Instructions for use

Sanquin Reagents B.V.
Plesmanlaan 125
1066 CX Amsterdam
The Netherlands

Phone: +31 20 5123599
Fax: +31 20 5123570
Reagents@sanquin.nl
www.sanquin.org/reagents

Cellbind A_1 reagent red cells	REF K7240	IVD CE 0344
Cellbind A_2 reagent red cells	REF K7241	IVD CE
Cellbind B reagent red cells	REF K7242	IVD CE 0344
Cellbind O positive reagent red cells	REF K7243	IVD CE

064_v02 01/2017 (en)

For professional use only

General information

These 0.5% cell suspensions should be used in Cellbind Screen cards (see package insert REF K7000) for the detection of antibodies anti-A and anti-B (A_1 and B reagent red cells) in the serum or plasma of the patient and for the use as positive or negative control (O positive and A_2 reagent red cells).
The inclusion of positive and negative controls with each series of blood group determinations is strongly recommended. The cells are suspended in a special preservation medium. These reagents meet the requirements of the concerned standards and guidelines. Performance characteristics are mentioned in the release documents, which are supplied with the product.

Precautions

For in vitro diagnostic use only. Red cells should be stored at 2–8°C; do not freeze. Leaking or damaged vials should not be used. Red cells (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the vial. Chloramphenicol 0.025%, neomycin sulfate 0.01% and gentamicin 0.001% 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 shelf life. The rate at which antigen reactivity is lost is partially dependent upon individual donor characteristics that are neither controlled nor can be 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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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 procedure

1. Remove cover strip from the required number of columns.
2. Add 40–50 µl of the 0.5% suspension of red cells into the incubation compartment.
3. Add the same volume (40–50 µl) of plasma or serum into the incubation compartment.
4. Immediately introduce cards into the Cellbind Centrifuge (10 minutes). The centrifugation parameters have already been programmed.
5. Read the reactions.

For further details, see package insert of Cellbind Screen: REF K7000.

Interpretation

A positive reaction indicates the presence of the corresponding antibody. A negative reaction indicates the absence of the corresponding antibody. The ABO blood group is determined by the reaction pattern obtained with the various reagents (see table). If the reaction pattern does not correspond with one of the 4 combinations below, then the reason for the discrepant results should be determined prior to assigning an ABO blood group to the patient / donor in question.

Reaction pattern in routine ABO grouping

red cells + blood grouping reagent			serum/plasma + reagent red cells		
anti-A	anti-B	anti-A,B	A_1 cells	B cells	blood group (frequency)
0	0	0	+	+	O (46.7%)[4]
+	0	+	0	+	A (41.7%)[4]
0	+	+	+	0	B (8.6%)[4]
+	+	+	0	0	AB (3.0%)[4]

Limitations
(ABO grouping)
Unexpected positive results with the reagent red cells due to e.g.: pseudoagglutination, presence of other than anti-A and/or anti-B antibodies.
Unexpected negative or weak results with the reagent red cells due to e.g.: the fact that serum or plasma under investigation is from a newborn, a (very) old person or from a patient with hypogammaglobulinemia, chimerism, decreased activity of the reagent red cells.
When strongly haemolytic samples are used, non-specific reactions may occur. If a sample contains fibrin residues, this may cause trapping of non-sensitized cells during centrifugation, resulting in a thin red line on top of the gel matrix.

For further details, see package insert of Cellbind Screen: REF K7000.

References

1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
2. Issit 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. Reid M.E. and Lomas-Francis C.; The Blood Group Antigen Facts Book. Facts Book Series, 1997.
5. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.

Sanquin products are guaranteed to perform as described in the original manufacturer's instructions for use. Strict adherence to the procedures, test layouts and recommended reagents and equipment is essential. Sanquin declines all responsibility arising from any deviation thereof.