Instructions for use

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PeliLISS REF K1110 IVD CE

038_v04 07/2019 (en)

For professional use only

Potentiating reagent for serological tests

General information
PeliLISS is a modified low ionic strength solution that has been demonstrated to enhance antibody uptake by red cells. Agglutination of red cells occurs in two stages. The first stage consists of the binding of antibody to antigens on the cells (cell sensitization). The second stage involves the agglutination of the sensitized cells. In some antigen-antibody reactions, the two stages occur almost simultaneously. Others do not continue to the second stage. Visible evidence of cell sensitization, i.e. agglutination, requires the addition of anti-human globulin. PeliLISS, a low ionic strength potentiating medium, enhances the formation of antigen-antibody complexes. This reagent is standardised for use in serological tests according to the procedure described below. The test procedure consists of two phases, which can provide valuable information on the serological characteristics of the antibody. 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, which is based on antigen/antibody reaction. 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. Thimerosal 0,01% is used as preservative. 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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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 procedure
Indirect Antiglobulin Test with PeliLISS
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 (commercial cells should be used as supplied).
2. Add to a test tube:
   - 2 drops of patient serum
   - 1 drop of the 3–5% cell suspension
   - 2 drops of PeliLISS

   and mix well.
3. Incubate the tube in a water bath for 10–30 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.
6. Resuspend the cells completely and wash the red cells three times in an excess of isotonic saline. Decant the last wash completely.
7. Add 2 drops of polyspecific anti-human serum and mix well.
8. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
9. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
10. If there is no visible agglutination add 1 drop of Coombs Control Cells and repeat steps 8 and 9; the reaction should now be positive. If the test remains negative the result is invalid and the test should be repeated.

Interpretation
The presence of agglutination indicates a positive test result. The absence of agglutination indicates that a positive test result could not be detected.
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.

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 by proteins (IgG) still present in the tube).
PeliLISS has 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.
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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.