ANTI-A, ANTI-B, ANTI- A, B

MONOCLONAL BLOOD GROUPING ANTIBODIES FOR SLIDE AND TUBE TESTS

INTENDED USE

Vitro Anti A, Anti B and Anti AB reagents are intended for the in vitro detection of blood groups A, B and AB.

METHOD

Slide agglutination test. These reagents are also suitable for use in automated test systems, spin tube or microplate and should be standardized and validated by the user.

BACKGROUND

Monoclonal antibodies are derived from hybridoma cell lines, created by fusing mouse antibody producing B lymphocytes with mouse myeloma cells. Each hybridoma cell line produces homogenous antibodies of only one immunoglobulin class, which are identical in their chemical structure and immunological activity.

Human red blood cell antigens can be divided into four groups A, B, AB and O depending on the presence or absence of the corresponding antigens on the red blood cells.

Approximately 41% of the Caucasian population have the A Antigen, 9% have the B Antigen, 4% have both A and B antigens, while the remaining have neither the A nor the B antigen.

ASSAY PRINCIPLE

Human red blood cells possessing A and/or B antigen will agglutinate in the presence of antibody directed towards the antigen. Agglutination of red blood cells with Anti-A, Anti-B, Anti-A, B reagents is a positive test result and indicates the presence of the corresponding antigen.

Absence of agglutination of red blood cells with Anti-A, Anti-B, and Anti-A, B reagents is a negative test result and indicates the absence of the corresponding antigen.

REAGENTS

Vitro Anti-A, Anti-B, and Anti-A, B are ready to use reagents prepared from supernatants of mouse hybridoma cell cultures. These antibodies of the immunoglobulin class IgM are a mixture of several monoclonal antibodies of the same specificity but having the capability of recognizing different epitopes of the human red blood cell antigens A and B. Each batch of reagent undergoes rigorous quality control at various stages of manufacture for its specificity, avidity and performance.

- **REAGENT STORAGE AND STABILITY**
  1. Store the reagent at 2-8^{0}C**.** DO NOT FREEZE.
  2. The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label.

SPECIMEN

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2-8^{0}C if not tested immediately. Do not use haemolysed samples.

Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

EDTA or HEPARIN	2 days
Sodium citrate or sodium oxalate	14 days
ACD or CPD	28 days
Clotted whole blood should be tested within	14 days.

Bring reagent and samples to room temperature before testing.

PROCEDURE

Slide Test

1. Place one drop of reagent Anti-A or Anti-B or Anti-A, B on a clean glass slide.
2. To each reagent, add one small drop of whole blood.
3. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm^2.
4. Rock the slide gently, back and forth.
5. Observe for agglutination macroscopically at two minutes.

Tube test

1. Prepare a 2-3% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of reagent Anti-A, Anti-B, Anti-A, B into corresponding labelled test tubes.
3. Pipette into each of the test tubes, one drop of the test red cell suspension and mix well.
4. Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g) or incubate at room temperature for 20-30 minutes.
5. Gently suspend the cell button, observing for agglutination macroscopically.

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INTERPRETATION OF RESULTS

Slide and tube tests

Agglutination is a positive test result and indicates the presence of A and/or B antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative test result and indicates the absence of A and/or B antigen.

PROCEDURAL NOTES

1. (a) Anti-A, Anti-B, Anti-A, B reagents do not show a reaction with crypt antigens (T, Tn, Tk activated cells).
   (b) Anti-B is truly negative reacting with acquired B characteristics.
2. In the tube test procedure, it is recommended that tubes with negative reactions should be re-centrifuged and results read again after 5 minutes so that weak antigens are not overlooked.
3. As under centrifugation or 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.
4. Results of forward grouping obtained by using Anti-A, Anti-B, Anti-A, B reagents should always be reconfirmed by performing reverse grouping with known red cells.
5. 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 the results.
6. After usage the reagents should be immediately recapped and replaced to 2-8^{0}C storage.

WARNINGS & PRECAUTIONS

1. In vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
2. The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
3. Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagents should be discarded.
4. Reagents are not from human source, hence contamination due to HBsAg and HIV is practically excluded. The shelf life of the reagents is as per the expiry mentioned on the reagent vial labels.

WARRANTY

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

BIBLIOGRAPHY

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3. **Issit P.D.**; Applied Blood Group Serology 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
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SYMBOL DECLARATION

	Manufacturer
	Consult instructions for use
LOT	Batch code (Lot #)
REF	Catalog number
	Temperature limitation
IVD	In vitro diagnostic medical device
	Use by
	Caution. Consult instructions
	Keep away from light

ORDERING INFORMATION

	REF	SIZE
Anti A	2011	10 X 10 ml
Anti B	2021	10 X 10 ml
Anti AB	2031	10 X 10 ml

Manufactured in Egypt by:
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