CE

ERYBANK®

ANTI-A_1 LECTIN

DOLICHOS BIFLORUS LECTIN FOR SLIDE AND TUBE TESTS

SUMMARY

Human red blood cells possessing the A antigen can be broadly subdivided into two main subgroups namely A_1, and A_2 based on their reaction with Anti-A_1 lectin. A_2 subgroups comprises of weaker subgroups of A such as A_{2}, A_{3}, A_{x}, A_{4}, A_{5}, A_{6}, etc.
Group A red blood cells which agglutinate with Anti-A_1 lectin are classified as subgroup A_1, whereas red blood cells which do not agglutinate with Anti-A_1 lectin are classified as subgroup A_2. It is estimated that about 80% of the group A population are A_1, and the remaining A_2 or weaker. Anti-A_1 lectin is especially useful in selecting blood for an A_2 or A_2B recipient whose blood may contain Anti-A_1 antibodies.

PRESENTATION

REF	10200005
ERYBANK® Anti-A_1 lectin	5 ml
Pack insert	1

REAGENT

ERYBANK® Anti-A_1 lectin is a ready to use purified extract of *Dolichos biflorus* seeds that is carefully calibrated to differentiate most A_1 red cells from A_2 red cells. It contains a phytohaemagglutinin, which is virtually specific for A_1 red blood cells in humans. Each batch of reagent undergoes rigorous quality control at various stages of manufacturing for its specificity, avidity and titre.

REAGENT STORAGE AND STABILITY

(a). Store the reagent at 2-8^{0}C. DO NOT FREEZE. (b).The shelf life of the reagent is as per the expiry date mentioned on the reagent vial label. Once opened the shelf life of the reagent vial is as described on the reagent vial label provided it is not contaminated.

PRINCIPLE

Human A group red blood cells possessing 2.5 - 4 X 10^5 'A' sites per red cell will agglutinate in the presence of seed extract (lectins) containing phytohaemagglutinin specifically directed towards it.
Agglutination of 'A' group red blood cells with ERYBANK® Anti-A_1 lectin is a positive test result and identifies the red cell as A_1 red cell. No agglutination of 'A' group red blood cells with ERYBANK® Anti-A_1 lectin is a negative test result and identifies the red cells as A_2 or weaker subgroups.

NOTE

(1). In vitro diagnostic reagent for laboratory and professional use only. To be used by a qualified personnel. Not for medicinal use. (2). The reagent contains sodium azide 0.1% as preservative. Avoid contact with skin and mucosa. MSDS available on request. (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, HIV and HCV is practically excluded. (5). It is necessary to use the calibrated dropper provided in the reagent vial to dispense a reagent drop. (6). It is advisable to wear gloves and safety spectacles and handle test specimens of human origin with caution. (7). Do not use damaged or leaking reagents. (8). Special protective measures, conditions for disposal and disinfection should be implemented in accordance with local regulations.

SAMPLE COLLECTION AND PREPARATION

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

ADDITIONAL MATERIAL REQUIRED FOR SLIDE AND TUBE TESTS

Glass slides (60 x 85 mm), Test tubes (12 x 75 mm), pipettes, isotonic saline, Centrifuge, Timer, Mixing sticks.

TEST PROCEDURE

Bring all reagents and samples to room temperature before testing.

Slide Test

1. Prepare a **10%** suspension of the red blood cells to be tested in isotonic saline.
2. Place one drop of ERYBANK® Anti-A_1 lectin on a clean glass slide.
3. Pipette 100µl of the cell suspension on the slide.
4. Mix well with a mixing stick uniformly over an area of approximately 2.5 cm^2.
5. Rock the slide gently, back and forth.
6. Observe for agglutination macroscopically **at one minute.**

Tube Test

1. Prepare a **5%** suspension of the red cells to be tested in isotonic saline.
2. Place one drop of ERYBANK® Anti-A_1 lectin into a labelled test tube.
3. Pipette into the test tube, 50µl of the test red cell suspension.
4. Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
5. 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_1 antigen. Do not interpret peripheral drying or fibrin strands as agglutination. No agglutination is a negative test result and indicates the absence of A_1 antigen.

REMARKS

(1). A_1 antigen are not fully expressed on the red blood cells of newborns below one year of age, hence false negative results may occur. (2). It is strongly recommended that known A_1 and A_2 red cells should be occasionally run, preferably on a daily basis to control reagent performance and validate test results. (3). A_1- A_2 (A_{int}) cells may agglutinate moderately with ERYBANK® Anti-A_1 lectin. These should be tested further with Anti-H lectin to confirm A_{int} cells. (4). As undercentrifugation or overcentrifugation can lead to erroneous results, it is recommended that each laboratory calibrate its own equipment and determine the time required for achieving the desired results. (5). Do not interpret peripheral drying or fibrin strands as agglutination.

PERFORMANCE CHARACTERISTICS

In an internal evaluation 127 samples with known red cell phenotypes were tested which included A_1 cells, A_2 cells, A_1B, A_2B cells, B cells and O cells.

	Red Cell phenotype						Total
	A_1	A_1B	A_2	A_2B	B	O	
No of samples	37	3	5	0	35	47	127
No of samples reactive with ERYBANK® Anti-A_1 lectin	37	3	0	0	0	0	40
No of samples non-reactive with ERYBANK® Anti-A_1 lectin	0	0	5	0	35	47	87

ERYBANK® Anti-A_1 lectin demonstrated 100 % specificity for A1 phenotype.

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

(1).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. (2). Blood Transfusion in Clinical Medicine, P.L. Mollison, C. P. Engelfreit, Marcela Contreras, 10th Ed., 1997, Blackwell Scientific Publications.(3). AABB Technical Manual, 13th Ed., 1999.(4). Human Blood Groups by Geoff Daniels, Ist Ed., Blackwell Science, Oxford 1995. (5).HMSO, Guidelines for the Blood Transfusion Services., 2nd Ed., 1994. (6).Data on file: Tulip Diagnostics (P) Ltd.

SYMBOL KEYS

Temperature limitation	Manufacturer	LOT Batch Number/Lot Number	This side up
Use by	Consult Instructions for use	EC REP Authorised Representative in the European Community	REAGENT Description of reagent
Date of Manufacture	REF Catalogue Number	IVD *In vitro* Diagnostic Medical Device	PS Production Site

TULIP DIAGNOSTICS (P) LTD.

PS

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EC REP

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