QUOTIENT

ANTI-A_1

BLOOD GROUPING LECTIN
Dolichos biflorus
Direct Agglutinin

REF Z241 CE

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
REF	Product code
	Manufacturer

INTENDED PURPOSE

The Anti-A_1 reagent is for the *in vitro* detection and identification of human A_1 red blood cells by direct agglutination.

INTRODUCTION

In 1911, von Dungern and Hirszfield reported a variation in the expression of A antigen which led to the discovery that group A antigens can be subclassified into A_1 and A_2. Approximately 80% of individuals whose red cells carry A antigen are group A_1 while most of the remainder are A_2 - a very small proportion are weaker subgroups of A e.g. A_3.

Serum from approximately 2% of A_2 and 25% of A_2B individuals contains anti-A_1. However, unless anti-A_1 is reactive *in vitro* at 37°C it is generally considered to be of no clinical significance. This distinction between A_1 and A_2 red cells is made with Anti-A_1 reagent which can be derived from a variety of sources including human serum. Extracts from the lectin *Dolichos biflorus* contain potent anti-A_1 reactivity and remain the most reliable available reagent for distinguishing between group A_1 and A_2 cord 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 A_1 antigen. Lack of agglutination demonstrates the absence of the A_1 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.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

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% sodium azide.
Sodium azide 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.
Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.
Appropriate care must be taken during the use and disposal of this reagent.
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 haemolysis 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 standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

Materials Provided

- Anti-A_1

Additional Materials and Reagents Required

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells suitable for the control of Anti-A_1
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge
- Timer

RECOMMENDED TECHNIQUE

NIS/LISS Spin, Direct Agglutination

- Add 1 drop of reagent to a 12 x 75mm glass test tube.
- Add 1 drop of red cells suspended to approximately 2-3% in PBS pH 7.0 ± 0.2 or 1.5-2% in LISS.
- Mix the test thoroughly and incubate for 5 minutes at 18-24 °C.
- Following incubation centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each batch of groups and with single groups.

As a minimum it is recommended that A_1 cells are used as a positive control and A_2 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 A_1 and A_1B, this Anti-A_1 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 resuspending 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.

UK frequencies: A_1 80%; A_2 20%

SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of Anti-A_1 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.

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For further information or advice please contact your local distributor.

EC REP

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