# Medcaptain Blood Grouping Gel Systems

## Forward ABO Patient

REF No: MCFP CE1434 IVD

**INTENDED USE**
This test allows the detection of ABO and Rh D grouping in gel technique.

**INTRODUCTION**
The ABO system is defined by the presence or absence of the A and/or B antigens in the red blood cells. The ABO blood group system is determined directly by testing the red blood cells with Anti-A and Anti-B reagents.
The determination of Rh D is defined by the presence or absence of the D antigen in the red blood cells.
Forward ABO patient allows the detection of ABO and Rh D. This gel card is used for 2 persons.

**PRINCIPLE OF TEST**
Forward ABO patient test allows the detection of ABO, Rh D antigen grouping simultaneously on a single gel card. The microtubes contain gel matrix six microtubes contain monoclonal antibodies and two microtubes (Ctl ) don't contain antibody in the gel. Ctl microtubes are used for control of the test.
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 ABO patient gel cards. 1 gel card contains 8x1 microtubes**

| A | B | D | Ctl | A | B | D | Ctl |
|---|---|---|---|---|---|---|---|

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 D : mixture of IgG and IgM antibodies (clone BS 225, LDM3, ESD1 )
This anti-D monoclonal reagent detects weak D and partial variants of the D antigen.But $D^{VI}$ variant of the D antigen will not be detected directly with this monoclonal reagent.This reagent will detect $D^{VI}$ by IAT method.
- microtube Ctl : buffered solution without antibodies (control microtube)

**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.

**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 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, CPDA can also be used until the expiry date indicated on the label of the bag at 2-8 °C ( 9 ).
Fibrin residues may interfere with the reaction pattern.

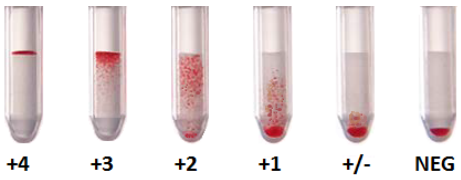
**PREPARATION OF BLOOD SAMPLE**

**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 1 % of the patient's red cell suspension to the microtubes 1-4 or 5-8 (A, B, D ,Ctl ).
**3**- Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
**4**- 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 | Ctl | ABO Group |
|---|---|---|---|
| Negative | Negative | Negative | **0** |
| +1 to +4 | Negative | Negative | **A** |
| Negative | +1 to +4 | Negative | **B** |
| +1 to +4 | +1 to +4 | Negative | **AB** |

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 | |
|---|---|
| +1 to +4 | **RhD Positive** |
| Negative | **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.

**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 ABO patient 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 |

**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 ABO patient
4x12 gel cards REF: MCFP


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