matrix™
GEL•SYSTEM

QAS-Level-II

Cat. No.	102780002
Presentation	0.5 ml Anti-D & 10 ml 6% BSA

Standardized Anti-D IgG (Lyophilized)

SUMMARY
In classical tube technique and in gel technology, it is very important to prevent neutralization of Coombs reagent which may lead to down grading of results. Techniques used in Classical tube technique and in gel technology play a very important role in sensitivity of detecting an antibody by IAT.
Matrix™ QAS Level-II can be used in quality assurance testing of AHG reagent and related procedures in Classical tube technique and in gel technology.

REAGENT
Matrix™ QAS Level-II contains Standardized, Lyophilized Anti-D IgG and 6% Bovine Serum Albumin for serial dilution of Anti-D IgG.

STORAGE AND STABILITY
Store the Matrix™ QAS Level-II at 2-8° C. Do Not Freeze.
Stability of 6% Bovine Serum Albumin in Matrix™ QAS Level-II is as per the expiry date mentioned on the label. Once opened the shelf life of the reagent is as per the expiry date indicated on the reagent vial label provided it is not contaminated.
After reconstitution, stability of Lyophilized Anti-D IgG in Matrix™ QAS Level-II is one week.
Do not use beyond expiry date.

ADDITIONAL MATERIAL REQUIRED
Appropriate Matrix™ gel card or Anti-Human Globulin reagent (Refer package insert before use). Gel card centrifuge (85g), Incubator (37°C), Work Station and Micropipette capable of delivering 5-50µl of specimen.

PRINCIPLE
Red cells coated with IgG antibodies do not agglutinate directly. These cells are said to be sensitized with IgG. In order for agglutination to occur, an additional antibody must be added to the system. This will form a "bridge" between the antibodies coating the red cells, causing agglutination. Agglutination of the IgG sensitized red cells indicates that Anti-IgG component of Anti-Human Globulin used is active.

TEST PROCEDURE
1. Bring the Matrix™ QAS Level-II to room temperature before testing.
2. Reconstitute lyophilized Anti-D IgG with 500µl of Distilled water.
3. Allow it to settle for 20 minutes and swirl gently.
4. For applications in gel technology, prepare serial dilution using 6% Bovine Serum Albumin provided in the kit. For applications in classical tube technique antibody-free serum of AB group should be used instead of 6% BSA for preparation of serial dilutions.
5. Test each dilution by routine method (Classical tube technique or gel technology) for antibody screening by IAT using Pooled 'O' Rh positive cells (Matrix™ ERYGEN-PO 0.8% also available with Tulip Cat. No. 102700015).

Note: Use of antibody-free serum of AB group for preparation of serial dilutions in classical tube technique instead of 6% BSA will cover the check for washing step for removal of unbound antibodies.

INTERPRETATION OF RESULTS
1. Observe and record the reaction strength for each dilution.
2. Record the highest dilution showing positive reaction as the titre end point.
3. Sensitivity to detect an antibody with the techniques practiced at specific laboratory can be calculated referring the strength of Anti-D printed on the kit or reagent vial label.

Example:

Dilution	Neat	1:2	1:4	1:8	1:16	1:32
Reaction Strength	4+	3+	2+	1+	±	Negative
Titre end point	1:16					

Laboratory specific antibody detection sensitivity with a concentration of 0.4IU/ml Anti-D (refer kit or reagent vial label).

0.4x1/16=0.025 IU/ml

IMPORTANT

1. For standardization of techniques, reference results or strength of reactions for all dilutions should be generated by each laboratory.
2. The dilutions must show the same strength of reaction every time tested irrespective of the person performing the test. Slight variations are accepted because of difference in amount of D antigen on cells used in testing.
3. Matrix™ QAS Level-II can be used in proficiency testing of laboratory staff in performing classical tube techniques. For classical tube techniques dilutions showing 2+ and 1+ reaction should be considered for testing.
4. In classical tube technique negative or downgraded results in comparison with reference reactions are suggestive of improper washing phase.

NOTE

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. Aged or stored red blood cells may exhibit weaker reactivity than freshly collected cells.
3. Bacterial or other contamination of reagents may cause false positive or negative results.
4. Use of red blood cell concentration/ volume other than those described may lead to erroneous results. Follow the instructions carefully.

REMARKS

1. Known negative and positive controls should be tested as per Good Laboratory Practices.

WARRANTY

This product is designed to perform as described on the label and package insert. The manufacturer disclaims any implied warranty of use and sale for any other purpose.

BIBLIOGRAPHY

1. Blood Transfusion in Clinical Medicine, P. L. Mollison; 10th Edition.
2. AABB, Technical Manual,15th Edition, 2005.
3. Applied Blood Group Serology, 4th Edition, P.D. Issitt and D.J. Anstee, 1998.
4. Data on file: Tulip Diagnostics (P) Ltd.

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