LISS into a clean test tube.
3. Add 10µl of packed red cells to Matrix™ Diluent -2 LISS collected ina test tube and mix gently.
4. Red blood cell suspension so obtained should be used for testing.

TEST PROCEDURE
FOR DIRECT ANTIGLOBULIN TEST (DAT)

1. Label the appropriate microtubes of the Matrix™ gel card with patient's / donor's name or identification number. Remove the aluminium foil of required number of microtubes carefully by pulling it backwards.
2. Pipette 50µl of 0.8% patient's / donor's red blood cell suspension to the microtube, taking care to ensure that the micropipette tip does not touches the microtube.

3. Immediately centrifuge the Matrix™ gel card for 10 minutes in the gel card centrifuge.
4. Retrieve the card from centrifuge, read and record the results.

FOR ANTIBODY SCREENING / ANTIBODY IDENTIFICATION (IAT)

1. Label the appropriate number of microtubes of Matrix™ gel card with patient's / donor's name or identification number. Remove the aluminium foil of required number of microtubes carefully by pulling it backwards.
2. Pipette 50µl of each reagent red blood cell suspension (0.8%) to appropriate labeled microtubes taking care to ensure that micropipette tip does not touches the microtube.
3. If an autocontrol is to be included, pipette 50µl of 0.8% patient's / donor's own red cell suspension in an appropriate labeled microtube.
4. Add 25µl of patient's / donor's serum or plasma to be tested in all the microtubes. The interval between cells and serum or plasma transfer should not exceed 10 minutes.
5. Incubate the Matrix™ gel card for 15 minutes at 37° C in an incubator.
6. After incubation, centrifuge the Matrix™ gel card for 10 minutes in the gel card centrifuge.
7. Retrieve the card from centrifuge, read and record the results.

FOR COMPATIBILITY TEST (MAJOR)

1. Label the appropriate number of microtubes of Matrix™ gel card with the patient's name or identification number. Remove the aluminium foil of required number of microtubes carefully by pulling it backwards.
2. Pipette 50µl of 0.8% donor's red blood cell suspension to appropriate microtubes of the Matrix™ gel card, taking care to ensure that micropipette tip does not touches the microtube.
3. If an autocontrol is to be included, pipette 50µl of 0.8% patient's own red cell suspension in an appropriate labeled microtube.
4. Add 25µl of patient's serum or plasma to the above microtubes of the Matrix™ gel card. The interval between cells and serum or plasma transfer should not exceed 10 minutes.
5. Incubate the Matrix™ gel card for 15 minutes at 37° C in an incubator.
6. After incubation, centrifuge the Matrix™ gel card for 10 minutes in the gel card centrifuge.
7. 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 blood cells settle at the bottom of the microtube forming a compact button.

DIRECT ANTIGLOBULIN TEST

Negative reaction indicates absence of detectable IgG antibodies or Complement component C3d on the red blood cells.
Positive reaction indicates that red blood cells are sensitized with IgG or Complement component C3d.

ANTIBODY SCREENING / ANTIBODY IDENTIFICATION

Positive reaction indicates the presence of irregular antibodies.
Negative reaction indicates absence of detectable irregular antibodies in the patient's / donor's serum or plasma.

COMPATIBILITY TEST

A negative reaction indicates compatibility of the donor blood with the patient.
A positive reaction indicates incompatibility of the donor's blood with the patient, due to presence of antibodies directed against antigens on the donor's red blood cells. Further investigations to identify the antibody specificity should be performed.

The autocontrol microtube must be negative to validate results. Positive reaction in autocontrol may indicate autoantibodies.

After incubation in indirect antiglobulin test, if hemolysis is observed in upper part of the gel column, it should be interpreted as a positive reaction.

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 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. 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 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, icteric and hyperproteic 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. Some pathological conditions are reported as causing non-specific reactions in AHG procedures.

REMARKS

1. Known positive and negative control should be tested as per Good Laboratory Practices. Agtrol™ (Cat. No. 10252010) can be used for quality control procedures related to AHG.
2. ERYWELL (Catalogue no. 10253020) can be used as red blood cell preservative solution for preservation of known cells.