

Test cell reagents for antibody screening: ID-DiaCell I-II, ID-DiaCell I-II-III, ID-DiaCell IP-IIP-IIIIP (papainized), ID-DiaCell I-II-III Asia, ID-DiaCell Pool; for antibody identification: ID-Panel, ID-Panel-P; special antigens: ID-Di^a (Diego) Positive, ID-I Negative Cell

Product-Identification:

ID-DiaCell I-II-III	Id-n°: 45184	Set of 3 vials (R ₁ ^w R ₁ -R ₂ R ₂ -rr)	3 x 10 ml		004310
ID-DiaCell I-II-III Asia	Id-n°: 45330	Set of 3 vials (R ₁ R ₁ -R ₂ R ₂ -GP.MUR)	3 x 10 ml		003614
ID-DiaCell IP-IIP-IIIIP	Id-n°: 45194	Set of 3 vials (R ₁ ^w R ₁ -R ₂ R ₂ -rr papainized)	3 x 10 ml		005310
ID-DiaCell I-II	Id-n°: 45151	Set of 2 vials (R ₁ R ₁ +R ₂ R ₂)	2 x 10 ml		003613
ID-DiaCell Pool	Id-n°: 06070	2 pooled cells (R ₁ R ₁ +R ₂ R ₂)	1 x 10 ml		003630
ID-DiaCell Pool	Id-n°: 06070	2 pooled cells (R ₁ R ₁ +R ₂ R ₂)	3 x 10 ml		003631
ID-DiaPanel	Id-n°: 45161	Set of 11 vials	11 x 4 ml		004114
ID-DiaPanel-P	Id-n°: 45171	Set of 11 vials	11 x 4 ml		004214
ID-Dia (Diego) Positive	Id-n°: 05980		1 x 10 ml		004134
ID-I Negative Cell	Id-n°: 06291		1 x 1.6 ml.		004111

INTRODUCTION

The reliability of antibody detection is largely dependent on the availability of test cells with appropriate antigens and on the sensitivity of the test methods used.

The requirements for antigen configuration are stringent: it must allow the safe detection of all clinically significant antibodies. For the Rh system, MNSs, Duffy and Kidd, the antigens must be in homozygous form. The Lewis antigens must be present, as should the rare antigen Kp^a.

It is generally considered most effective to perform screening tests by both anti-human globulin (AHG) and enzyme test procedures. Due to higher sensitivity of the indirect antiglobulin test (IAT) with procedures such as the ID-System, some scientists in various countries have formed the opinion that the enzyme test has become somewhat less important.

However, enzyme techniques are useful when increased sensitivity in antibody screening is desired or where more than one antibody may be present. They enhance the reactions of certain antibodies, notably in the Rh, Kell and Kidd systems, whereas antibodies to enzyme-sensitive antigens may not be detected, notably in the Duffy and MNS Systems.

The test cell reagents are specially designed for the ID-System.

REAGENTS

All test cell reagents are of human origin, in a buffered suspension medium at 0.8% (± 0.1%).
Preservatives: the antibiotics trimethoprim and sulfamethoxazole.

For antibody screening, single donors, blood group O:

ID-DiaCell I-II	R ₁ ^w R ₁ +R ₂ R ₂ for IAT and NaCl test
ID-DiaCell I-II-III	R ₁ ^w R ₁ +R ₂ R ₂ +rr for IAT and NaCl test
ID-DiaCell IP-IIP-IIIIP	papainized, for enzyme technique
ID-DiaCell Pool	R ₁ R ₁ +R ₂ R ₂ (2 pooled cells for donor screening)
ID-DiaCell I-II-III Asia	R ₁ R ₁ +R ₂ R ₂ +cell of the GP.MUR phenotype, for IAT and NaCl test

For antibody identification, single donors, blood group O:

ID-DiaPanel	11 test cells for IAT and NaCl test
ID-DiaPanel-P	11 test cells papainized, for enzyme technique

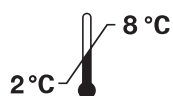
Special antigens:

These cells are for use as an adjunct with other routine antibody screening cell sets.

ID-Di^a (Diego) positive
ID-I negative cell

Shipment on standing order, every 4 weeks.

Caution: The source materials from which these products were manufactured, were found non-reactive for HBsAg, HCV and HIV (1+2) when tested with licensed reagents. However, no known test method can assure that infectious agents are absent. Products from human blood should be considered potentially infectious.



Stability: see expiry date on label.

ADDITIONAL REAGENTS REQUIRED

- ID-Card "LISS Coombs + Enzyme Test" 3 microtubes with polyspecific anti-human globulin AHG) serum and 3 microtubes containing neutral gel (Id-n° 50581).
- ID-Card "LISS/Coombs" 6 microtubes with polyspecific AHG serum (Id-n° 50531).
- ID-Card "Coombs Anti-IgG" 6 microtubes containing rabbit anti-IgG (Id-n° 50540).
- ID-Card "NaCl, Enzyme test and cold agglutinins" 6 microtubes containing neutral gel (Id-n° 50520).
- ID-Card "Reverse Grouping with Antibody Screening" 3 microtubes containing neutral gel and 3 microtubes containing polyspecific anti-human globulin (AHG) serum (Id-n° 50510).
- ID-Diluent 2: modified LISS for red cell suspensions (Id-n° 05761).

(see related package insert)

FURTHER MATERIALS REQUIRED

- ID-Dispenser
- ID-Pipetor
- ID-Tips (pipetor tips)
- ID-Working Table
- Suspension Tubes
- ID-Incubator 37 °C
- 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.

CONTROLS

Controls should be included in accordance with the relevant guidelines of quality assurance.

USE OF THE ID-TEST CELL REAGENTS

- All test cell reagents are for use with the ID-Cards of the ID-System only.
- **Strictly follow the test procedures as described in the specific package inserts of the ID-Cards to be used.**
- Always gently resuspend the red cells, by inverting the vial several times before use and also before placing the vials into a pipetting automate.
- Make sure that the test cells are at room temperature (18–25 °C) when in use.
- During the working procedures, check that the test cell reagents remain in suspension. If there is settling of the cells, resuspend again.
- **For the ID-System, precise pipetting is of importance.** Use the ID-Pipetors for serial pipetting.
- Avoid contamination of the test cell reagents.
- When recording the reactions, ensure that the lot number of the antigen table corresponds with the lot number of the reagent vials.
- After use, close the vials and replace them in the refrigerator.

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.

Note: Test cell reagents for antibody screening containing pooled cells can show a double cell population appearance depending on the antibody present. This is considered to be a positive result.

B) Reactions

See package inserts of the corresponding ID-Cards.

LIMITATIONS

- a) Bacterial or other contamination of materials used can cause false positive or false negative results.
- b) Strict adherence to the procedures and recommended equipment is essential. The equipment should be checked regularly according to GLP procedures.

BIBLIOGRAPHY

1. Technical Manual of the American Association of Blood Banks, 13th edition, 1999.
2. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reaction. Transfusion 1990;30:109-113.

GLOSSARY OF SYMBOLS

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

	Catalog reference
	Batch number
	<i>In vitro</i> 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.