Medcaptain Blood Grouping Gel Systems

Forward / Reverse Donor

REF No: MCFRD CE 1434 IVD

INTENDED USE

This test allows the detection of ABO, RhD ,Rh Dvı , K and reverse grouping in gel technique.

INTRODUCTION

Classification of blood groups should be based on both forward and reverse grouping. The ABO blood group system is determined directly by testing the red blood cells with Anti-A and Anti-B reagents. Confirmation of the test results is provided by testing the serum with known group A1 and group B red blood cells. Forward / Reverse K test allows the detection of ABO, Rh D, Rh D ^{VI} and reverse grouping.

PRINCIPLE OF TEST

Forward / Reverse Donor test allows the detection of forward and reverse ABO, Rh D, RhD^{VI} and K antigen grouping simultaneously on a single gel card. The microtubes contain gel matrix. First five microtubes contain monoclonal antibodies and last three microtubes don't contain antibody in the gel.

The Anti-A, Anti-B, Anti-D and control microtubes are used for ABO and RhD antigen forward grouping. The microtubes without antibodies are used for reverse grouping. The red blood cells will agglutinate in the presence of antibody directed towards the antigen. Agglutinated cells forming a red button on the surface of the gel or agglutinates dispersed in the gel is a positive result and indicates the presence of the corresponding antibody.

KIT CONTENTS

48 Forward/Reverse Donor gel cards.

1 gel card contains 8x1 microtubes

A	B	AB	DVI+	K	Ctl	$A1_{Cell}$	B_{Cell}

Ready to use. Contains Sodium azide < 0,1% as preservative.

Each microtube of the card contains buffered gel medium with preservative and mixed different reagent.

- microtube A : monoclonal anti-A IgM (clone A-11H5)
- microtube B : monoclonal anti-B IgM (clone B-6F9)
- microtube AB : monoclonal anti-AB (clones LA2/ LB2/ ES15)
- microtube DVI+ : monoclonal anti-D IgM (clones LDM1 / ESD1M)

This anti-D monoclonal reagent detects weak D and partial variants of the D antigen, including the DVI variant. The ESD1M antibody will directly detect Rh DVI red cells

- microtube K: Monoclonal anti-K
- microtube Ctl.: buffered solution without antibodies (control microtube)
- microtube A1 cell: buffered solution without antibodies (reverse ABO group test)
- microtube B cell: buffered solution without antibodies (reverse ABO group test)

MATERIAL REQUIRED BUT NOT PROVIDED

- 10 µl, 50 µl and 1 ml automatic pipettes.
- Disposable pipette tips.
- Test tubes.
- LISS Diluent
- Centrifuge for Blood Grouping Gel System.
- Red blood cells for reverse group test (A1/B).

STORAGE CONDITIONS AND STABILITY

- Store the gel cards at 2-24 °C in upright position.
- Do not use reagents over the expiration date.
- **All the components of the kit are stable until the expiration date on the label when stored 2-24 °C.**
- **Do not remove foil seal until ready to use. Once opened, the gel may begin to dry out which could affect test results.**
- **Use the card within 2 hours after removing the aluminum foil. Otherwise, don't use the card.**

PRECAUTIONS AND WARNINGS

- This reagent kit is for in vitro diagnosis only.
- This reagent kit is for professional use only.
- All human sourced material (monoclonal antibodies) 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 (EDTA, Citrate) for determination of the antigens. If necessary, samples stored at 2-8 °C can be used up to 48 hours.

Red blood cells collected in ACD, CPD, CPDA can also be used until the expiry date indicated on the label of the bag at 2-8 °C (9).

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

PREPARATION OF BLOOD SAMPLE

1 % red blood cell suspension:

1- Bring LISS Diluent to reach room temperature before use
2- Dispense 1 mL of LISS Diluent into a clean tube.
3- Add 20 µL of whole blood or 10 µL of packed cells to the diluent and mix gently.

TEST PROCEDURE

If the gel cards are centrifuged before use the accuracy of the results will increase.

Allow the test card and cell reagent to reach room temperature before use.

1- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.

2-Pipette 50 µL of the patient's red blood cell suspension to the microtubes 1– 6 (A, B,AB, D^{VI} +,K ,Ctl).

3- Pipette 50 µl of 1% A1 cell suspension to the microtube 7 (A1 cell).

4- Pipette 50 µl of 1% B cell suspension to the microtube 8 (B cell).

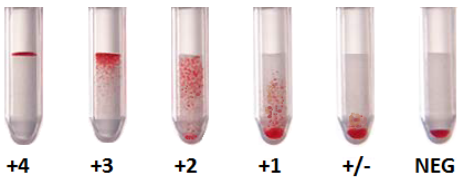
5- Pipette 50 µL of the patient serum to both microtubes 7 and 8.

6-Allow the cards to incubate for 10 minutes at room temperature (18– 25 °C).

7- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.

8- Read the results

Negative	*Band of red blood cells at the bottom of the column and no visible agglutinations in the rest of the column.*
+/-	*Scarce small-sized agglutinations in the lower half of the column*
+1	*Most agglutinated red blood cells remain in the lower half of the column. A button of cells may also be visible at the bottom of the gel column*
+2	*Agglutinated red blood cells are observed throughout the length of the column. A small Agglutinated red blood cells are observed throughout the length of the column.*
+3	*Most agglutinated red blood cells remain in the upper half of the gel column*
+4	*Agglutinated red blood cells form a band at the top of the gel column*



Stability of the results:

it is recommended an immediate reading of the results after centrifuging the cards. Do not leave processed cards in horizontal position.If necessary, a delayed reading can be made up until 24 hours after processing the cards if kept in vertical position, refrigerated (2-8°C) and sealed with parafilm or similar material to avoid evaporation of the supernatant.

Interpretation of the results:

ABO system

Anti A	Anti B	Anti AB	Ctl
Negative	Negative	Negative	Negative
+1 to +4	Negative	+1 to +4	Negative
Negative	+1 to +4	+1 to +4	Negative
+1 to +4	+1 to +4	+1 to +4	Negative

The microtube Ctl must be negative. If it is positive, invalidate the test.
The reactions between +/- and +3 may indicate A or B subgroups and further investigations should be performed

Rh System

D^{VI} +	K	
+1 to +4	+1 to +4	**RhD Positive**
Negative	Negative or Positive	**RhD Negative**

The reactions weaker than +2 should be subject to further investigations to distinguish between weak and partial D types as appropriate for the category of sample being tested.

Reverse Group

A1 cell	B cell	ABO Group
+1 to +4	+1 to +4	**0**
Negative	+1 to +4	**A**
+1 to +4	Negative	**B**
Negative	Negative	**AB**

If questionable reactions are obtained, repeat reverse grouping with 4 red cell reagents (A1, A2, B and O).

LIMITATIONS

- The Aluminum foil on the matrix gel card should be removed carefully and gently.
- Do not use matrix gel cards, which show signs of drying.
- 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
- Do not touch the pipet tip inside the gel card. Carryover problem may occur.
- Do not use hemolyzed, cloudy or contaminated samples or with clot presence
- Use of suspension solutions other than REDCELL LISS Diluent may modify the reactions.
- Red blood cells from individuals with A or B variants may present a weak expression of the antigens.
- Abnormal concentrations of serum proteins, the presence of macromolecular solutions in the serum may cause the non-specific agglutination of the red blood cells. It is recommended to wash the red blood cells before performing the test.
- Transfused patients or those subjected to bone marrow transplant may present images of double population.
- Patients with high-potency cold antibodies may coat the red blood cells completely so spontaneous agglutination may occur.

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity and specificity of

ABO/Rh system :

The diagnostic sensitivity and specificity of the antibodies present in Forward/Reverse Donor for the determination of the antigens of the ABO and Rh systems have been studied in a representative number of positive and negative samples. In the study using 3070 blood samples the sensitivity and specificity of REDCELL Blood Grouping Gel System was as follows.

Blood Group	A	B	AB	O	TOTAL
REDCELL Gel Blood grouping	1350	420	262	1038	3070
Reference Test	1350	420	262	1038	3070

	Rh (+)	Rh (-)	TOTAL
REDCELL Gel Blood grouping	2678	392	3070
Reference Test	2678	392	3070

	Number of samples	Sensitivity	Specificity
A	3070	% 100	% 100
B	3070	% 100	% 100
D (Rh)	3070	% 100	% 100

Reverse ABO group

We conducted our own performance study in 240 different samples and obtained same results with other established products of equivalent intended use. Forward/Reverse Donor test performance characteristics suitable for the determination of the reverse group.

Precision:

Inter-assay and intra-assay reproducibility tests; no false positive or false negative results were obtained. Variability between agglutination views in positive samples were 1 agglutination rating or less in all assays.

Label symbols

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

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Products : Forward/Reverse Donor

4x12 gel cards REF: MCFRD

Manufacturer:

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