DiaClon Rh-Subgroups + K

English

B002124 v.01 2020-12-18

C, c, E, e, K, ctl
monoclonal
Determination of Rh phenotypes and K

Product-Identification: 50110
ID-Card ″DiaClon Rh-Subgroups + K″

4 x 12. . . . . REF 002124
24 x 12. . . . . REF 002127
60 x 12. . . . . REF 002126
112 x 12. . . . . REF 002125

INTRODUCTION

Besides the RhD (RH1) antigen, other important antigens of the Rh system (ISBT, number 004) are: C (RH2), E (RH3), c (RH4) and e (RH5).

According to Issitt [1] their frequencies in the Caucasian population are as follows:

C.....70%
c.....80%
E 30%
e.....98%

Appropriate antigen-positive red cells may stimulate antibody production in antigen C (RH2), c (RH4), E (RH3) and e (RH5) negative individuals. The determination of the Rh phenotypes can, therefore be important during pregnancy, for previously transfused patients and for patients with known irregular antibodies [2].

Approximately 9% of the Caucasian population are K (KEL1, K, K1) positive. The K antigen is strongly immunogenic. Anti-K has been reported as the cause of hemolytic transfusion reactions, both immediate and delayed, and hemolytic disease of the newborn.

The ID-Card ″DiaClon Rh-Subgroups + K″ offers a complete profiling of the Rh phenotype and includes K typing.

REAGENTS IVD

ID-Card ″DiaClon Rh-Subgroups + K″ contains monoclonal antibodies anti-C (cell line MS-24), anti-c (cell line MS-33), anti-E (cell line MS-260), anti-e (cell lines MS-16, MS-21, MS-63) and anti-K (cell line MS-56) within each gel matrix. The microtube (ctl) is the negative control.
Preservative: < 0.1% NaN_3.

Caution: All reagents should be treated as potentially infectious.

18 °C – 25 °C *Do not store near any heat, air conditioning sources or ventilation outlets.*

Stability: see expiry date on label.

ADDITIONAL REAGENTS REQUIRED

ID-Diluent 2: modified LISS for red cell suspensions.

(see related package insert)

Digitally signed by Bolea Petru
Date: 2024.08.15 10:48:47 EEST
Reason: MoldSign Signature
Location: Moldova

BIO-RAD

FURTHER MATERIALS REQUIRED

- ID-Dispenser
- ID-Pipetor
- ID-Tips (pipetor tips)
- Suspension Tubes
- ID-Working table
- ID-Centrifuge 6, 12 or 24

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample, or in accordance with local laboratory procedures for sample acceptance criteria. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used.

PREPARATION OF BLOOD SAMPLE

Prepare a 5% red cell suspension in ID-Diluent 2 as follows:

Allow the diluent to reach room temperature before use.

1. Dispense 0.5 ml of ID-Diluent 2 into a clean tube.
2. Add 50 µl of whole blood or 25 µl of packed cells, mix gently.

The cell suspension may be used immediately.

CONTROLS

Known positive and negative samples should be included in accordance with the relevant guidelines of quality assurance.

TEST PROCEDURE

Do not use ID-Cards which show signs of drying, have bubbles, damaged seals, drops of gel or supernatant in the upper part of the microtubes or on the underside of the aluminium foil.

1. Identify the ID-Card with the unique patient or donor number/details as appropriate.
2. Remove the aluminium foil from as many microtubes as required by holding the ID-Card in the upright position.
3. Add 10 or 12.5 µl of the patients' red cell suspension to all microtubes of the ID-Card.
4. Centrifuge the ID-Card for 10 minutes in the ID-Centrifuge.
5. Read and record the results.

INTERPRETATION OF THE RESULTS

A) Principle [3]
Positive: Agglutinated cells forming a red line on the surface of the gel or agglutinates dispersed in the gel.
Negative: Compact button of cells on the bottom of the microtube.

B) Reactions for Rh phenotypes and K
- A positive reaction (+ to ++++) indicates presence of the corresponding antigen. (see ˝REMARKS 2. + 3.˝)
- Reactions of ≤ 2+ may indicate the presence of weak or variant forms of the antigen.
- A negative reaction indicates absence of the corresponding antigen.

Important: The microtube ctl must show a negative reaction. If the ctl is positive, the antigen determination is not valid. Repeat the test as described under ˝REMARKS 1.˝.

REMARKS

1. The negative control must always show a negative reaction.
   - If the negative control is positive, wash the red cells in warm isotonic saline solution or ID-Diluent 2, before preparing the red cell suspension.
   - Proceed as under ″PREPARATION OF BLOOD SAMPLE″ and ″TEST PROCEDURE″.
   - If the negative control subsequently shows a negative result, the reactions can be interpreted as described in sections A and B.
   - If the negative control remains positive, the results of the phenotype determination should be considered invalid and further investigations following recommended techniques should be undertaken to ascertain the reason, before valid antigen typing can be assured.

2. Mutations in the blood group gene may give rise to weak or variant forms of an antigen, which may result in unexpectedly weak or negative results. DiaClon anti-C is specific for the C (RH2) antigen and does not react with the C^w (RH8) antigen. The C antigen may be very weak in Cw+ individuals as well as other phenotypes exhibiting depressed C expression. Very weak or negative reactions may therefore be seen in these rare circumstances.

3. Kp^a (K3) antigen in *cis* weakens the expression of K antigens.

LIMITATIONS

a) ID-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.
b) Fibrin residues in the red cell suspension may trap non-agglutinated cells presenting a fine pink line on top of the gel while most of the cells are on the bottom of the microtube after centrifugation.
c) Use of suspension solutions for red cells other than ID-Diluent 2 may modify the reactions.
d) Bacterial or other contamination of materials used can cause false positive or false negative results.
e) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regulary according to GLP procedures.
f) Too heavy or too weak red cell suspensions can cause aberrant results.
g) A pinkish color in the gel may be observed in the anti-e microtube when tested with an e-/RH:-5 quality control sample. This slight coloration may impact the automatic reading of this negative reaction by an instrument. Therefore, as long as the reaction fits with a negative reaction (refer to ″ID-Card – Interpretation Guide″), it can be edited and corrected as negative.

PERFORMANCE CHARACTERISTICS

Specificity/sensitivity

Performances of the monoclonal antibodies present in the ID-Cards ″DiaClon Rh-Subgroups + K″ have been evaluated according to the Common Technical Specification (CTS) [4] on reagents used for determining RH/KEL1 phenotype.
Evaluation was performed with samples coming from donors, patients and newborns for which RH/KEL1 phenotypes have been previously determined by a reference method. Total number of tested samples exceeded the CTS requirements.

Antibodies	Total number of samples	Sensitivity	Specificity
RH2/RH3/RH4/RH5	1871	100%	100%
KEL1	1871	100%	100%

Reproducibility

Intra-assay reproducibility (repeatability) and inter-assay reproducibility of the ID-Cards ″DiaClon Rh-Subgroups + K″ have been evaluated internally. Neither false positive nor false negative results were observed. Differences between reactions in positive samples were less than one reaction strength.

BIBLIOGRAPHY

1. Issitt, P. D. + Anstee: Applied Blood Group Serology, 4th ed. 1998; Montgomery Scientific Publications, Miami, Florida, U.S.A.
2. Mollison, P.L., Engelfriet, C.P. and Contreras, M.: Blood Transfusion in Clinical Medicine, 10th ed. 1997; Blackwell Scientific Publications, Oxford.
3. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109-113.
4. Official Journal of the European Union L 318/25: Commission decision of 27 November 2009 amending decision 2002/364/EC on common technical specifications for *in vitro* diagnostic medical devices. (2009/886/EC)

GLOSSARY OF SYMBOLS

The following symbols **may** be used for labelling purpose.

REF	Catalog reference
LOT	Batch number
IVD	*In vitro* diagnostic
	Consult instructions for use
	Expiry date (YYYY-MM-DD)
	Storage temperature
	Legal manufacturer
	Consult **downloads.bio-rad.com** to download the latest version of these instructions for use

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.