Medcaptain Blood Grouping Gel Systems

A1 Gel

REF No: MCA1 CE 1434 IVD

INTENDED USE
This test allows the detection of A1 antigen in gel technique.

INTRODUCTION
The two main subgroups of A are A1 and A2 . The serologic distinction between A1 and A2 is based on results obtained in tests with reagent anti-A1, the lectin of Dolichos biflorus seeds.
Anti-A1 reagents agglutinate A1 but not A2 red cells.

PRINCIPLE OF TEST
A1 Gel test allows the detection of A1 on a gel card. The microtubes contain gel matrix. Each microtubes contain Anti –A1 lectin in the gel.
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 A1 gel cards. 1 gel card contains 8x1 microtubes

A1	**A1**	**A1**	**A1**	**A1**	**A1**	**A1**	**A1**

Ready to use. Contains Sodium azide as preservative.
Each microtube of the card contains buffered gel medium with preservative and mixed different reagent.
- microtubes A1: Anti-A1 Lectin

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 freeze.
- Avoid exposure of the cards to any heat source, direct air-conditioning sources or direct sunlight.
- 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.
- Stability of the opened gel card is 2 hours.

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.

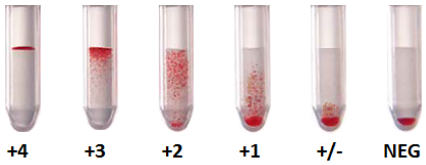
SAMPLE COLLECTION
Fresh red blood cells are preferred for testing . Use the red blood cells collected with anticoagulants for determination of the antigens of the ABO/Rh system . If necessary, samples stored at 2-8 °C can be used up to 48 hours . Red blood cells collected in ACD, CPD, SAGM and PAGGSM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

PREPARATION OF BLOOD SAMPLE
1 % red blood cell suspension :
Do not use haemolysed, cloudy or contaminated samples or those containing clots

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
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 aluminum foil carefully.
2-Pipette 50 µL 1% patient's red cell suspension to the microtubes.
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:

Reactions for A subgroups antigens

	Anti A	**Anti AB**	**Anti A1**
A_1	+4	+4	+2 to +4
A_2	+3 to +4	+4	Neg. to +1
A_3	+1 to +3	+2 to +4	Neg.
A_x	Neg. to +1	+1 to +3	Neg.
A_1B	+4	+4	+2 to +4
A_2B	+3 to +4	+4	Neg. to +1
A_3B	+2 to +4	+4	Neg.
A_xB	Neg. to +1	+4	Neg.

indicated on the label of the bag at 2-8 °C.

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 A1 Gel:

The diagnostic sensitivity and specificity of the antibodies present in A1 test for the determination of the antigens of the A1 have been studied in a representative number of positive and negative samples. In the study using 353 blood samples the sensitivity and specificity of REDCELL Blood Grouping Gel System was as follows.

	Number of samples	Sensitivity	Specificity
Anti-A1	353	% 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

LOT	Batch code
	Expiry date
24°C 2°C	Storage temperature
	Consult instructions for use
IVD	In vitro diagnostic medical device
REF	Product code
	Manufacturer

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Products: A1 Gel

4x12 REF : MCA1

Manufacturer:

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