Medcaptain Blood Grouping Gel Systems

Neutral Gel

REF No: MCNEU CE1434 IVD

INTENDED USE
This test allows the detection of reverse grouping, antibody screening and identification, compatibility tests in gel technique.

INTRODUCTION
Antibody screening is the most reliable and sensitive method of detecting a clinically significant antibody. When an antibody has been detected in the screening test, the specificity should be determined by testing the patient's serum/plasma against a panel of reagent red cells of known phenotypes. Enzyme and saline techniques are used for antibody screening and identification.

PRINCIPLE OF TEST
Neutral Gel allows the detection of reverse grouping, antibody screening and identification, compatibility tests. The test contains 8 microtubes neutral gel matrix .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 Neutral Gel cards. 1 gel card contains 8x1 microtubes

NEUT	NEUT	NEUT	NEUT	NEUT	NEUT	NEUT	NEUT

Ready to use. Contains Sodium azide as preservative.
Each microtube of the card contains buffered neutral gel medium.

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.
- Papain or Bromelin solution.
- Red Blood Cells Reagent (papainized and untreated)
- Incubator

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.**

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. 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.
Plasma and serum must be cleared. Fibrin residues may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE
1 % red blood cell suspension :
Do not use hemolyzed, 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.

Plasma or Serum :
If necessary, samples stored at 2-8 °C can be used up to 48 hours after their extraction; or frozen samples (from -20 °C to -70 °C) up to the time of performing the test.

TEST PROCEDURE

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

Antibody Screening

A- Enzyme Test
1- Homogenise the vials of reagent red blood cells (papainized).
2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
3-Pipette 50µl of 1% reagent red cell suspension (papainized) to the appropriate microtubes .
4- When an autocontrol is to be included, pipette 50 µL of the patient's red cell suspension to the appropriate microtube.
5- Add 25 µl of the patient's plasma or serum to the microtubes .
6- For the autocontrol, add 25 µL Papain or Bromelin solution to the appropriate microtube.
7-Incubate the gel card for 15 minutes at 37°C in the incubator.
8-Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
9- Read the results.

B- Saline Test (for cold agglutinins)
Keep the gel cards in the refrigerator (2–8 °C).
1- Homogenise the vials of reagent red blood cells .
2- Label the appropriate gel card with patient's name or identification number. Remove the aluminum foil carefully.
3-Pipette 50µl of 1% reagent red cell suspension (untreated)to the appropriate microtubes
4- When an autocontrol is to be included, pipette 50 µL of the patient's red cell suspension to the appropriate microtube
5- Add 25 µl of the patient's plasma or serum to the microtubes .
6-Incubate the gel card 30 minutes at 2 –8 °C.
7-Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
8- Read the results.

Compatibility Test

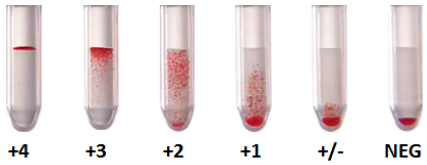
A- Enzyme Test
1- Homogenise the vials of reagent red blood cells.
2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
3-Pipette 50 µl of 0.8% donor's red cell suspension to the appropriate microtubes.
4- When an autocontrol is to be included, pipette 50 µL of the patient's red cell suspension to the appropriate microtube.
5- Add 25 µl of the patient's plasma or serum to the microtubes .
6- Add 25 µl of papain or bromelin solution to the microtubes.
7-Incubate the gel card for 15 minutes at 37°C in the incubator.
8-Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
9- Read the results

B-Saline Test
1- Homogenise the vials of reagent red blood cells.
2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
3-Pipette 50µl of 1% donor's red cell suspension to the appropriate microtubes.
4- When an autocontrol is to be included, pipette 50 µL of the patient's red cell suspension to the appropriate microtube.
5- Add 25 µl of the patient's plasma or serum to the microtubes .
6- Incubate the gel card for 15 minutes at room temperature (18–25 °C).
7-Centrifuge the gel cards for 10 minutes in the gel card centrifuge.
8- Read the results.

Reverse Grouping

1- Homogenise the vials of reagent red blood cells.
2- Label the appropriate gel card with patient's name or identification number. Remove the aluminium foil carefully.
3. Pipette 50 µL of each ABO test cells (A1, A2, B and O) to the appropriate microtubes.
4. Add 50 µL of the patient's or donor's plasma or serum to each microtube.
5. Incubate the gel card for 10 minutes at room temperature (18–25 °C).
6-Centrifuge the gel card for 10 minutes in the gel card centrifuge.
7- 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	*Some small-sized agglutinations in the column*
+2	*Small or medium-sized agglutinations throughout 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:
Antibody Screening
-A negative reaction indicates the absence of detectable irregular antibodies in the patient's or donor's serum or plasma.
-A positive reaction indicates the presence of irregular antibodies.
- Following the reaction pattern and the antigen configuration, the type of antibody present may be indicated.
-A positive reaction with some test cells and a negative auto control suggest the presence of a specific antibody.
- A positive reaction with all test cells and a positive auto control may be due to an auto-antibody.
- Where there is a positive reaction with all test cells and a positive auto control but with one or several test cells showing a stronger positive reaction than the auto control, the patient sample should be submitted for further testing, to investigate the possibility of an underlying allo-antibody.

Compatibility test
-A positive reaction indicates possible incompatibility due to the presence of irregular antibodies present in the recipient's serum or plasma, and further investigation is required.
- A negative reaction indicates that there are no detectable antibodies in the recipient's plasma/serum which are directed against antigens present on the donor's red cells, by the technique used.
- When results indicate an incompatible cross-match, antibody screening and identification tests should be performed and ABO and Rh blood groups of both recipient and donor should be retested.

Reverse grouping
Test cell reagents

A1	A2	B	O	Blood Group
Neg	Neg	+1 to +4	Neg	A
+1 to +4	+1 to +4	Neg	Neg	B
Neg	Neg	Neg	Neg	AB
+1 to +4	+1 to +4	+1 to +4	Neg	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 hemolysed, 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.

PERFORMANCE CHARACTERISTICS

Diagnostic sensitivity and specificity of Neutral Gel :
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 240 samples and obtained comparable results with other established products of equivalent intended use.

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 : Neutral Gel

4x12 REF : MCNEU

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