ARENA BioScien

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Anti-CDE Monoclonal (IgG & IgM)

Diagnostic reagent for the in-vitro qualitative detection of Blood groups antigenic determinant CDE in Human red cells manually.

REF: BS.1/RS01.005.0100	100 tests for Anti-CDE	REF: BS.1/RS01.010.0200	200 tests for Anti-CDE

CLINICAL SIGNIFICANCE

Levine and Stetson discovered the Rh blood group system in 1940. The Rh blood group system consists of forty-five antigens, which are expressed on human red blood cells. Besides the Rho (D) antigen other important antigens of Rh system are C (rh'), E (rh"), c (hr'), e (hr").
Antigen D is by far the most immunogenic of the Rh antigens. All the antibodies against all Rh antigens should be considered to have the potential to cause hemolytic transfusion reactions (HTRs) and hemolytic disease of the newborn (HDN).

Frequency of each antigen in Caucasian population				
D	C	E	c	e
85	70	30	80	98

METHOD PRINCIPLE

The reagents will cause direct agglutination of red cells that carry the C and/or D and/or E antigen. No agglutination generally indicates the absence of the corresponding Rh antigen. All negative test results should be further tested for D^u (weak/partial D´s) by performing the Du test procedure, as described later.

REAGENT COMPOSITION

Reagents:	Composition
Anti-CDE Monoclonal	Monoclonal blend of IgG / IgM and antibodies diluted in: - bovine albumin (6 g%). - sodium azide (<0.1%). - sodium chloride (0.9 g%). - macromolecular potentiators.

PRECAUTIONS AND WARNINGS

Reagent to be handled by entitled and professionally educated person. Do not ingest or inhale as reagents contains sodium azide which is classified as dangerous substance for environment.

Good Laboratories practices using appropriate precautions should be followed in:

- Wearing personnel protective equipment (overall, gloves, glasses,).
- Do not pipette by mouth.
- In case of contact with eyes or skin; rinse immediately with plenty of soap and water. In case of severe injuries; seek medical advice immediately.
- Respect country requirement for waste disposal.
  S56: dispose of this material and its container at hazardous or special waste collection point.
  S57: use appropriate container to avoid environmental contamination.
  S61: avoid release in environment.

For further information, refer to the Blood Group reagent material safety data sheet.

REAGENT PREPARATION, STORAGE AND STABILITY

BioScien Anti-CDE reagent is ready-to-use and is stable until expiration date stated on label when properly stored in an upright position and refrigerated at 2-8°C (do not freeze).

Deterioration

The ***BioScien*** Anti-CDE reagent can be damaged due to microbial contamination or on exposure to extreme temperatures which is indicated by reagents turbidity. It is recommended that such reagent should be discarded.

SPECIMEN COLLECTION AND PRESERVATION

Clean and dry glassware free from detergents must be used for sample collection, blood samples drawn with anticoagulant are used. Samples should be stored at 2-8 °C if not tested immediately. Do not use hemolyzed samples.
Anticoagulated blood using various anticoagulants should be tested within the below mentioned time period:

- EDTA or heparin : 2 days
- Sodium citrate or Sodium oxalate : 14 days
- ACD or CPD : 28 days

EQUIPMENT REQUIRED NOT PROVIDED

- Sterile Syringe
- Analytical tubes (12x75 mm)
- Glass slides (50x75 mm)
- Centrifuge
- Stop watch
- Mixing sticks
- Pipettes (drop volume 40 to 50 µl)
- Isotonic saline solution
- Anti-Human Globulin reagent

ASSAY PROCEDURE

Allow the reagents and samples to reach room temperature.

Slide Test

1. Place in a labelled clean glass slide one volume (one drop) of ***BioScien*** Anti-CDE reagent on specific place.
2. Add one volume (one drop approximately 50 µl) of whole blood.
3. Mix reagent and cells over an area of about 20x40mm. with separate mixing sticks.
4. Rotate the slide gently back and forth, for 1 minute and observe for agglutination macroscopically.
5. Any weak reactions should be repeated by the tube technique.

Tube Test

1. Prepare a 5% suspension of red cells to be tested in isotonic saline or buffered isotonic saline.
2. Place one drop of Anti-CDE reagent into labelled test tubes.
3. Add one drop of the 5% cell suspension and mix well.
4. Centrifuge for 1 minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
5. Gently resuspend the cell button, observing and read macroscopically for agglutination

Du Test Procedure

1. Prepare a 5% suspension of the red cells to be tested in isotonic saline.
2. Place one drop of ***BioScien*** Anti-D reagent into labelled test tube.
3. Add to the test tube, one drop of the red cell suspension, mix well, and incubate at 37 ºC for 15 minutes.
4. Wash the contents of the tube at least three times, with isotonic saline and decant completely after the last wash.
5. Add 2 drops of Anti Human Globulin reagent and mix well.
6. Centrifuge for one minute at 1000 rpm (125 g) or 20 seconds at 3400 rpm (1000 g).
7. Resuspend the cell button gently and observe for agglutination macroscopically.

STABILITY OF THE REACTIONS

1. Read all tube and slide tests straight after centrifugation.
2. Complete washing steps without interruption and centrifuge and read tests immediately after reagent addition because delays may result in dissociation of antigen-antibody complexes, leading to false negative or weak positive reactions.
3. Slide tests should be interpreted within two minutes to ensure specificity and to avoid the possibility a negative result may be incorrectly interpreted as positive due to drying of the reagent.
4. Caution should be exercised in the interpretation of results of tests performed at temperatures other than those recommended.

READING AND INTERPRETATION

	Slide and Tube Technique
Positive	Agglutination as indication for the presence of C and / or D and / or E antigen.
Negative	No agglutination as indication for the absence of corresponding antigen.

QUALITY CONTROL

The reactivity of all Anti-CDE reagents should be confirmed by testing with known positive and negative red blood cells to monitor the performance of the reagent. Good physiological saline may be used as a negative control, if the expected results have not been observed, the reagent should not be used. For more information, please contact ***BioScien*** technical support.

LIMITATIONS OF PROCEDURE

Some conditions that may cause false positive results are:

- Contamination of sample or reagents
- Autoantibodies
- Improper storage or preparation of red blood cells
- Antibodies to antibiotics or other reagents
- Cold Antibodies

REFERENCES

1. Kohler C. & Milstein C. (1975), Continuous cultures of fused cells secreting antibody of predefined specificity, Nature, 256, 495-497.
2. Lee H.H., Rouger P, Germain C., Muller A. & Salmon C. (1983), The production and standardisation of monoclonal antibodies as AB blood group typing reagents. Symposium of International Association of Biological Standardisation on Monoclonal antibodies.
3. Human Blood Groups by Geoff Daniels, 1st Ed., Blackwell Science, Oxford 1995.
4. HMSO, Guidelines for the Blood Transfusion Services, 2nd Ed., 1994.
5. AABB Technical manual, 13th Ed., 1999.

SYMBOLS IN PRODUCT LABELLING	
IVD For in-vitro diagnostic use	Number of <n> test in the pack
LOT Batch Code/Lot number	Caution
REF Catalogue Number	Do not use if package is damaged
Temperature Limitation	Consult Instruction for use
Expiration Date	
Manufactured by	