

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	
Monospecific anti-human IgG (green)	REF K1124	IVD CE 0344
Monospecific anti-human IgG	REF K1131	IVD CE 0344
042_v03 01/2017 (en)	For professional use only	

Reagents for the detection of IgG antibodies on human red cells or the detection of red cell antibodies in human serum

General information

Monospecific anti-human IgG is prepared by immunising goats with purified Fc fragments of human IgG. For reasons of a visible control on the addition of the monospecific anti-human IgG during the test this product is also supplied as a green coloured reagent. These reagents meet the requirements of the concerned standards and guidelines. Performance characteristics are mentioned in the release documents, which are supplied with the products upon request. The principle of the test is the agglutination technique. These reagents can be used in direct antiglobulin test (DAT), for antibody detection and identification and for compatibility testing (crossmatch) in the indirect antiglobulin test (IAT). The inclusion of a positive control with each series of tests is strongly recommended.

Precautions

For in vitro diagnostic use only. Reagents should be stored at 2–8°C. Leaking or damaged vials may not be used. Reagents (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the vial. Na₃ O.1% (w/v) is used as preservative. Although the sources have been tested for infectious diseases and found negative, the reagent cannot be assumed to be free from infectious agents. Care must be taken in the use and disposal of each container and its contents. Turbidity may indicate microbial contamination. To recognise reagent deterioration, testing of the reagent as part of the laboratory quality control program using appropriate controls is recommended. Waste-disposal, after completion of the test, should be performed according to your laboratory regulations.

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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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

Direct Antiglobulin Test

Tube requirements: round bottom glass tubes; size 75 x 10/12 mm.

1. Prepare a 3–5% cell suspension of red cells to be tested in isotonic saline.
2. Add to a test tube 1 drop of this cell suspension.
3. Wash the tube three times in an excess of isotonic saline. Decant the last wash completely.
4. Add 2 drops of monospecific anti-human IgG and mix well.
5. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
6. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
7. If there is no visible agglutination add 1 drop of Coombs Control Cells and repeat steps 5 and 6; the reaction should now be positive.
If the test remains negative the result is invalid and the test should be repeated.

Indirect antiglobulin test (IAT) with PEG 4000 20%

See package insert **REF** K1159.

Interpretation

A positive reaction (i.e. agglutination) indicates the presence of the corresponding IgG antibodies. A negative reaction (i.e. no visible agglutination) indicates the absence of the corresponding IgG antibodies.

Limitations

Unexpected negative or weak results due to: too vigorous shaking of the tubes during resuspension or ineffective washing of the red cells (causing neutralisation of the monospecific anti-human IgG by proteins (IgG) still present in the tube).

The reagents have been optimised for use by the technique recommended in this package insert. Unless otherwise stated their suitability for use by other techniques must be determined by the user.

False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.

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. 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.