CE-Immundiagnostika GmbH
Karl-Landsteiner-Str. 6, D-69151 Neckargemünd
Tel.: +49 6223-80094 00 Fax: +49 6223-80094 99
www.ce-immundiagnostika.com

CE

Instruction for use

Rev.002/09-2021

Description	REF
Anti-H (A2) 10934C11 monoclonal 5 ml	31105
Anti-H (A2) 10934C11 monoclonal 10 ml	31110

IN-VITRO-DIAGNOSTICUM MEDICAL DEVICE

ZUSAMMENFASSUNG

The H substance is the basic molecule of the A, B antigens on the erythrocytes. The corresponding A and B alleles control glycosyltransferases, which add a-N-acetyl-D-galactosamine (A-substance) and a-D-galactose (B-substance), respectively. The blockage of the H antigen is quantitatively different. It is practically complete with A_1A_1 and A_1B bleeding, so that no reaction can be detected with anti-H. With A_1 0 and especially with BO types, small residues of H-substance can still remain, which can lead to weak reactions with anti-H. The least amount of H-substance is blocked when the allele A_2 is present (especially in the case of the heterozygous A20 bleeds), so that strong reactions (3+) with anti-H are observed here. This is why Anti-H is used as a so-called "Anti-A_2" to differentiate it from the A¬1 type. By definition, anti-H gives the strongest reaction with 0 bleeds, in which the H antigen is unchanged.
The results with blood group test reagent Anti-H depend on the genotype. The conversion of the H substance by the glycosyltransferases controlled by A and B alleles into A or B antigen is less complete with gene type A0 than with AB and AA, with A_2 less complete than with A_1. As a result, depending on the H-substance still present, very weak or negative reactions are possible on the one hand with A_2B bleeding and, on the other hand, occasionally weak agglutinations are possible with A_1 or A_1B bleeds.

Occurrence of the H antigen:

Anti-H	Phänotyp	Occurence in %
+	H+	99,9%
-	H-	Extrem selten

The H antigen is part of the Hh system and is present on all erythrocytes, except for the 0h (hh) Bombay phenotype.

Reaction strength:

Very strong (4+)				very weak (+/-)	
0	**A_2**	**B**	**A_2B**	**A_1**	**A_1B**

INTENDED USE

The specified test method is based on the principle of direct haemagglutination. After adding erythrocytes to the anti-H monoclonal reagent, an agglution reaction takes place if the corresponding H antigen is present on the erythrocytes. This reaction can be seen optically after centrifugation of the erythrocytes. If agglutination does not occur, this indicates a negative result and, taking into account the limitations of the test method, indicates the absence of the corresponding antigen.

PRODUCT INFORMATION

Anti-H (IgM) is a monoclonal antibody from mouse hybridoma cells for the tube test (clone: 10934C11).
The reagent contains bovine albumin (without stabilizer) and sodium azide (<0.1%) as a preservative.
Anti-H monoclonal is used without further dilution / additives.
LOT and expiration date are on the vial label.

STORAGE

Store the test reagents at 2°C-8°C until the expiry date detailed on the product label. After opening a product for the first time, tightly close again and store at 2°C-8°C.

SPECIMEN COLLECTION AND PREPARATION

Blood specimens for AB0 blood typing should be collected aseptically in EDTA or citrate tubes. The specimen should be tested as soon as possible following collection. If a delay in testing should occur, store the specimen at 2°C-8°C. Specimens displaying haemolysis or microbial contamination should not be tested with this reagent as this may result in false positive or false negative results.
All blood samples should be washed twice with a 0.9% NaCl solution before being tested by the tube technique.

WARNINGS AND PRECAUTIONS

1. The reagents are intended for in vitro diagnostic laboratory use only
2. The reagents may only be used by authorized specialists.
3. The test sera are not intended for personal use.
4. After the expiry date, the test sera may no longer be used
5. Damaged vials must not be used
6. The test sera contain <0.1% sodium azide. In high concentrations, sodium azide can react with lead and copper and form an explosive metal azide compound.
7. Wear protective clothing such as a gown and disposable gloves when using the products
8. The test sera were filtered through a 0.2 µm membrane in order to reduce the bacterial load.
9. Once opened, the contents should be used up to the expiration date. Should it become cloudy or contaminated after opening, the contents should be discarded.
10. CE-Immundiagnostika GmbH cannot guarantee that human and animal raw materials are free from infectious agents, so the products should be used with caution.

DISPOSAL OF REAGENTS AND DEALING WITH SPILLAGES

For information on disposal of the reagent and decontamination of a spillage site, see the Material Safety Data Sheet, available on request from CE-Immundiagnostika GmbH.

CONTROLS AND ADVICE

1. Positive and negative control erythrocytes must be included with each experiment. If the controls do not show the expected results, the test batch should be discarded.
2. Since the test reagents do not contain any macromolecular enhancement media, it is very unlikely that false positive or false negative signals will occur, which are caused by IgG-laden cells.
3. 1 drop from the pipette vial corresponds to 35-45µl.
4. Only authorized specialists are allowed to read and evaluate the results.
5. The product may only be used as described here

REQUIRED MATERIAL AND REAGENTS

- 0.9% NaCl solution
- Glass test tubes
- Test tube holder
- Test tube centrifuge
- Positive and negative control erythrocytes
- Chronometer

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RECOMMENDED METHODS

A. METHOD: TUBE TEST

1. A 2-4% erythrocyte suspension is prepared in 0.9% NaCl solution
2. 1 drop of test reagent and 1 drop of erythrocyte suspension are placed in a labeled tube.
3. Mix well and incubate for 10 minutes at room temperature.
4. Centrifuge for 1 min. At 400g (1500 rpm, or at an alternative speed with an adapted time).
5. Read the result immediately: loosen the erythrocyte pellet from the bottom of the tube by gently shaking it and read the agglutination strength macroscopically and record it.

INTERPRETATION OF THE RESULTS

1. **Positive:** The agglutination of the erythrocytes indicates the presence of the H antigen on the erythrocytes. Please note the limits of the test method (see below).
2. **Negative:** no agglutination indicates the absence of the H antigen on the erythrocytes. Please note the limits of the test method (see below).

LIMITATIONS OF TEST METHODS

1. Blood that is not freshly drawn can lead to weaker results.
2. False positive or false negative results can be caused by:
   - Contamination of the material to be tested
   - Incorrect storage, incorrect erythrocyte concentration, incorrect incubation time, incorrect temperature
   - Incorrect centrifugation
   - Deviations from the recommended methods
3. **According to the Hemotherapy Guideline, Chapter 4.4.8, 2017, two different clones must always be used to determine blood group antigens.**

STABILITY OF RESULTS

1. Tube tests must be read immediately after centrifugation. Delays can lead to dissociation of the antigen-antibody complex.
2. If a temperature other than the recommended one has been selected, the results must be discarded

SPECIFIC PERFORMANCE CHARACTERISTICS

1. The test serum has been tested using the recommended method prior to release.
2. Each batch of Anti-H monoclonal is tested against a panel of antigen-positive erythrocytes prior to release to ensure good reactivity.
3. The specificity of Anti-H monoclonal is proven by means of a panel with antigen-negative erythrocytes.
4. Erythrocytes or whole blood washed twice in 0.9% saline solution are used in quality control.
5. 5.Tested on over 500 samples with sensitivity and specificity of > 98%

DISCLAIMER

1. The user is liable if methods other than those recommended are used.
2. Any deviations from the recommended test methods must be validated prior to use.

BIBLIOGRAPHY

1. Race RR, Sanger R. Blood Groups in Man, 6th Edition. Blackwell Scientific, Oxford 1975; Chapter 2
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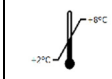
3. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6
4. Richtlinien zur Gewinnung von Blut und blutbestandteilen und zur Anwendung von Blutprodukten (Hämotherapie); Aufgestellt vom wissenschaftlichen Beirat der Bundesärztekammer und vom Paul-Ehrlich-Institut, Fassung 2017.
5. Immunhämatologie und Transfusionsmedizin, Reinhold Eckstein, 6. Auflage, Urban & Fischer bei Elsevier, 2010
6. Blutgruppen und Transfusion, M. Metaxas-Bühler, Verlag Hans Huber, 1994.

INDEX OF SYMBOLS

LOT	lot	IVD	In-vitro Diagnosticum
REF	Product code		Storage between +2°C bis +8°C
	Expiry date		manufacturer
	Instruction for use inside		

CATALOGUE NUMBER

REF	Quantity
31105 Anti-H (A_2) Clone 10934C11	1 x 5 ml 5 x 5 ml 10 x 5 ml 50 x 5 ml
31110 Anti-H (A_2) Clone 10934C11	1 x 10 ml 5 x 10 ml 10 x 10 ml 50 x 10 ml