

## INSTRUCTIONS FOR USE

# Anti-A<sub>1</sub> (lectin)



IN VITRO DIAGNOSTICUM

### **1. Description of product**

Anti A<sub>1</sub> (lectin) is a purified plant hemagglutinin from *Dolichos biflorus*. Anti-A<sub>1</sub> (lectin) is used for the determination of A subtypes because it reacts strong positive with erythrocytes of blood type A<sub>1</sub> by binding to the N-acetyl-D-galactosamine groups of the A<sub>1</sub> blood type receptors. Anti-A<sub>1</sub> (lectin) does not react or reacts only weakly with the erythrocytes of blood type A<sub>2</sub>. Anti-A<sub>1</sub> is suitable for test tube and plate test.

NaN<sub>3</sub> (< 0.1%) is added to the test reagent as a preservative.

### **2. Principle of the test**

The testing methods indicated are based on the principle of hemagglutination. A specific agglutination reaction takes place once erythrocytes are added to the test reagent if the corresponding A<sub>1</sub> antigen is present on the erythrocytes. If no agglutination takes place, this indicates a negative result and, allowing for the limitations of the testing method, the absence of the corresponding antigen.

### **3. Storage and stability**

Store the test reagent at 2...8°C and cool to 2...8°C again immediately after use. Once it has been opened the first time, the test reagent may be used up to the expiration date indicated on the label if the specified storage conditions are observed. Do not use the reagent past the expiration date indicated on the label.

### **4. Preparation of samples**

The blood samples should be collected according to the customary medical procedure. Blood samples with and without anticoagulants (EDTA, citrate) are suitable for testing. Do not use hemolytic samples! Testing should take place without delay whenever possible.

If erythrocytes are stored for too long before testing, the erythrocyte antigens may change, which can lead to weakened reactions (see 9. Important Notes/Limitations of the Method).

### **5. Additional materials required**

Isotonic NaCl solution  
Test tubes (75 x 12 mm)  
Test plates for blood type determinations  
Single-use Pasteur pipettes  
Centrifuge

### **6. Test procedure**

#### **Plate test**

1. Wash the erythrocytes to be examined once and then make a suspension of about 10% in isotonic NaCl solution.
2. Mix well 1-2 drops of test reagent and 1 drop of the erythrocyte suspension on a plate and incubate at room temperature for 10 - 15 minutes.
3. By slowly rotation the plate, examine macroscopically for agglutination.

#### **Tube test**

1. Wash the erythrocytes to be examined once and then make a suspension of about 2-3% in isotonic NaCl solution.
2. Mix well 1 - 2 drops of test reagent and 1 drop of the erythrocyte suspension in a labeled test tube and incubate at room temperature for 1 minute.
3. Centrifuge 1 minute at 400 x g (1500 rpm) or at an alternative rpm with an appropriate time adjustment.
4. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.

Comments: Do not examine the test microscopically.  
A known A<sub>1</sub> positive and a known A<sub>2</sub> positive erythrocyte suspension and an auto-control to check for autoagglutination must also be tested as controls. Samples that react weakly or dubiously in the plate test must be tested again in the tube test.  
The determination of A subtypes should always be carried out with two different anti-A<sub>1</sub> test reagents and be verified by testing with an anti-H test reagent.

### **7. Interpretation of the results**

An agglutination of erythrocytes of blood type A with Anti-A<sub>1</sub> (lectin) at a reaction strength of  $\geq 2+$  indicates A<sub>1</sub>. No agglutination or a weak agglutination (+/- or 1+ reaction) of blood type A erythrocytes with Anti-A<sub>1</sub> (lectin) indicates A<sub>2</sub> or weak A variants.

The test results cannot be evaluated if there is no agglutination with the known A<sub>1</sub>-positive erythrocyte suspension or if agglutination occurs with the known A<sub>2</sub>-positive erythrocyte suspension (>1+) and/or the auto-control.

If discrepant results occur with different test reagents when determining A subtypes, the determination must be repeated with another test method and/or an additional test reagent.

The limitations of the method must be considered when interpreting the results (see 9. Important Notes/Limitations of the Method).

### **8. Stability of reactions**

All test results must be interpreted immediately once the test is performed.

### **9. Important notes/limitations of the method**

1. The test reagent is suitable for in vitro diagnostic use only and may only be used by trained, qualified personnel.
2. The determination of A subtypes with this test procedure is not possible in neonates since these subtypes are not yet sufficiently developed.
3. Samples that react weakly or dubiously in the plate test must be tested again in the tube test.
4. The test reagent may show weak, non-specific reactions in the presence of A<sub>2</sub> erythrocytes. In high concentrations, Anti-A<sub>1</sub> lectin may also react strongly with A<sub>2</sub> erythrocytes; therefore, the amount of test reagent indicated for testing should be adhered to.
5. False positive results may occur because of bacterial or chemical contamination of the test reagent, the samples or the physiological NaCl solution and/or because of incorrect centrifuging.
6. If the plate test is read too late, the appearance caused by drying may simulate false positive results.
7. False negative results or unexpected weak reactions may be caused by an insufficient cell concentration, insufficient incubation temperature or time and/or insufficient centrifugation, but also by storing the erythrocytes for too long and/or under inappropriate conditions. Reading the results of the test tube procedure too late, agitating the erythrocyte sediment too strongly, and other deviations from the indicated testing procedure can also lead to false negative results or results that are too weak.
8. In general, false negative or false positive results can result from inappropriate techniques, incorrect centrifugation or incubation, dirty tubes, incorrect pH of the isotonic NaCl solution and/or contaminated materials and samples.
9. A microbial or chemical contamination of the test reagents must be absolutely avoided because this shortens the shelf life of the products and can lead to false results.
10. Light cloudiness does not influence the reactivity of the product.
11. Whether transfusions or transplants have taken place should always be taken into consideration when interpreting the results. Any history of transfusions and/or transplants, as well as the patient's medication history, should be taken into consideration when interpreting results.

### **10. Warnings and Instructions for Disposal**

All materials of biological origin used for the test, especially the erythrocytes to be tested, should be regarded as potentially infectious. Lectins can cause symptoms of poisoning if ingested. Therefore, appropriate safety precautions are recommended when handling

biological materials (do not pipette using the mouth; wear protective gloves when performing the test; disinfect hands after testing).

Biological materials must be deactivated before disposal (e.g., by autoclaving). Single-use materials must be autoclaved or incinerated after use.

Spills of potentially infectious material should be removed without delay with an absorbent paper towel and the contaminated area disinfected with an appropriate disinfectant or 70% ethanol. Materials used for the removal of spills must be deactivated before disposal (e.g., by autoclaving).

The test reagent contains  $\text{NaN}_3$  as a preservative. The reagent contains < 0.1%  $\text{NaN}_3$  which is not considered to be a harmful concentration. Nevertheless avoid contact with the skin and mucous membranes. The copper and lead used in some plumbing systems can react with azides to form explosive salts. The quantities of azide used in this reagents are small; nevertheless when disposing of azide-containing materials, they should be flushed away with a large volume of water.






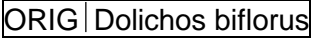


Disposal of all specimen and test materials should be in accordance with state and local law.

**11. Package Sizes** See price list.

**12. Bibliography**

Applied Blood Group Serology, PD Issitt and DJ Anstee, 4<sup>th</sup> Edition, Montgomery Scientific, Durham SC, 1998

Technical manual of the American Association of Blood Banks, 15<sup>th</sup> ed., 2005

Explanation of symbols used on Labelling	
	For in vitro diagnostic use
	Storage temperature
	Batch code
	Use by
REF	Catalogue number
	Consult instructions for use
	Origin: Dolichos biflorus
	Contains Natriumazide
	Titer

Instructions for use	Issue: August 2007
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