Instructions for use

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Screening set 1 + 2	REF K1388	IVD CE 0344
Screening panel 123	REF K1148	IVD CE 0344
Makropanel 16	REF K1385	IVD CE 0344
Makropanel 16-P (papain)	REF K1384	IVD CE 0344
Wr^a positive reagent red cells	REF K1393	IVD CE 0344

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For professional use only

3% cell suspensions for the screening and identification of red cell antibodies in human serum and plasma

General information
All cell suspensions are derived from individual donors possessing blood group O. The screening cells consist of 10 ml vials. The identification panel cells and the Wr^a positive cell consist of 3 ml vials. The cells are suspended in a preservation medium. These cell suspensions meet the requirements of the concerned standards and guidelines. Performance characteristics are mentioned in the release documents, which are supplied with the product upon request. The principle of the test is the agglutination technique, which is based on antigen/antibody reaction. The cells can be used to screen for and/or identify red cell antibodies in human serum or plasma in various techniques (e.g. in the indirect antiglobulin test with BSA 22% (REF K1106) or BSA 30% (REF K1107), PeliLISS (REF K1110) or PEG 4000 20% (REF K1159).

Antigen profile sheet
An antigen profile sheet is included with every panel except the Wr^a positive cells. Shaded columns in the sheet indicate antigens destroyed or diminished in reactivity by enzyme treatment. Presence or absence of the antigens marked with * on the sheet may have been determined with a single source of the specific antibody directed against this particular antigen.

Precautions
For in vitro diagnostic use only. Reagent red cells should be stored at 2–8°C; do not freeze. Leaking or damaged vials may not be used. Reagent red cells (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the vial. Chlooramphenicol 0.025%, neomycin sulfate 0.01% and gentamicin 0.005% are used as preservatives. Although all blood products are tested for infectious diseases and found negative, the reagents cannot be assumed to be free from infectious agents. Care must be taken in the use and disposal of each container and its contents. If contamination or excessive hemolysis is evident, discard. Waste-disposal, after completion of the test, should be performed according to your laboratory regulations. As with all reagent red cells, the reactivity of the cells may decrease during the shelf life. The rate at which antigen reactivity (e.g. agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

Specimen collection and preparation
Blood samples should be withdrawn aseptically with or without the addition of anticoagulants. If testing of the blood samples is delayed, storage should be at 2–8°C.
Preparation of the specimen is described in the respective test procedures.

Test procedures (optional)
Tube requirements: round bottom glass tubes; size 75 x 10/12 mm.

Indirect anti-globulin test (IAT) with PeliLISS
See package insert (REF K1110).

Indirect anti-globulin test (IAT) with BSA 22% or 30%
See package insert (REF K1106 or K1107).

Indirect anti-globulin test (IAT) with PEG 4000 20%
See package insert (REF K1159).

Test with papain treated cells (Makropanel 16P):
1. Add to a test tube:
   - 2 drops of patient's serum or plasma (diluted 1:2 in isotonic saline)
   - 1 drop of cell 1 of the Makropanel 16P

   and mix well.
2. Repeat this procedure for cell 2 up to and including cell 16.
3. Incubate in a water bath for 15–20 minutes at 37°C.
4. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
5. Resuspend the cells by gentle agitation and read macroscopically for agglutination.

Interpretation
A positive reaction (i.e. agglutination or hemolysis) indicates that red cell antibodies against one or more specific antigens on the red cells concerned are present in the patient serum. If these red cell antibodies are not present, the reaction will be negative. Attention should be paid to the occurrence of hemolysis when examining tests at any stage. Hemolysis indicates the presence of complement-binding antibodies, which may be responsible for the intravascular destruction of red cells. The presence of possible underlying antibodies should be excluded.

Limitations
Unexpected negative or weak results due to: too vigorous shaking of the tubes during resuspension, interruptions during the test performance or ineffective washing of the red cells (causing neutralisation of the polyspecific anti-human serum or the monospecific anti-human IgG serum by proteins (IgG) and/or complement components still present in the tube). The use of plasma in combination with enzyme treated cells may cause red cells to stick to each other, however, not caused by an antigen/antibody reaction.

References

1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
4. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.