DiaClon ABO/D

English

B001324 v.01 2020-11-05

A, B, AB, DVI+, DVI-, ctl

Blood grouping ABO with double determination RhD

Product-Identification: 50481
ID-Card ″DiaClon ABO/D″

4 x 12 . . . . . REF 001324
24 x 12 . . . . . REF 001323
60 x 12 . . . . . REF 001326
112 x 12 . . . . . REF 001325

INTRODUCTION

According to Mollison [1], the frequencies of the different ABO blood groups in the Caucasian population are approximately as follows:

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

To detect the presence or absence of the A/B antigens 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.

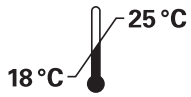
Approximately 85% of the Caucasian population are RhD positive [1]. The expression ″Rh positive″ or ″Rh negative″ is based on the presence or absence of the RhD antigen on the red cells. This may be determined using anti-D test serum which can be of human or monoclonal origin. The sensitivity of the ID-System allows a direct detection of most weak D's.

The ID-Card ″DiaClon ABO/D″ provides the complete profile for ABO/RhD in one single procedure step, including the confirmation of RhD. The first anti-D detects the presence of the D variant DVI, the second anti-D is negative for the DVI variant.
Some DVI variants can give very weak reactions.

REAGENTS IVD

ID-Card ″DiaClon ABO/D″ 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 ESD-1M + 175-2], anti-D [cell lines LHM59/20 (LDM3) + 175-2] within a gel matrix. The microtube ctl is the negative control.
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.

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)
- Suspension Tubes
- ID-Working table
- ID-Centrifuge 6, 12 or 24

Digitally signed by Bolea Petru
Date: 2024.08.15 10:42:43 EEST
Reason: MoldSign Signature
Location: Moldova

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 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 [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	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. See ″Bio-Rad Quick Reference Chart, Resolving ABO Discrepancies″.

In the presence of weak or very weakly expressed antigens the reaction can be negative.

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 2″.

C) Reactions for RhD

Anti-DVI+	Anti-DVI-	Interpretation
+++ to ++++	+++ to ++++	RhD pos.
± to ++**	± to ++**	RhD weak
neg.	neg.	RhD neg.
+ to ++++	neg.	DVI+ *
neg.	+ to ++++	DVI- *

* For safe interpretation, it is advised to further investigate the sample using ˝ID-Partial D Typing˝ (REF 001451).
** ±, 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.

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 2˝.

The reaction strength of both anti-D may vary with weak D's. If the detection of all D weak phenotypes are required, proceed to further tests of negative reactions such as with the ID-Card ˝Anti-D˝ with human antibodies and red cell suspension in ID-Diluent 1.

PERFORMANCE CHARACTERISTICS

Specificity/sensitivity
Performances of the monoclonal antibodies present in the ID-Cards ˝DiaClon ABO/D˝ have been evaluated according to the Common Technical Specification (CTS) [3] for *in vitro* diagnostic medical devices. Evaluation was performed with samples coming from donors, patients and newborns for which ABO/RH1 phenotypes have been previously determined by a reference method:

Antibodies	Total number of samples	Sensitivity	Specificity
Anti-A, Cell line: A5	4385	100%	100%
Anti-B, Cell line: G1/2	4385	100%	100%
Anti-AB, Cell lines: ES131 (ES-15), Birma-1, ES-4	4737	100%	100%
Anti-D(DVI+), Cell lines: ESD-1M, 175-2	3724*	99.90%	100%
Anti-D(DVI-), Cell lines: LHM59/20(LDM3), 175-2	4679**	99.72%	100%

* These samples include 57 samples with weak (Weak/variant) expression of the RH1 antigen. 54 weak/variant samples have been detected directly. All the DVI variants were detected.
** These samples include 81 samples with weak (Weak/variant) expression of the RH1 antigen. 62 weak/variant samples have been detected directly. The DVI variants were not detected.

Remark: The Anti-DVI- is not conceived to detect every weak/variant expressions of the RH1 antigen.

REMARKS

1. The monoclonal anti-B in the ID-Card ˝DiaClon ABO/D˝ has been shown not to react with red cells possessing an acquired B-antigen.
2. If the negative control ctl is positive, wash the red cells first with isotonic saline solution (or ID-Diluent 2) before preparing the red cell suspension. Where the ctl microtube subsequently shows a negative result, the reactions can be interpreted as under B and C.
3. If the ctl remains positive, the results of the ABO/RhD determination should be considered invalid and further investigation is required.
4. Some examples of DVI red cells have weak expression in serological tests, possessing lower numbers of DVI antigen sites than other DVI cells. Reaction strengths for DVI red cells can therefore vary. For safe interpretation of a positive result, it is advised to further investigate the sample using the ID Partial-D Typing kit (REF 001451; see related package insert).

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. 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.