Instructions for use

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Coombs Control Cells strong	REF K1138	IVD CE 0344
Coombs Control Cells	REF K1145	IVD CE 0344

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For professional use only

3% Cell suspensions for the control of the antiglobulin test

General information
The reagent red cells are suspended in a special preservation medium. These reagents meet 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. Reliable results from the (in)direct antiglobulin test in blood group serology are essential. As a result of inadequate washing procedures, serum proteins (IgG) which are still present may neutralise the antiglobulin serum and thus inhibit agglutination. To detect this and other causes of neutralised antiglobulin reagent, Coombs Control Cells should be added to every test tube yielding a negative result. Coombs Control Cells are prepared in accordance with an optimal procedure developed by Sanquin. Coombs Control Cells and Coombs Control Cells strong are IgG sensitised Group O Rhesus D-positive human red cells that have been sensitised in vitro with different amounts of anti-D (IgG) antibodies. Coombs Control Cells strong are manufactured to produce strong agglutination in the presence of active antiglobulin reagents. Coombs Control Cells are prepared to produce less strong agglutination in the presence of active antiglobulin reagents. Coombs Control Cells moderately sensitised with IgG provide a more sensitive and reliable indication of (partial) neutralisation of the antiglobulin reagents. The Coombs Control Cells are washed and resuspended in a special preservation medium and can be added directly to the test tubes.

Precautions
For in vitro diagnostic use only. Reagent red cells should be stored at 2–8°C; do not freeze. Leaking or damaged vials may not be used. Reagent red cells (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the vial. Chlooramphenicol 0.025%, neomycin sulfate 0.01% and gentamicin 0.005% are used as preservatives. Although all blood products are tested for infectious diseases and found negative, the reagents cannot be assumed to be free from infectious agents. Care must be taken in the use and disposal of each container and its contents. If contamination or excessive hemolysis is evident, discard. To recognise deterioration, testing of the reagent red cells 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. As with all reagent red cells, the reactivity of the cells may decrease during the shelf life. The rate at which antigen reactivity (e.g. agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

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
1. To every test tube containing an antiglobulin test with no visible agglutination, add 1 drop of Coombs Control Cells and mix well.
2. Centrifuge for 20 seconds at 1000 rcf or for a time appropriate to the calibration of the centrifuge.
3. Resuspend the cells by gentle agitation and read macroscopically for agglutination; the reaction should now be positive.

Interpretation
A positive reaction (i.e. agglutination) after addition of the Coombs Control Cells indicates that the washing procedure has been performed correctly and that the antiglobulin reagent was working. A negative reaction (i.e. no visible agglutination) indicates that the antiglobulin reagent did not work. A negative result is not reliable and the test must be repeated. The cause of the problem should be investigated and corrected.

Limitations
See interpretation.

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. 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.