EN

INSTRUCTIONS FOR USE

Anti-C^w (human)

CE

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

REF 6837 1 x 5 ml

FOR IN VITRO DIAGNOSTIC USE

1. Description of product

Anti-C^w is manufactured from human sera from immunized donors. The test reagent contains polyclonal IgG antibodies, 0.9% NaCl solution, bovine albumine and enhancer medium.
Anti-C^w aids for the detection of the corresponding antigen on red blood cells and is designed for use in tube and plate tests.
NaN_3 (< 0.1%) is added to the test reagent as a preservative.

2. Principle of the test

The tests used with this blood grouping reagent are based on the principle of hemagglutination. Incubation of test red cells with the test reagent will result in a specific antigen-antibody reaction if the corresponding antigen is present on the test red cells. Visible detection of this reaction is demonstrated by agglutination of the cells. No agglutination indicates a negative test result, and within the accepted limitations of the test procedure, indicates the absence of the corresponding antigen.

3. Storage and stability

Store the test reagent at 2...8°C. Do not freeze! After opening the bottle the test reagent can be used until the expiry date printed on the label, if appropriate storage conditions be observed. Do not use the reagent after the expiry date printed on the label.

4. Preparation of samples

Blood samples should be collected by approved medical procedure. Blood collected without or with anticoagulant (EDTA, citrate) is acceptable. Do not use haemolytic samples.
Testing should performed without delay if possible. If this is not possible, store blood samples at 2...8°C.
Prolonged or improper storage of red cells prior to testing may result in false positive or false negative reactions (s. 9. Important notes/Limitations of the method).

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com

5. Additional materials required

Isotonic NaCl solution (isotonic saline)
22% bovine albumine
AB Serum
Test plates for Blood Group Typing
Test tubes (75 x 12 mm)
Test tube rack
Single-use Pasteur pipettes
Centrifuge
Incubator / Water bath 37°C ± 1°C
Red blood cells of known phenotype

6. Test procedure

Plate test

1. Wash the red cells to be examined at least once with isotonic saline or use whole blood.
2. Place 1 drop of test reagent and 1 drop of whole blood or a 10% suspension of test red cells in AB serum on a labeled test plate and mix.
3. Incubate the covered test plate for 15 - 30 minutes at 37°C in an incubator.
4. By slowly rotation of the plate, examine macroscopically for agglutination.

Tube test

1. Wash the red cells to be examined at least once with isotonic saline and then make a red cell suspension of 2 – 3% in isotonic saline.
2. Mix 1 drop of test reagent and 1 drop of the red cell suspension in a labeled test tube.
3. Incubate at 37°C for 15 - 30 minutes.
4. Centrifuge 1 minute at 700 x g (2000 rpm) or of equivalent force.
5. Resuspend the cells by gently shaking the tube and examine macroscopically for agglutination.

Comments: Red blood cell suspensions known to be positive and negative for the C^w antigen and a patient control should always be included in the test.

Use at least two different test reagents to determine the antigen.

For titer determination it is recommended to suspend the red cells in 22% bovine albumine.

7. Interpretation of the results

Agglutination of test red cells with the test reagent indicates the presence of the corresponding antigen (within the accepted limitations of the test procedure).
No agglutination of test red cells with the test reagent indicates the absence of the corresponding antigen (within the accepted limitations of the test procedure).

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com

If no agglutination occurs with the test red cells known to be positive for the antigen or if agglutination occurs with the test red cells known to be negative for the antigen or with the patient control the test results should not be interpreted.

If different test results occur with two different test reagents, repeat the determination of the antigen with another test method and/or another test reagent (e.g. BAGene RH-TYPE).

Pay attention to the limitations of procedure and important directions (s. 9. Important notes/limitations of the method).

8. Stability of reactions

All test results should be interpreted immediately upon completion of the test.

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 strength of positive reactions depends on the age of the used blood.
3. Light cloudiness does not influence the reactivity of the product.
4. Use the test reagent without any supplements.
5. False positive results may occur because of bacterial or chemical contamination of the test reagent, the samples or the isotonic saline and/or because of incorrect centrifugation. Therefore a microbial or chemical contamination of the test reagent must be absolutely avoided because this shortens the shelf life of the product and can lead to false results.
6. If the plate test is read too late, the appearance caused by drying may simulate false positive results. Therefore the plate test results should be interpreted after 30 minutes at most.
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 red cells for too long and/or under inappropriate conditions. Reading the results of the test too late, agitating the red cell sediment too strongly, and other deviations from the indicated testing procedure can also lead to weaker or false negative results.
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 saline and/or contaminated materials and samples.
9. 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.
10. 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.
11. For interpretation of the test results, consider if transfusion or transplantation had happened. Take the case history of the transfusion or transplantation and also the patient's medication history into consideration.

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com

12. 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.

10. Warnings and instructions for disposal

Human source material used to produce this reagent has been tested and found negative for HBsAg and HIV and HCV antibodies. Bovine albumine is sourced from supervised BSE-free cattle herds. Nevertheless all used biological material should be handled as potentially infectious, because no test method can guarantee that material derived from biological sources are free from infectious agents. When handling biological material appropriate safety precautions are recommended (Do not pipette by mouth; wear disposable gloves while handling biological material and performing the test; disinfect hands when finished the test).
Biological material should be inactivated before disposal (e.g. in an autoclave). Disposables should be autoclaved or incinerated after use.

Spillage of potentially infectious materials should be removed immediately with absorbent paper tissue and the contaminated areas swabbed with a suitable standard disinfectant or 70% alcohol. Material used to clean spills, including gloves, should be inactivated before disposal (e.g. in an autoclave).

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 reagent 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

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com

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 | HUM	Origin: human
POLYCL	polyclonal
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

BAG Diagnostics GmbH
Amtsgerichtsstr. 1-5
35423 Lich/Germany
Tel.: +49 (0) 6404 / 925 - 100
Fax: +49 (0) 6404 / 925 - 460
www.bag-diagnostics.com
info@bag-diagnostics.com

Ordering:
Tel.: +49 (0) 6404 / 925 - 450
Fax: +49 (0) 6404 / 925 - 460
order@bag-diagnostics.com

Customer Service:
Tel.: +49 (0) 6404 / 925 - 125
Fax: +49 (0) 6404 / 925 - 421
service@bag-diagnostics.com