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CE

Instruction for Use

Rev. 002 2021-12

Productname	Product-Code
Anti-C^w incomplete 2 ml	32302
Anti-C^w incomplete 5 ml	32305

IN-VITRO DIAGNOSTIC

SUMMARY

Anti-C^w ist part of the Rh System which contains more than 40 antigenes and complexes. The frequency of C^w varies between populations, it is very rare in people of African or Asian descent, in Caucasians, the overall frequency is 2.6%, but can be as high as 8% in some European populations. Cells positive for C^w are almost always C positive, but in rare cases C^w is accompanied bei c instead of C.
Anti-C^w has been implicated in transfusion reactions and in morbus haemolyticus neonatorum.

PRINCIPLE

Anti-C^w incomplete is based on the principle of hemagglutination. When used by recommended techniques, this reagent will cause agglutination of red cells carrying the C^w antigen (positive test result). Absence of agglutination indicates a negative test result and, within the accepted limitations of the test procedure, indicates the absence of the C^w antigen on the test red cells.

PRODUCTINFORMATION

Polyclonal test reagents are derived from a pool of human sersa containing the appropriate antibody. Raw material is tested of HBsAg, HCV and HIV. Only negative tested products are used for manufacturig of antisera. The Bovine Albumin Solution is sourced from donor animals of United states origin that have been inspected and certified by US Veterinary Service inspectors to be disease free (low Transmissible Spongiform Encephalopathy risk)
Preservative: Sodium acide <0,1% final concentration.
LOT and expiry date you will find on the vial label.

STORAGE

Reagent vials should be stored at 2°C-8°C when not in use.

SAMPLE COLLECTION

Blood should be taken aseptically in EDTA or citrate tubes. The evaluation should be carried out as soon as possible after the blood collection. If the blood IS not used immediately, the tubes must be stored at 2°C - 8°C. Blood samples with hemolysis or microbial contamination must not be used for the test. Such blood samples can lead to incorrect results.
All blood samples are washed twice in 0.9% saline for the tube, microtiter plate and card tile test before use.

PRECAUTIONS

1. This reagent is intended for in vitro diagnostic use only.
2. Do not use the reagent past the expiration date (See vial label)
3. Do not use the reagent if a precipitate is present.
4. Protective clothing should be worn when handling the reagent, such as disposable gloves and a laboratory coat.
5. This reagent is only to be used by properly trained and qualified personnel.
6. The reagent is not intended for self-use.
7. If a vial is cracked or leaking, discard content immediately.
8. No henolytic samples may be used.
9. The reagent has been filtered through a 0.2 µm mambrane to reduce bio-burden.
10. Once a vial has been opened the content should remain viable up until the expiry dateas long as there is no marked turbidity, which can indicate reagent deterioration or contamination.
11. CE-Immundiagnostika GmbH cannot guarantee that human and animal raw materials are free of infectious agents, so the products should be used with caution.

DISPOSAL OF REAGENT AND DEALING WITH SPILLAGES

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

CONTROLS AND ADVICE

1. Positive and negative control erythrocytes shall be carried with each experiment. If the controls do not show the expected results, the experimental approach shall be rejected.
2. 1 drop from the pipette vial is equivalent to 35-45 ul.
3. Only authorized personnel may read and evaluate the results.
4. Test reagents may only be used as described herein.

REAGENTS AND MATERIALS REQUIRED

- 0.9% saline
- Glass tubes
- Glass stick
- Tube rack
- Card tiles
- Microtiter plate
- Centrifuge
- Water bath
- Positive and negative control erythrocytes
- 22% bovine albumin (RA)
- Timer

RECOMMENDED TECHNIQUES

A. METHOD: TUBETEST

1. A 2-3% erythrocyte suspension is produced in 0.9% saline. In the case of a weak result, the test is repeated with a suspension in 22% bovine albumin.
2. 1 drop of antiserum and 1 drop of erythrocyte suspension are placed in an labeled tube.
3. Mix well and incubate for 30 min. at 37°C.
4. Centrifugation for 2 min. at 700g (2000 rpm), or at alternative speed with adjusted time.
5. Read the result immediately: gently resuspend the erythrocyte button by carefully shaking from the bottom of the tube and read the gglutination strength macroscopically.
6. positive and negative controls are to be tested.
7. Should the result be weak, the test has to be repeated with a 22% bovine albumin suspension.

B. METHOD: MIKROTITERPLATE TEST

Pre-treatment of microtiter plates (MTP):

MTP from different manufacturers/suppliers show different static properties, which can result in non-specific reactions of red blood cells and proteins. It is recommended to pre-treat unused MTP before use to minimize the adhesion of red blood cells. MTP with plastic U-profile is recommended.

1. In each MTP well, add 1 drop of 22% bovine albumin
2. Move gently or shake on an MTP shaker so that the wells are evenly coated.
3. Leave the MTP at least 10- max. 15 min. at room temperature (18-25°C).

4. Drain the bovine albumin and place the contents of the MTP wells in a suitable waste container.
5. Rinse the MTP at least 10 times with tap water.
6. Then rinse the MTP twice with distilled or deionized water.
7. Tilt and drain the MTP to remove excess water.
8. Allow the MTP to dry before use.

Alternative methods are possible if they have been validated by the user.

Performance of the test:

1. Make a 2 - 3% erythrocyte suspension in 0.9% saline.
2. Add 1 drop of the corresponding anti-serum into the marked MTP wells.
3. Add a drop of prepared erythrocyte suspension to the MTP.
4. Mix MTP manually or on a shaker for 30 seconds.
5. Centrifuge MTP 1 min. at 700g (2000 rpm) or at alternative speed with adjusted time.
6. Shake MTP carefully for a short time, if necessary with shaker.
7. record the result and reaction strength, positive and negative controls must be carried out. When using readers, they must be validated. The use of additional visual aids such as test reading mirrors or magnifying glasses can facilitate reading.

C. METHOD: CARD TILE TEST

1. For card tile test a 10% erythrocytesuspension in 0.9% saline is produced.
2. Add 1 drop testreagent + 1 drop erythrocytesuspension on the card tile.
3. Mix both drops carefully with a glass stick.
4. Incubate 15-30 min. at 37°C. The plate has to be covered to avoid drying.
5. Read the result macroscopically.
6. Use positive and negative control red cells.
7. In case of improper treatment or too long incubation period, drying artifacts may occur.

INTERPRETATION OF TEST RESULTS

1. Positive: The agglutination of the erythrocytes indicates the presence of the C^w antigen on the erythrocytes. Please observe the limits of the test method (see below).
2. Negative: no agglutination indicates the absence of the C^w antigen on the erythrocytes. Please observe the limits of the test method (see below).

LIMITATIONS

1. blood should be not older than 4 days, otherwise it may 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 techniques
   - Hemolytic or contaminated samples are not to be used.

STABILITY OF THE REACTIONS

1. Tubetests must be read immediately after centrifugation.
2. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

SPECIFIC PERFORMANCE CHARAKTERISTICS

1. The antisera have been tested with all recommended methods before release.
2. Each batch of anti-cw incomplete is tested against a panel with antigen-positive erythrocytes before release to ensure good reactivity.
3. The specificity of the antibodies is proven by a test panel with antigen-negative erythrocytes.
4. In quality control, erythrocytes washed twice in 0.9% saline are used.
5. Tested on over 500 samples with sensitivity and specificity of > 99%

DISCLAIMER

1. The user is responsible for the performance of the reagent by any method other than those mentioned in the Recommended Techniques.
2. Any deviations from the method recommended should be validated prior to use.

BIBLIOGRAPHY

1. Brecher M.E.(2002), ed. Technical manual. 14th ed. Bethesda MD: American association of blodd Banks.
2. Issit P.D. and Antsee D.J. (1998), Applied Blood Group serology, 4th. Edition, Montgomery Scientific Publications, Chapter 12.
3. Daniels G. (1995), Human Blood Groups, Blackwell Science Ltd., Chapter 5

TABLE OF SYMBOLS

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

CATALOGUE NUMBERS

REF	Articel	Amount
32302	Anti-Cw incomplete	1 x 1 x 2 ml 5 x 1 x 2ml 10 x 1 x 2 ml 50 x 1 x 2 ml
32305	Anti-Cw incomplete	1 x 1 x 5 ml 5 x 1 x 5 ml 10 x 1 x 5 ml 50 x 1 x 5 ml