

Instructions for use



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Pelikloon anti-C3d monoclonal	REF K1377 IVD CE
Pelikloon anti-C3c,-C3d monoclonal	REF K1378 IVD CE
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Reagents for the detection of complement components on human red cells

General information

Pelikloon anti-C3d monoclonal and Pelikloon anti-C3c, -C3d monoclonal are produced as culture supernatants from stable hybridoma cell lines as first described by Köhler and Milstein (Nature 1975). 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 the direct antiglobulin test (DAT).

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. NaN₃ 0.1% (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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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 Pelikloon anti-C3d monoclonal or Pelikloon anti-C3c, -C3d monoclonal 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.
Note: the sensitivity of the anti-complement/complement reaction can be increased by incubating the tube for 5 minutes at room temperature (18–25°C) and repeating step 5 and 6 as described above.

Interpretation

A positive reaction (i.e. agglutination) indicates that C3c and/or C3d components are present on the red cells. A negative reaction (i.e. no visible agglutination) indicates the absence of the C3c and/or C3d components.

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 anti-complement antibodies by complement components still present in the tube).

These 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. 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.

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.