Instructions for use

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Pelikloon anti-C^{w} (IgM) monoclonal

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For professional use only

Blood grouping reagent for the detection of the C^{w} antigen on human red cells

General information
Pelikloon anti-C^{w} (IgM) monoclonal blood grouping reagent (clone number is mentioned on the corresponding certificate of analysis/release document and product label) is prepared from culture supernatant from stable hybridoma cell lines as first described by Köhler and Milstein (Nature 1975). This monoclonal reagent contains human IgM antibodies and has been specially selected and developed to provide a reliable alternative to polyclonal reagents. This reagent meets 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 reagent is optimised for use in the spin tube method. The inclusion of positive and negative controls with each series of blood group determinations 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. NaN_3 0.1% (w/v) is used as preservative. 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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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
Spin tube method
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 or in their own plasma or serum.
2. Add to a test tube:
   - 1 drop of Pelikloon reagent
   - 1 drop of the 3–5% cell suspension
   and mix well.
3. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
4. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
5. In case of negative or doubtful test results incubate for 5 minutes at 37°C and repeat step 3 and 4.

Interpretation
A positive reaction (i.e. agglutination) indicates the presence of the C^{w} antigen. A negative reaction (i.e. no visible agglutination) indicates the absence of the C^{w} antigen.

Occurence	Caucasians	Negroids
C^{w} antigen	2%	1%

Limitations
Unexpected positive results due to: pseudoagglutination, autoagglutination, mixed field reaction, the presence of Whartons jelly together with umbilical cord cells.
Unexpected negative or weak results due to: weak antigens, mixed field reaction, decreased activity of the reagent.
Antigen variant cells may produce unexpected positive or negative reactions with samples previously typed with blood grouping reagents of polyclonal or other cell line-derived monoclonal sources. False positive or false negative results may occur through contamination of test materials or any deviation from the recommended technique.
Red cells that have a positive direct antiglobulin test (DAT) produce false positive test result. Use of Pelikloon control monoclonal is recommended for detection of such invalid test results.
Pelikloon monoclonal blood grouping reagents have been optimised for use by the technique(s) recommended in this package insert. Unless otherwise stated their suitability for use by other techniques must be determined by the user.

References

1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
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3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
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5. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.