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

Intended Use
Spectrum Diagnostics 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 homogeneous 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
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 reagent should be discarded.
4. Spectrum blood grouping reagents are not from human sources, hence contamination due to HBsAg and HIV is practically excluded.

Reagents
Spectrum 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
1. Store the reagent at 2-8 °C. Don’t freeze.
2. The shelf life of reagent is as per the expiry date mentioned on the reagent vial label.

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

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 results and indicates the absence of A and/or B antigen.

Remarks
1. (a) Spectrum Anti-A, Anti-B and Anti-AB reagent do not show a reaction with crypt antigens (T, Tn, Tk activated cells).
(b) Spectrum 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 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.
4. 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.
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 test results.
6. After usage the reagents should be immediately recapped and replaced to 2-8 °C storage.
7. The label minimum titre claim is based on A1 group cells for Spectrum Anti-A reagent, B group cells for Spectrum Anti-B reagent and A1B cells for Spectrum Anti-AB reagent. This is based on titration procedure as recommended by the manufacturer. Any deviation in test procedure could result in variable results.

SYMBOLS IN PRODUCT LABELLING

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

References

ORDERING INFORMATION

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Egyptian Company for Biotechnology (S.A.E)
Obour city industrial area. block 20008 piece 19 A. Cairo. Egypt.
Tel: +202 4489 2248 - Fax: +202 4489 2247
www.spectrum-diagnostics.com
E-mail: info@spectrum-diagnostics.com