MeriSera Anti-A (Monoclonal IgM)

Blood Grouping Reagent

Product Code : ANASER-01

Meril Diagnostics

IVD For *in vitro* diagnostic use
Read this pack insert thoroughly before use

INTENDED USE

Anti-A(monoclonal IgM) reagent is intended for use by healthcare professionals, blood banks and is a qualitative, *in-vitro* diagnostic anti-sera for the recognition of A antigen on human red blood cells by the slide and tube method.

INTRODUCTION

The ABO system is the most important among all blood groups in transfusion practice.The four groups are determined by the presence or absence of blood group antigen on the red cells and accordingly an individual's group is determined as A, B, AB or O (O denotes the absence of A or B antigens). In addition, it has been shown that corresponding antigens to A and B, occur naturally as antibodies Anti-A and Anti-B(agglutinations) in the plasma/serum of individual whose red cells lack the corresponding antigens. Group A individual have anti-B, Group-B individual have anti-A, Group O individual have both anti-A and anti-B and Group AB individual have no agglutination in the plasma/serum.

The ABO blood grouping reagents contain sera of monoclonal IgM antibodies derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells. Each hybridoma cell line produces homogeneous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

ABO blood grouping reagents are of four types, namely Anti-A, Anti-B, Anti-A,B and Anti-D Blood Grouping Reagents. Anti-A Blood Grouping Reagent agglutinates human red corpuscles containing A antigens. It does not agglutinate human red corpuscles of groups O and B.

PRINCIPLE OF THE TEST

Anti-A defines the presence of A antigens(A_1,A_2,A_3 and A_X) on the surface of red blood cells. Agglutination of red blood cells with a known Anti-A monoclonal antibodies indicates the presence of A antigen, absence of agglutination of red blood cells with known Anti-A monoclonal antibodies is a negative test result and indicate the absence of corresponding antigen.

Kit contain following Reagents

No	Reference No	Name of Product	Antibody type	Pack Size
1	ANASER-01	MeriSera Anti-A	IgM	1x10ml

No	Reference No.	Name of Product	Colour	Dye Used
1	ANASER-01	MeriSera Anti-A	Blue	Patent Blue

MATERIALS REQUIRED

Glass slides, test tubes, pasture pipettes, isotonic saline (0.9% NaCl solution), centrifuge, timer, applicator sticks, Sodium hypochlorite(1%).

STORAGE OF TEST KIT

Unopened test kits should be stored at 2-8°C upon receipt. Sodium azide is added to the antibodies at 0.1% concentration as preservative. The test kit may be used till the time of the expiry date mentioned. Prolonged storage at temperatures outside this range may result in accelerated loss of reagent reactivity.

Do not freeze.

SAMPLE COLLECTION AND STORAGE

Do not use haemolysed samples. Samples should be collected with a suitable anticoagulant in a sterile container and should be tested immediately. If testing is delayed, blood should be stored at 2-8°C. EDTA and citrate samples should be typed within 48 hours. Samples collected into ACD, CPD or CPDA-1 may be tested up to 35 days from the date of withdrawal. Clotted samples should be used within 24 hours of collection.

PRECAUTIONS AND WARNINGS

1. Test for *In-vitro* diagnostic use only and should be run by competent and trained person only.
2. Not for medicinal use.
3. Use clean and dry glass wares.
4. The reagent contains 0.1% sodium azide as a preservative . Avoid contact with skin & mucosa.
5. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
6. Always wear hand gloves while performing the test. Avoid re-using gloves or use of washed gloves.
7. Do not smoke, eat and drink in the testing area.
8. Do not use haemolysed specimen for testing.
9. Do not use the reagent beyond expiry date.
10. Do not pipette by mouth.
11. All the materials used in the assay and samples should be decontaminated in 1% sodium hypochlorite. They should be disposed of in accordance with established safely procedure.
12. Spills should be decontaminated promptly with sodium hypochlorite or any other suitable disinfectant.
13. Wash hands thoroughly with soap or any suitable detergent, after the use of kit. Consult a physician immediately in case of accident or contact with eyes.

CONTROLS AND ADVICE

1. It is recommended a positive control and a negative control be tested in parallel with each batch of tests. Tests must be considered invalid if controls do not show expected results.
2. Since these reagent do not contain macromolecular potentiators, it is very unlikely that false positive reactions are caused with IgG coated cells.
3. Blood specimens of weak A may give rise to false negative or weak reactions when tested using slides, microtitre plates or gel cards. It is advisable to re-test weak subgroups using tube technique.

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4. Individuals older than six months should have their ABO blood grouping results confirmed by testing their serum or plasma against known group A1 and B cells before their ABO blood group can be confirmed.
5. In the Recommended Techniques one volume is approximately 50µl when using the vial dropper provided.
6. The use of the reagents and the interpretation of results must be carried out by properly trained and qualified personnel in accordance with the requirements of the country where the reagents are in use.
7. The user must determine the suitability of the reagents for use in other techniques.

TEST PROCEDURE

Bring reagent and blood specimen to room temperature before testing. Blood grouping should be performed at room temperature by:

- Slide method
- Tube method

1. Slide method:-

- Place a one volume of reagent Anti-A on a clean labelled glass slide at room temperature (18-25°C).
- Add one volume of whole blood.
- Mix well using a clean applicator uniformly.
- Slowly tilt the slide back and forth and observe for agglutination macroscopically and note the time in seconds.

INTERPRETATION OF RESULTS :

Agglutination is a positive test result and indicates the presence of A antigen. No agglutination is a negative test result and indicates the absence of A antigen.

Avidity : It is defined as the reactivity time (In seconds) taken by the antibodies to show the agglutination.

Intensity : It shows the strength of the reaction (clumping).

2. Tube method :-

- Prepare a 5% suspension of the red cells to be tested in isotonic saline.
- Place one volume of reagent Anti-A into correspondingly labelled test tubes.
- Add one volume of the test red cell suspension, mix well and incubate at room temperature(18-25°C) for 5minutes.
- Gently shake tube to mix the contents thoroughly.
- Centrifuge for 1 minute at 1000rpm.
- Gently re-suspend the cell button, observing for agglutination macroscopically.
- For specificity, observe all the negative tubes under the microscope for clear cut negative reaction.

NTERPRETATION OF RESULTS :

Grades	Description
4+	1 big clump
3+	2 or 3 clumps
2+	many small clumps with clear supernatant
1+	many small clumps with turbid supernatant
w	granular suspension
Zero or -ve	smooth suspension
H	partial or complete hemolysis (positive reaction)

Symbols used on Meril Diagnostics labels:

	Do not reuse		Attentions, See Instruction for Use
REF	Catalogue No.	IVD	*In vitro* Diagnostics
LOT	Batch No.		Consult Instruction for Use
	Expiry Date		Storage Temperature
	Manufacturer		Manufacturing Date
	Keep Dry		Keep Away from Sunlight
Σ	Sufficient for		Do not use if package is damaged
EC REP	Authorised European Representative inthe European Community		

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The reagents have been characterized by all the procedures mentioned in the Recommended Techniques.
2. Prior to release, each lot tested by the Recommended Techniques against a panel of antigen-positive red cells to ensure suitable reactivity.
3. Specificity of source monoclonal antibodies is demonstrated using a panel of antigen-negative cells.
4. The potency of the reagents has been tested against the minimum potency reference standards obtained from National Institute of Biological Standards and Controls (NIBSC).
5. The Quality Control of the reagents was performed using red cells that had been washed at least twice with PBS or Isotonic saline prior to use

DISCLAIMER

1. The user is responsible for the performance of the reagents by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the Recommended Techniques should be validated prior to use.

REMARKS

1. Anti-A reagent do not show a reaction with crypt antigens.
2. Over centrifugation could lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and determine the time required for achieving the desired results.
3. It is strongly recommended that red cells with known ABO characteristics should be occasionally run, preferably on a daily basis so as to control reagent performance and validate test results.
4. After usage of the reagent should be immediately recapped and stored at 2-8°C.
5. The minimum titre claim is based on A group cells for Anti- A reagent, This is based on the titration procedure as recommended by the manufacturer. Any deviation in the test procedure result in variable result.

WARRANTY

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

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