

Medcaptain Blood Grouping Gel Systems

Red blood cells for antibody screening and identification

REF No: RCRBCAS3, RCRBCAS11, RCRBCAS3P, RCRBCAS11P



INTENDED USE

These test cells are used for antibody screening and identification.

INTRODUCTION

Patient and donor serum is screened for atypical antibodies using cells are prepared in advance. They are group O cells that have been tested for the presence of the most commonly encountered antigens. The reliability of antibody detection is largely dependent on the availability of test cells with appropriate antigens and on the sensitivity of the test methods used.

REAGENT

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

RCRBCAS3	Cell Screen 1-2-3	(3 x 5 ml)	
RCRBCAS11	Cell ID 11	(11 x 3 ml)	Identification Panel 11 test cells
RCRBCAS3P	Cell Screen 1-2-3 Pap	(3 x 5 ml)	
RCRBCAS11P	Cell ID 11 Pap	(11 x 3 ml)	Identification Panel 11 test cells

NOT: The antigenic table of each lot may be different, please note the antigenic table inside the box.

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 for antibody detection
- 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, SAGM and PAGGSM 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.

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








Diagnostic sensitivity and specificity :

There is no described procedure or technique capable of detecting all the possible unexpected antibodies present in a sample. We conducted our own performance study. Coombs, saline and enzymatic technique have been studied in 40 samples and obtained comparable results with other established products of equivalent intended use.

BIBLIOGRAPHY

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- 5-Neil D. Avent and Marion E. Reid , The Rh blood group system: Blood 2000 95: 375-387
- 6- Christopher D. Hillyer ... BLOOD BANKING AND TRANSFUSION MEDICINE, Second Edition, Churchill Livingstone 2007
- 7-Lapierre Y., Rigal D., Adam J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109 –113.
- 8- Immunohematology for Medical Laboratory Technicians Sheryl A. Whitlock 2010 Delmar, Cengage Learning

Labels:

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

Products:

Cell Screen 1-2-3	Set of 3 vials	3 x 5 ml	REF: RCRBCAS3
Cell ID 11	Set of 11 vials	11 x 3 ml	REF: RCRBCAS11
Cell Screen 1-2-3 Pap	Set of 3 vials	3 x 5 ml	REF: RCRBCAS3P
Cell ID 11 Pap	Set of 11 vials	11 x 3 ml	REF: RCRBCAS11P



Manufacturer:

RED CELL BIOTECHNOLOGY A.S
Tel : 0090 216 4994927

Ferhatpaşa Mahallesi 91.Sokak No:12-14 B Blok Ataşehir/İstanbul/TURKEY www.redcell.com.tr Email :info@redcell.com.tr

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