

Anti-A, Anti-B, Anti-AB Monoclonal (IgM) Blood Grouping Reagents

IVD

	REF.	Pack size
Anti-A	431 10 010	10 x 10 ml
	431 10 011	1 x 10 ml
Anti-B	435 10 010	10 x 10 ml
	435 10 011	1 x 10 ml
Anti-AB	433 10 010	10 x 10 ml
	433 10 011	1 x 10 ml

Intended Use

Anti-A, Anti-B and Anti-AB reagent is intended for the detection of Blood groups A, B and AB in Human Blood.

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 remaining have neither A nor 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-AB 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, Anti-AB reagents is a negative test result and indicates the absence of the corresponding antigen.

Note

- In-vitro diagnostic reagent for laboratory and professional use only. Not for medicinal use.
- The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. On disposal flush with large quantities of water.
- Extreme turbidity may indicate microbial contamination or denaturation of protein due to thermal damage. Such reagent should be discarded.
- blood grouping reagents are not from human sources, hence contamination due to HBsAg and HIV is practically excluded.

Reagents

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

Reagent Storage and Stability

- Store the reagent at 2-8 °C. Don't freeze.
- The shelf life of reagent is as per the expiry date mentioned on the reagent vial label. Open vial is stable for 6 months at 2-8 °C.

Specimen Collection and Storage

No special preparation of the patient is required prior to sample collection by approved techniques. Samples should be stored at 2 - 8 °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.

Additional Material Required For Slide And Tube Tests

Glass slides (50x75 mm), Test tubes (12x75 mm), Pasteur pipettes, isotonic saline, Centrifuge, timer, mixing sticks.

Procedure

Bring reagent and samples to room temperature before testing.

Slide Test

- Place one drop of Anti-A, Anti-B or Anti-AB reagent on a clean glass slide.
- To each reagent drop, add one small drop (50 µl) of whole blood.
- Mix well with a mixing stick uniformly over an area of approximately 2.5 cm². Rock the slide gently, back and forth.
- Observe for agglutination macroscopically at two minutes.

Tube Test

- Prepare a 2-3% suspension of the red cells to be tested in Isotonic saline.
- Place one drop of Anti-A, Anti-B or Anti-AB into correspondingly labeled test tubes.
- Pipette into each of the test tubes, one drop (50 µl) of the test red cell suspension and mix well.
- 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.
- Gently resuspend the cell button, observing for agglutination macroscopically.

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.

Remarks

- (a) Anti-A, Anti-B and Anti-AB reagent do not show a reaction with crypt antigens (T, Tn, Tk activated cells).
(b) Anti-B is truly negative reacting with acquired B characteristics.
- In the tube test procedure, it is recommended that tubes with negative reactions should be recentrifuged and results read again after 5 minutes so that weak antigens are not overlooked.
- As undercentrifugation or overcentrifugation 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.
- Results of forward grouping obtained by using Anti-A, Anti-B, Anti-AB reagents should always be reconfirmed by performing reverse grouping with known red cells.
- It is strongly recommended that red cells with known ABO characteristics should be occasionally run, preferably on daily basis so as to control reagent performance and validate test results.
- After usage the reagents should be immediately recapped and replaced to 2-8 °C storage.
- The label minimum titre claim is based on A1 group cells for Anti-A reagent, B group cells for Anti-B reagent and A1B cells for Anti-AB reagent. This is based on titration procedure as recommended by the manufacturer. Any deviation in test procedure could result in variable results.

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.

Precautions and Warnings

Do not ingest or inhale. In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.

Waste Disposal

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.









S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. refer to special instructions/safety data sheets.

References

1. Kohler C. & Milstein C. (1975), Continuous cultures of fused cells secreting antibody of predefined specificity, Nature, 256, 495-497.
2. Lee H.H., Rouger P, Germain C., Muller A. & Salmon C. (1983), The production and standardisation of monoclonal antibodies as AB blood group typing reagents. Symposium of International Association of Biological Standardisation on Monoclonal antibodies.
3. Human Blood Groups by Geoff Daniels, 1st Ed., Blackwell Science, Oxford 1995.
4. HMSO, Guidelines for the Blood Transfusion Services, 2nd Ed., 1994.

SYMBOLS IN PRODUCT LABELLING

	For in-vitro diagnostic use
	Batch Code/Lot number
	Catalogue Number
	Consult instructions for use
	Temperature Limitation
	Use by/Expiration Date
	CAUTION. Consult instructions for use
	Manufactured by