EN

INSTRUCTIONS FOR USE

Anti-A_1 (lectin)

CE

Electronic instructions for use see www.bag-diagnostics.com

REF 6811 1 x 5 ml

FOR IN VITRO DIAGNOSTIC USE

1. Description of product

Anti A_1 (lectin) is a purified plant hemagglutinin from Dolichos biflorus. Anti-A_1 (lectin) is used for the determination of A subtypes because it reacts strong positive with erythrocytes of blood type A_1 by binding to the N-acetyl-D-galactosamine groups of the A_1 blood type receptors. Anti-A_1 (lectin) does not react or reacts only weakly with the erythrocytes of blood type A_2. Anti-A_1 is suitable for test tube and plate test.
NaN_3 (< 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_1 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. If possible use fresh samples and do not use hemolytic samples and/or contaminated 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).

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5. Additional materials required

Isotonic NaCl solution (isotonic saline)

Test tubes (75 x 12 mm)

Tube rack

Test plates for blood type determinations

Single-use Pasteur pipettes

Centrifuge

Red blood cells of known phenotype

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 or use whole blood.
2. Mix well 1 drop of test reagent and 1 drop of whole blood or 1 drop the 10% erythrocyte suspension on a plate and incubate at room temperature for 5 - 10 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 drop 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_1 positive and a known A_2 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_1 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_1 (lectin) at a reaction strength of $\geq$ 2+ indicates A_1. No agglutination or a weak agglutination (+/- or 1+ reaction) of blood type A erythrocytes with Anti-A_1 (lectin) indicates A_2 or weak A variants.

The test results cannot be evaluated if there is no agglutination with the known A_1-positive erythrocyte suspension or if agglutination occurs with the known A_2-positive erythrocyte suspension (>1+) and/or the auto-control.

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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 (e.g. BAGene ABO-TYPE / BAGene ABO-TYPE variant).

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_2 erythrocytes. In high concentrations, Anti-A_1 lectin may also react strongly with A_2 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. Use the test reagent without any supplements.
12. No single centrifugation speed or time can be recommended for all types of available centrifuges or test applications. Centrifuges should be calibrated individually to determine the optimal time and speed required to produce a clear supernatant and a clearly delineated red cell button that can be easily resuspended.

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13. Deviation from the recommended Instructions for use may result in less than optimal product performance. User-defined deviations such as modifications of test procedures, serum dilution for use in automat or cards, freezing of serum on microtiter plates etc. may require validation by the user.
14. 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 NaN_3 as a preservative. The reagent contains < 0.1% 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 samples, unused reagent and waste should be in accordance with country, federal, state and local regulations.

A Material Safety Data Sheet (MSDS) is available to download at www.bag-diagnostics.com

11. References

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

Technical manual of the American Association of Blood Banks, 18th ed., 2014

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Explanation of symbols used on Labelling	
IVD	For in vitro diagnostic use
	Manufacturer
	Storage temperature / Temperature limitation
LOT	Batch code
	Use by
REF	Catalogue number
	Consult instructions for use
ORIG | Dolichos biflorus	Origin: Dolichos biflorus
CONT | NaN_3	Contains Natriumazide
TIT	Titer

Instructions for use	Version 2/2019 / Issue 2019-06

Instructions for use in other languages see:
http://www.bag-diagnostics.com
or phone +49 (0) 6404-925-125

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