DiaClon ABO/D + Reverse Grouping for Patients ID-Card

English B001265 08.13

A, B, DVI-, ctl/A_1, B

Determination of the ABO/Rh blood groups combined with reverse grouping

Product-Identification: 50093

INTRODUCTION

ABO blood group typing, using anti-A and anti-B test sera, is known as direct or forward grouping test.

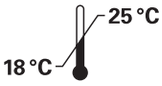
Reverse grouping uses red cell reagents of known ABO antigen specificity to indicate the presence or absence of anti-A and anti-B isoagglutinins, the results of which determine the reverse group. Discrepancies between forward and reverse grouping require further investigation [1].
Classification of blood groups must be based on both forward and reverse grouping.
The ID-Card "DiaClon ABO/D + Reverse Grouping for Patients" allows combined testing of forward and reverse grouping as well as RhD determination.

REAGENTS

IVD

ID-Card "DiaClon ABO/D + Reverse Grouping for Patients" contains monoclonal anti-A [cell line A5], anti-B [cell line LM306/686 (LB-2)] and anti-D (cell lines LHM 59/20 (LDM3)/175-2] within the gel matrix. The microtube ctl is the negative control. Two microtubes with "neutral" gel serve for reverse grouping with A_1 and B cells.
Preservative: < 0.1% NaN_3.

Caution: All reagents should be treated as potentially infectious.



Do not store near any heat, air conditioning sources or ventilation outlets.

Stability: see expiry date on label.

ADDITONAL REAGENTS REQUIRED

- ID-Diluent 2: modified LISS for red cell suspension.
- Test cell reagents: ID-DiaCell A_1 and B in a 0.8% suspension, in 10 ml vials, ready-to-use.

(see related package insert)

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.

When the use of serum instead of plasma is required, the serum must be well cleared, by centrifugation at 1500 g for 10 minutes, before use avoid fibrin residues, which may interfere with the reaction pattern.

PREPARATION OF BLOOD SAMPLE

a) Red cell suspension (for ABO/D determination)

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 glass tube.
2. Add 50 µl of whole blood or 25 µl of packed cells, mix gently.

The cell suspension may be used immediately.

b) Plasma or Serum for reverse grouping

Where samples are not for immediate testing they should be stored at 2–8 °C after separation for a maximum of 48 hours, thereafter at -20 °C or in accordance with local/national policies/guidelines.

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

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. Pipette 50 µl of "ID-DiaCell A_1" to microtube 5 (A_1).
4. Pipette 50 µl of "ID-DiaCell B" to microtube 6 (B).
5. Pipette 50 µl of the patient serum or plasma to both microtubes 5 and 6. An incubation for 10 minutes at room temperature is recommended *(see "Remarks 4.").*
6. Pipette 10 or 12.5 µl of the patient's red cell suspension to the microtubes 1–4 (A, B, DVI-, ctl).
7. Centrifuge the ID-Cards for 10 minutes in the ID-Centrifuge.
8. Read and record the reactions.

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INTERPRETATION OF RESULTS

A) Principle [2]

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

Weaker reactions than +++ may indicate A or B subgroups. For correct interpretation, a complete grouping test should be performed (anti-A, anti-B, anti-AB). 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 1.˝.

C) Reactions for reverse grouping

A_1	B	Blood group
+ to ++++	negative	**B**
negative	+ to ++++	**A**
+ to ++++	+ to ++++	**O**
negative	negative	**AB**

If questionable reactions are obtained, repeat reverse grouping with 4 red cell reagents (A_1, A_2, B and O).

D) Reactions for RhD

+++ to ++++	± to ++*	-
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.

The anti-D used has been selected so as **not to react** with DVI variants.

Weak D may give a negative reaction. If all weak D's are required to be detected, all D negative results must be retested. 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 1.˝.

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. Where a discrepancy occurs between the results of ABO typing and reverse grouping, consult the ˝Bio-Rad Quick Reference Chart, Resolving ABO Discrepancies˝ for appropriate information.
3. Full forward and reverse grouping requires the use of anti-A, -B, -AB, and A_1, A_2, B and O cells. The ID-Card ˝DiaClon ABO/D + Reverse Grouping for Patients˝ does not contain anti-AB and allows the use of A_1 and B cells only. It should be used only for confirmation of previously fully tested samples with established blood group status or in accordance with local or national guidelines/recommendations for blood grouping.
4. For reverse grouping, an incubation of at least 10 minutes at 18–25 °C prior to centrifugation will enhance the reactions and minimise repeat testing due to weak isoagglutinins.

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, 10th ed. 1997; 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.

PRODUCTS

ID-Card ˝DiaClon ABO/D + Reverse Grouping for Patients˝

4 x 12 . . . . . REF 001264
24 x 12 . . . . . REF 001267
60 x 12 . . . . . REF 001266
112 x 12 . . . . . REF 001265

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.

Changes to the version 03.12 are shaded grey.

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