matrix™
GEL•SYSTEM

QAS-Level-I

0.8 ± 0.1% Suspension of Coombs Control Cells

SUMMARY

The antiglobulin test, which is also referred to as the anti-human globulin test (AHG) or the Coombs test, is the cornerstone of detecting clinically significant unexpected antibodies that have sensitized cells either *in vivo* or *in vitro*.
Erythrocytes sensitized with Anti-D (IgG) monoclonal also known as Coombs Control Cells are used as positive control in anti-human globulin testing. Erythrocytes sensitized with Anti-D (IgG) monoclonal should be used with anti-human globulin containing anti-IgG. The binding of anti-IgG in anti-human globulin, to IgG molecules attached to red cells results in agglutination and validates the functioning of Anti-human globulin reagent.
Matrix™ QAS Level-I can be used for quality assurance testing of AHG reagent in Matrix™ gel cards.

REAGENT

Matrix™ QAS Level-I contains 0.8±0.1% suspension of human red blood cells of group "O Rho(D) Positive" sensitized with monoclonal Anti-D (IgG). The reagent red blood cells are suspended in isotonic medium to which a red cell preserving solution is added to preserve the red cell integrity and antigenicity.

STORAGE AND STABILITY

Store the Matrix™ QAS Level-I at 2-8º C. Do Not Freeze.
Stability of the Matrix™ QAS Level-I 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. Do not use beyond expiry date.

ADDITIONAL MATERIAL REQUIRED

Appropriate Matrix™ gel card (Refer package insert before use). Gel card centrifuge (85g), Work Station and Micropipette capable of delivering 5-50µl of specimen.

PRINCIPLE

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

TEST PROCEDURE

1. Bring the Matrix™ QAS Level-I to room temperature before testing.
2. Dispense 50µl of Matrix™ QAS Level-I to appropriate Matrix™ gel card microtube.
3. Centrifuge the card for 10 minutes in gel card centrifuge.
4. Retrieve the card from centrifuge, read and record the results.

INTERPRETATION OF RESULTS

1. 2+ to 4+ reaction of Matrix™ QAS level-I indicates that anti-IgG component of anti-human globulin used is active.
2. +/- to 1+ reaction with Matrix™ QAS level-I may be due to insufficiently reactive anti-human globulin.
3. No agglutination with Matrix™ QAS level-I indicates that anti-IgG component of anti-human globulin used is inactive.

NOTE

1. *In vitro* diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. Indications of deterioration are notable hemolysis (which may be caused by microbial contamination or improper handling), darkening of cells or spontaneous clumping. Such reagents should be discarded.
3. The reactivity of the product may diminish slightly during the dating period.
4. All blood related products should be treated as potentially infectious. Matrix™ QAS Level-I contains red cells derived from donors found negative for HIV, HBsAg, HCV and Syphilis. However, absence of infectious agents in products derived from human blood cannot be guaranteed by any test method.

REMARKS

1. Known Negative and Positive controls should be tested as per Good Laboratory Practices.
2. Matrix™ Neutral Gel Card (Cat. no. 102740024) can be used with Matrix™ QAS Level-I as negative control.

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.
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QAS-L-I/0812/AE/VER-1

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