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. 002/11-2021

Description	REF
Bovine albumin 22 % 10 ml	39110
Bovine albumin 22 % 50 ml	39150

IN-VITRO-DIAGNOSTICUM

SUMMARY

Incomplete blood group antibodies predominantly belong to the IgG class. Their detection succeeds in the indirect Coombs test, especially after the addition of a supplement.

INTENDED USE

Bovine albumin 22% serves as a reaction enhancer for the detection of incomplete antibodies in the search, identification and cross-propene test and as an enhancer for weak antigen detection in the indirect Coomb test.
A specific antigen-antibody reaction leads to agglutination. The absence of agglutination suggests the lack of the corresponding antibody / antigen (see below Limits of the test methods).

PRODUCT INFORMATION

Bovine albumin 22% is produced from 30% bovine albumin and adjusted to the optimum reaction with NaCl.
Bovine serum albumin comes exclusively from cattle herds that are free from BSE (certified by the veterinary office).
Preservative: Na azide <0.1% final concentration
The LOT and expiration date are on the vial label.

Storage

When stored between +2°C and + 8°C, the test reagents can be used up to the expiry date stated on the label. After opening for the first time, the test reagents are tightly close again and store at +2°C to +8°C.

SPECIMEN COLLECTION AND PREPARATION

Blood samples should be collected in EDTA or citrate tubes according to standard medical procedures. The evaluation should be carried out as soon as possible after the blood sample has been drawn. If the blood is not to be used immediately, the tubes must be stored at +2°C to +8°C. Blood samples showing hemolysis or microbial contamination should not be used for the test. Such blood tests can give incorrect results.
For direct detection, all blood samples are washed three times in cold 0.9% NaCl solution before use.

WARNING AND PRECAUTIONS

1. The reagents are intended for in vitro diagnostic laboratory use only
2. The reagents may only be used by authorized and trained specialist personnel.
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 as a preservative.
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 REAGENT AND DEALING WITH SPILLAGE

For disposal of the test sera or decontamination in the event of spillage, please request the safety data sheet from CE-Immundiagnostika GmbH.

CONTROLS AND ADVICE

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

REQUIRED MATERIAL AND REAGENTS

- Cold, 0,9% NaCl solution
- 22% Bovines albumin (BSA) (optional)
- Coombs Control Erythrocytes
- Coombs reaktive Test reagent (optional)
- Glass test tubes
- Test tube holder
- Water bath
- Centrifuge
- Positive and negative Control erythrocytes or Control sera
- Chronometer

RECOMMENDED TECHNIQUES

A. METHODE: Indirect Coombs Test (ICT)

1. A 2-3% erythrocyte suspension is prepared in 0.9% NaCl solution or 22% bovine albumin.
2. 1 drop of the serum to be tested (if NaCl suspension: 1 drop of bovine albumin 22 %) is placed in a tube and mixed with 1 drop of the 2-3% erythrocyte suspension.
3. The batch is incubated at 37 ° C. for 15-60 minutes.
4. The erythrocytes are then washed 3 times with cold 0.9% NaCl solution and the last supernatant is carefully decanted.
5. Add 2 drops of AHG reagent to the washed erythrocytes and mix well.
6. The batch is centrifuged for 1 min at 400 g (1,500 rpm), or at an alternative speed with an adapted time.
7. The erythrocyte sediment is then checked for agglutination.
8. Record the result and reaction strength. Positive and negative controls are to be carried along.
9. Check all negative or weak positive tests by adding Coombs control cells.

INTERPRETATION OF TEST RESULTS

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

The agglutination in the antibody screening test shows one or more antibodies in the serum to be examined. Further examinations must follow to identify the antibody.

The agglutination in the cross match shows that an antigen-antibody reaction has taken place between the donor and recipient, i.e. there is an intolerance and the donor blood is not suitable for transfusion.

The agglutination during antigen detection shows that an antigen-antibody reaction has taken place between the reagent and erythrocytes, i.e. the antigen has been detected.

Limitations

1. Blood / serum that has not been freshly used 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. Patients with certain diseases can show false positive / negative reactions. Umbilical cord blood with Wharton's jelly can react with false positive results.
4. Erythrocytes showing a positive direct antiglobulin test cannot be typed using the indirect antiglobulin test.
5. Antibodies against Dia, Doa, Yta, Cob, Wra, Bga and Vw cannot be excluded in routine testing; the detection of these antigens depends on the test cells available.

STABILITY OF THE REACTIONS

1. Tube tests must be read immediately after centrifugation.
2. If a temperature other than the recommended one has been selected, the results must be discarded

SPECIFIC PERFORMANCE CHARACTERISTICS

The performance evaluation for AHG polyspecific is based on the Common Technical Specifications (CTS: Decision of the EU Commission of February 3, 2009).

1. AHG have been tested using all recommended methods prior to release.
2. The specificity of Coombs-reactive antibodies is proven by means of a panel of erythrocytes.
3. Erythrocytes washed three times in 0.9% saline solution are used in quality control.
4. 4.Tested on over 500 samples with sensitivity and specificity of > 99%

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. Brecher ME, ed. Technical manual, 14 th ed. Bethesda MD: American Association of Blood Banks, 2002.
2. Widman FK. Technical Manual, 9th Edition. American Association of Blood Banks, Arlington, VA, 1985; Chapter 8
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5. Issitt PD. Applied Blood Group Serology, 3rd Edition. Montgomery Scientific, Miami 1985; Chapter 6
6. Guidelines for the Blood Transfusion Service in the United Kingdom. H.M.S.O. Current Edition.
7. Richtlinie Hämotherapie, Gesamtnovelle 2017.

INDEX OF SYMBOLES

LOT	Lot number	IVD	For in-vitro diagnostic use only
REF	Catalogue number	2 °C 8 °C	Storage between +2°C to +8°C
	Expiry date		Manufacturer
	Consult instructions for use (insert)		

CATALOGUE NUMBER

REF	Menge
39110 Bovine albumin 22%	1 x 1 x 10 ml 5 x 1 x 10 ml 10 x 1 x 10 ml 50 x 1 x 10 ml
39150 Bovine albumin 22%	1 x 1 x 50 ml