Instructions for use

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BSA 22% (Bovine Serum Albumin)	REF **K1106**	IVD CE
BSA 30% (Bovine Serum Albumin)	REF **K1107**	IVD CE
037_v04 07/2019 (en)		*For professional use only*

Potentiating reagent for serological tests

General information
Bovine serum albumin (BSA 22% and 30%) are media, which are used as a potentiator in serological tests. The addition of these reagents increases the dielectric constant of the reaction medium, which in turn causes a reduction of the zeta potential of the red cells. This reduction in the negative charge reduces the minimum distance over which red cells can approach each other and allows IgG antibodies to agglutinate the red cells more easily. These reagents are standardised for use in serological tests according to the procedure described below. They have been prepared by fractionating bovine serum. The test procedure consists of three phases. This 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. NaN_3 0.1% (w/v) is used as preservative. Although the bovine serum albumin has 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Blood samples should be withdrawn aseptically with or without the addition of anticoagulants.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 procedure
Indirect Antiglobulin Test with BSA 22% or 30%
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 BSA 22% or 30%

   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. Resuspend the cells and incubate the tube in a water bath for 15–20 minutes at 37°C.
6. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
7. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
8. Resuspend the cells completely and wash the red cells three times in an excess of isotonic saline. Decant the last wash completely.
9. Add 2 drops of Pelikloon polyspecific anti-human serum (REF K1193 or K1194) and mix well.
10. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
11. Resuspend the cells by gentle agitation and read macroscopically for agglutination.
12. If there is no visible agglutination add 1 drop of Coombs Control Cells and repeat steps 10 and 11; 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) and/or complement components still present in the tube).
BSA 22% and 30% 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.