

Medcaptain Blood Grouping Gel Systems

Red blood cells for reverse grouping

REF No: RCRBC2

CE 1434

IVD

INTENDED USE

Test cells are used for detection of naturally occurring ABO antibodies in the serum of donors and recipients.

INTRODUCTION

The regular presence of anti-A and anti-B is made use of in the routine determination of ABO blood groups; in addition to testing red cells for A1, A2, B, and O antigens, the group is checked, in serum or reverse grouping, by testing the serum against red cells of known ABO groups.

REAGENT

All test cell reagents are of human origin, in a buffered suspension medium at 0,8 %. Contains Gentamicin as preservative.

RBC2 Cell Reverse A1, B ; 2 x 10 ml

MATERIAL REQUIRED BUT NOT PROVIDED

- Dispenser
- 10 µl, 50 µl ml automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- LISS Diluent
- Appropriate gel cards and reagents
- Centrifuge for Blood Grouping Gel System.
- Medcaptain Automated Gel Systems.

STORAGE CONDITIONS AND STABILITY

The reagent should be stored at 2°C - 8°C.

The reagent is stable until the expiry date stated on the product label.

Once opened the shelf life of the reagent vial is as described on the reagent vial label if stored 2-8°C

After usage immediately replace the reagent vial back to 2-8°C.

The antigenicity of the cells may decrease during the shelf life due to the physiological ageing process.

PRECAUTIONS AND WARNINGS

- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material are tested free from HBsAg, Anti-HCV and Anti-HIV. However, all materials of human origin should be considered as potentially infectious and it is recommended that all kit materials and test specimens to be handled using established good laboratory practice.
- All kit components and specimens should be regarded as potential hazards to health. It should be used and discarded according to your own laboratory's safety procedures.

SAMPLE COLLECTION

Fresh red blood cells are preferred for testing . Use the red blood cells collected with anticoagulants for determination of the antigens of the ABO/Rh system . If necessary, samples stored at 2-8 °C can be used up to 48 hours . Red blood cells collected in ACD, CPD can also be used until the expiry date indicated on the label of the bag at 2-8 °C.

Serum samples must be cleared . Fibrin residues may interfere with the reaction pattern.

TEST PROCEDURE

- All test cell reagents are for use with the REDCELL Blood Grouping Gel System .
- Follow the test procedures as described in the specific package inserts to be used.
- Bring the test cells to reach room temperature (18-25 °C) before use
- Mix gently the bottles of red cells by inverting a few times before use.
- During operation, check that the test cell reagents remain in suspension. If there is settling of the cells, resuspend again.
- Avoid contamination of the test cell reagents.
- After use, close the bottles and replace them in the refrigerator.

Products:

Cell Reverse A1, B Set of 2 vials 2 x 10 ml
REF:RCRBC2

INTERPRETATION OF THE RESULTS

- Agglutination indicate the presence of the antibodies.
- No agglutination indicate the absence of antibodies.

| A1 | A2 | B | O | Antibody | Blood group |
|-----|-----|-----|-----|-------------------|-------------|
| Neg | Neg | Pos | Neg | Anti-B | A |
| Pos | Pos | Neg | Neg | Anti-A | B |
| Neg | Neg | Neg | Neg | None | AB |
| Pos | Pos | Pos | Neg | Anti-A and Anti-B | O |








LIMITATIONS

- The gel cards which show air bubbles in the gel or drops in the upper part of the microtubes and/or the seal, must be centrifuged before use
- Bacterial or other contamination of materials used can cause false positive or false negative results
- Hemolysed samples may interfere the final interpretation of results.

PERFORMANCE CHARACTERISTICS

Red blood cells for reverse grouping were evaluated with 240 samples (from donors, patients). The evaluation demonstrated 100% specificity and sensitivity of the reagent versus the expected results with known ABO serums.

Label symbols

| | |
|---|------------------------------------|
|  | Batch code |
|  | Expiry date |
|  | Storage temperature |
|  | Consult instructions for use |
|  | In vitro diagnostic medical device |
|  | Product code |
|  | Manufacturer |

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Manufacturer:

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