DiaClon ABO/Rh for Patients

English B001025 v.01 2021-02-15

A, B, AB, DVI-, CDE, ctl
Determination of the ABO/Rh blood groups

Product-Identification: 50012
ID-Card ″DiaClon ABO/Rh for Patients″

4 x 12. . . . . REF 001044
24 x 12. . . . . REF 001043
60 x 12. . . . . REF 001046
112 x 12. . . . . REF 001045

INTRODUCTION

According to Mollison [1], the frequencies of the different ABO blood groups (ISBT symbol ABO, number 001) in the Caucasian population are as follows:

O..... 46%
A..... 41%
B..... 9%
AB..... 4%

Approximately 85% of the Caucasian population are RhD positive [1].

To detect the presence or absence of the A/B antigens (ABO1/ABO2) on red cells, antibodies against the corresponding antigens, anti-A and anti-B are used which can be of human or monoclonal origin. ABO forward typing should not be considered complete without reverse grouping whereby the patient's serum is tested against known A_1, A_2, B and O red cells.

The expression ″Rh positive″ or ″Rh negative″ is based on the presence or absence of the RhD antigen (RH1) on the red cells. This may be determined using anti-D test serum which can be of human or monoclonal origin. The sensitivity of the ID-System allows a direct detection of most examples of the weak D phenotype.

Current recommendations for RhD typing suggest that for transfusion recipients and antenatal patients, anti-D reagents should not detect the DVI phenotype. The D antigen consists of many epitopes, and in the 9 epitope model, DVI red cells lack all but three. This means that individuals possessing the DVI phenotype may produce an anti-D to the missing epitopes after immunisation by fetal or transfused RhD positive red cells. To ensure that appropriate therapeutic measures are instigated, DVI patient's red cells should be assigned ″Rh negative″ status.
Conversely, donor bloods should be tested with anti-D that does detect DVI and assigned ″Rh positive″ status, to avoid the unit being transfused to an RhD negative or partial-D patient.

The Rh antigens C (RH2) and/or E (RH3) may be present on red cells with or without the presence of D (RH1) antigens. The presence of either C and/or E antigens can be indicated by the use of an anti-CDE reagent.

The ID-Card ″DiaClon ABO/Rh for Patients″ offers a complete test profile for forward typing of ABO plus RhD and CDE status in one single test procedure.

REAGENTS IVD

ID-Card ″DiaClon ABO/Rh for Patients″ contains monoclonal anti-A [cell line A5], anti-B [cell line G½], anti-AB [cell lines ES 131 (ES-15), Birma-1, ES-4], anti-D [cell lines LHM 59/20 (LDM 3) and 175-2] and anti-CDE (cell lines MS-24, MS-201, MS-26, MS-80) within the gel matrix. The microtube (ctl) is the negative control.
Preservative: < 0.1% NaN_3.

Caution: All reagents should be treated as potentially infectious.

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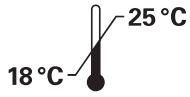
STABILITY



ID-Card ″DiaClon ABO/Rh for Patients″ is stable up to the expiry date indicated on the label, with an intact seal of the aluminium foil and stored at 18–25 °C in the position indicated on the outer packaging. Do not store near any heat, air conditioning sources of ventilation outlets. Do not freeze.

ADDITIONAL REAGENTS REQUIRED

ID-Diluent 2: modified LISS for red cell suspensions. *(See related package insert)*

FURTHER MATERIALS REQUIRED

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

SAMPLE MATERIAL

For optimal results, the determination should be performed using a freshly drawn sample. Samples that cannot be analysed rapidly should be stored between +2 °C and +8 °C and tested within 48 hours. Preferably, blood samples should be drawn into citrate, EDTA or CPD-A anticoagulant. Samples drawn into plain tubes (no anticoagulant) may also be used. For automated testing please refer to the user manual of the corresponding instrument.

The reliability of the results depends on correct compliance to the Good Laboratory Practices for reagents and samples.

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 25 µl of packed cells, mix gently. Where whole blood from a segment of the blood bag is used directly, add 50 µl of blood cells to the 0.5 ml of ID-Diluent 2.

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:
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 blood groups ABO

Anti-A	Anti-B	Anti-AB	Blood group
+++ to ++++	negative	+++ to ++++	**A**
negative	+++ to ++++	+++ to ++++	**B**
+++ to ++++	+++ to ++++	+++ to ++++	**AB**
negative	negative	negative	**O**

Weaker reactions than +++ may indicate A or B subgroups and further investigations should be performed. For correct interpretation, a complete grouping test should be performed (forward and reverse grouping). In the presence of weak or very weakly expressed antigens the reaction can be negative. The anti-B of monoclonal origin does not react with the acquired B antigen.

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

C) Reactions for RhD

+++ to ++++	± to ++*	negative
RhD positive	RhD weak positive	RhD negative

* ±, trace or weak reactions should be subject to further investigations to distinguish between weak and partial D types as appropriate for the category of sample being tested.

Weak D may give a negative reaction. If all weak D's are required to be detected, all D negative results must be retested. The monoclonal anti-D used in the ID-Card ˝DiaClon ABO/Rh for Patients˝ does not react with red cells of the partial DVI phenotype. For the complete procedure see box insert ID-Cards ˝ABO/Rh˝ or ˝Anti-D˝ with polyclonal reagents of human origin. Note that most guidelines do not recommend further testing for weak or partial-D in patients.

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

D) Reactions for CDE

Presence of the antigens RhD, C or E is indicated by positive reactions of +++ to ++++.

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

PERFORMANCE CHARACTERISTICS

Specificity/sensitivity

Performances of the monoclonal antibodies present in the ID-Cards ˝DiaClon ABO/Rh for Patients˝ have been evaluated according to the Common Technical Specification (CTS) on reagents used for determining ABO/RH1 blood group systems. Evaluation was performed with samples coming from donors, patients and newborns for whom ABO/RH1 group/phenotypes has been previously determined by a reference method. Total number of tested samples exceeded the CTS requirements.

Antibodies	Total number of samples	Sensitivity	Specificity
Anti-A/Anti-B/Anti-AB	3363	100%	100%
Anti-DVI-	3416*	99.7%**	100%
Anti-CDE	1633	100%	100%

* These samples include 54 samples with weak expression of the RH1 antigen.
** 85% of RHW1 (weak D) tested antigens were detected.

Reproducibility

Intra-assay reproducibility (repeatability) and inter-assay reproducibility of the ID-Cards ˝DiaClon ABO/Rh for Patients˝ 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.

REMARKS

1. The negative control must always show a negative reaction.
   - If the negative control is positive, wash the red cells first in warm isotonic saline solution or ID-Diluent 2, before preparing the red cell suspension.
   - Then 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 B, C and D.
   - If the negative control remains positive, the results of the ABO/Rh 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. The anti-D test sera were selected so as **not to react** with DVI variants.

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) Bacterial or other contamination of materials used can cause false positive or false negative results.
c) 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.
d) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.
e) Use of suspension solutions other than ID-Diluent 2 may modify the reactions.
f) Too heavy or too weak red cell suspensions can cause aberrant results.

BIBLIOGRAPHY

1. Mollison, P. L., Engelfriet, C. P. and Contreras, M.: Blood Transfusion in Clinical Medicine, 9th ed. 1993; Blackwell Scientific Publications, Oxford.
2. 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.
3. Daniels Geoff: Human Blood Groups, 1995. Blackwell Science Ltd. Oxford.
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.