REDCELL Blood Grouping Gel Systems

Rh Phenotype Plus

Product ID: RCRPP CE1434 IVD

INTENDED USE

This test allows the detection of clinically important Rh antigens and K antigen in gel technique.

INTRODUCTION

All Rh antibodies should be considered to have the potential to cause hemolytic transfusion reactions and hemolytic disease of the fetus and newborn (HDFN). Anti-c is clinically the most important Rh antigen after anti-D and often causes severe HDFN, whereas anti-C, -E, and -e rarely cause HDFN, and when they do the disease is generally mild.

Antibodies of the Kell system should be considered potentially clinically significant, both from the point of view of causing severe HDFN and HTRs.

PRINCIPLE OF TEST

Rh Phenotype Plus allow the detection of clinically important Rh antigens and K antigen on a single gel card. The microtubes contain gel matrix . Seven microtubes contain monoclonal antibodies and last 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 Rh Phenotype Plus gel cards. 1 gel card contains 8x1 microtubes

C	c	Cw	E	e	K	Dvı+	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 C : monoclonal anti-C IgM (clone P3X25513G8)
- microtube c : monoclonal anti-c IgM (clone H48)
- microtube E : monoclonal anti-E IgM (cloneDEM1)
- microtube e : monoclonal anti-e IgM (cloneP3GD512, MS-63)
- microtube K : polyclonal anti-K
- microtube Cw : monoclonal anti-Cw IgM
- 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 RhDVI red cells

- 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. 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 :

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.

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 aluminium foil carefully.

2-Pipette 50 µL of the patient's red cell suspension to the microtubes 1-8.

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

4- Read the results.

Interpretation of 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*

A positive reaction (+ to ++++) indicates presence of the corresponding antigen.

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.

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.
- 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

Rh Phenotype :

The diagnostic sensitivity and specificity of the antibodies present in Rh Phenotype +K for the determination of the antigens have been studied in a representative number of positive and negative samples. In the study using 1004 blood samples the sensitivity and specificity Rh Phenotype Plus was as follows.

	Positive Samples	Negative samples	Number of total samples	Sensitivity	Specificity
Anti-C	806	198	1004	% 100	% 100
Anti-c	984	20	1004	% 100	% 100
Anti-Cw	11	993	1004	% 100	% 100
Anti-E	489	515	1004	% 100	% 100
Anti-e	960	44	1004	% 100	% 100
Anti K	61	943	1004	% 100	% 100

Precision:

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

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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

Products : Rh Phenotype Plus

4x12 REF : RCRPP

Manufacturer:

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