

Instructions for use



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MASPAT Indicator Red Cells

REF K1139

IVD CE

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For professional use only

0.3% cell suspension for use in the MASPAT kit

General information

The reagent red cells are suspended in a special preservation medium. 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 a solid phase technique (antigen/antibody reactions). MASPAT Indicator Red Cells are intended for use in the Sanquin MASPAT kit (Monoclonal Antibody Solid-phase Platelet Antibody Test). With this kit platelet antibodies can be detected. MASPAT Indicator Red Cells are added in the last step of the test and are meant to make the presence of the antibodies visible. See also instructions

for the use of the Sanquin MASPAT kit **REF** K1360.

MASPAT Indicator Red Cells are group O red cells which are sensitized with IgG antibodies according an optimal procedure developed by Sanquin. The reagent red cells can be added directly to the test wells after thoroughly mixing.

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. Chloramphenicol 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.

Test procedure

See instructions for the use of the Sanquin MASPAT kit **REF** K1360.

Interpretation

A positive reaction is indicated by adherence of the MASPAT Indicator Red Cells to the platelet monolayer. A weak positive reaction is indicated by adherence of the MASPAT Indicator Red Cells to part of the platelet monolayer. The area of adherence is larger than the negative control. A negative reaction is indicated by a small defined ring or cell button of MASPAT Indicator Red Cells on the bottom of the well.

A (weak) positive reaction indicates the presence of platelet antibodies in the patient serum against donor platelets.

A negative reaction indicates the absence of platelet antibodies in the patient serum.

Limitations

See instructions for the use of the Sanquin MASPAT kit **REF** K1360.

References

See instructions for the use of the Sanquin MASPAT kit **REF** K1360.

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.