

BLOOD GROUPING LECTIN

ANTI-A₁

ALBAlect™

Dolichos biflorus

For the *in vitro* detection and identification of human A₁ red blood cells

For Tube Technique
Direct Agglutinin

REF Z241U

- No U.S. standard of potency
- Discard if turbid
- Preservative: 0.1% sodium azide

CAUTION: THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.

INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)



In vitro diagnostic medical device



Consult instructions for use



Manufacturer



Product Code



Rx only

INTENDED USE

The Anti-A₁ reagent is for the *in vitro* detection and identification of human A₁ red blood cells by direct agglutination.

SUMMARY AND EXPLANATION

In 1911, von Dungern and Hirsfeld reported a variation in the expression of A antigen which led to the discovery that group A antigens can be sub-classified into A₁ and A₂. Approximately 80% of individuals whose red cells carry A antigen are group A₁ while most of the remainder are A₂ - a very small proportion are weaker subgroups of A e.g. A₃.

Serum from approximately 2% of A₂ and 25% of A₂B individuals contains anti-A₁. However, unless anti-A₁ is reactive *in vitro* at 37 °C it is generally considered to be of no clinical significance. This distinction between A₁ and A₂ red cells is made with Anti-A₁ reagent which can be derived from a variety of sources including human serum. Extracts from the seeds of *Dolichos biflorus* contain potent anti-A₁ reactivity and remain the most reliable available reagent for distinguishing between group A₁ and A₂ red cell samples.

PRINCIPLE OF THE PROCEDURE

When used by the recommended technique, this reagent will cause agglutination (clumping) of red blood cells carrying the A₁ antigen. Lack of agglutination demonstrates the absence of the A₁ antigen.

REAGENT DESCRIPTION

This reagent was prepared from an extract of the seeds of *Dolichos biflorus*. The extract is diluted in PBS pH 7.0 containing 20g/L bovine serum albumin and 1g/L sodium azide.

The volume delivered by the reagent dropper bottle is approximately 40µL; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

STORAGE CONDITIONS

The reagent should be stored at 2–8 °C. Do not use if turbid. Use as furnished, do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide build-up.

Appropriate care must be taken during the use and disposal of this reagent.

This product has components (dropper bulbs) containing dry natural rubber.

This reagent is for *in vitro* professional use only.

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected following general blood sampling guidelines. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2–8 °C. Blood specimens exhibiting gross hemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within fourteen days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

General Information

This reagent has been standardized for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

Materials Provided

- ALBAlect™ Anti-A₁

Additional Materials and Reagents Required

- Isotonic saline
- Reagent red cells suitable for the control of Anti-A₁
- 10 x 75mm or 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Timer

RECOMMENDED TECHNIQUE

5 Minute Incubation / Spin, Direct Agglutination

- Add 1 drop of reagent to a glass test tube.
- Add 1 drop of red cells suspended to approximately 2-4% in isotonic saline.
- Mix the test thoroughly and incubate for 5 minutes at 18-24 °C.
- Centrifuge the test tube.
- Suggested centrifugation: 1000g for 10 seconds or at a time and speed appropriate for the centrifuge used that produces the strongest reaction of antibody with antigen-positive red blood cells, yet allows easy resuspension of antigen-negative red blood cells.
- After centrifugation, gently shake the tube to dislodge the cell button from the bottom and immediately observe macroscopically for agglutination.

QUALITY CONTROL

Quality control of reagents is essential and should be performed on each day of use and in accordance with local, state and federal regulations.

As a minimum it is recommended that A₁ cells are used as a positive control and A₂ cells are used as a negative control.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

PERFORMANCE LIMITATIONS

ABH antigens are not fully expressed at birth. Consequently, subgrouping tests on cord and neonatal samples, particularly those involving premature infants should be interpreted with care.

In addition to agglutinating red cells of groups A₁ and A₁B, this Anti-A₁ reagent will also agglutinate red cells which express the rare Sd (a++) and Cad phenotypes, or the cryptantigen Tn, IRRESPECTIVE OF THEIR ABO GROUP.

The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

In tube tests it is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in re-suspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBAlect™ Anti-A₁ is tested by the method detailed in the instructions-for-use against a panel of antigen-positive and antigen-negative red blood cells to ensure suitable reactivity.

BIBLIOGRAPHY

Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.

Standards for Blood Banks and Transfusion Services. 26th ed. Bethesda, MD: American Association of Blood Banks, 2009.

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