

Instructions for Use - rr Screening Cells in CellMedia



IVD



Blood and Transplant

Reagent red cells for the detection of red cell antibodies in patients who have received prophylactic Anti-D

For in vitro diagnostic use only
Product codes: PR108 and PR109
Reagents, NHSBT Liverpool,
14 Estuary Banks, Liverpool L24 8RB
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Intended use

These reagent red blood cells are intended to screen plasma/serum samples for presence of red cell antibodies by serological means using DG GelSystem.

Principles of the examination method

Plasma/serum samples are incubated with reagent red cells to determine the presence of agglutinins in DG Gel system. It is important to detect the presence of clinically significant red cell antibodies in a patients serum/plasma and subsequently identify the specificity of such antibodies in order to ensure that any subsequent transfusion is as free from risk of a red cell transfusion reaction as possible within the limits of the techniques used.

Components

These cells are supplied as a 0.8±0.2% suspension to be used directly from the vial in DG Gel System, in accordance with the manufacturer's package insert.

These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative solution – DG CellMedia solution, which has been formulated to maintain the appropriate physical and chemical characteristics to maintain red cell and red cell antigen integrity to allow detection in the DG Gel system. The solution provides a buffered isotonic medium with essential nutrients for preserving viability and functionality, that contains sodium chloride, phosphate buffer, glucose, glycine, EDTA and preservatives (chloramphenicol 0.17g/L and neomycin sulphate 0.10g/L).

Reagent Preparation

Mix before use.

Storage and shelf life after first opening

Store at 2°- 8°C.

Do not freeze.

Do not use beyond the notified expiry date.

Warnings and precautions

For professional use only.

This screening set must not be used for general antibody screening.

This screening cell set is intended for use with patients who have received prophylactic Anti-D as part of their antenatal care.

For use only with DG Gel System .

For red cells that have been treated with the enzyme papain the following antigens will be absent or reduced: M, N, S, s Fya, Fyb, Ch/Rg, In, JMH, Xga.

Some loss of antigenic expression may occur during the stated shelf life. Since this loss cannot be predicted or controlled and is partly determined by the characteristics of individual blood donations or donors, the recommended conditions of storage and use must be rigidly applied.

Do not use if red cells appear obviously discoloured or haemolysed.

Cells must not be pooled.

The donations used in this product have been tested at source and found negative for the mandatory microbiological tests required by the Guidelines for UK BTS at the time of donation. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. Appropriate care should be taken in the use and disposal of this product.

Primary sample collection, handling and storage

Clotted serum or EDTA plasma samples may be used, usually less than 7 days old, different time scales apply to recently transfused patients.

Examination procedure

For method of use refer to package insert of the system being used. Only this technique should be used. NHSBT cells in CellMedia may be used in place of the DG CellMedia reagents recommended in the package insert.

Control procedure

Each batch of tests should be controlled with suitable positive and negative controls.

Interpretation of results

The presence of agglutination indicates a positive result, meaning that an antibody may be present in the sample and may only be seen against 1 cell of the set and will require further investigation to assign specificity to the reaction seen.

Performance characteristics

The rr (PR108) reagent red cells selected to be used for the detection of antibodies are negative for Wra, and positive for Lub and Kpb unless stated.

The r^r and r^rr subset (PR109) reagent red cells selected to be used for the detection of antibodies are negative for Wra with one of them being positive for Kpa unless otherwise stated.

The antigenic status of these red cells has been determined using, wherever possible, at least two examples of antisera directed against that antigen.

The designation of positive or negative status for a particular antigen relates to the normal expression of that antigen, if an individual cell is known to possess a weak or variant form of an antigen, this is indicated on the profile.

Limitations of the examination procedure

If controls set up with the batch of tests fail to give required results then all tests must be repeated.

Literature references

These reagents comply with:

The requirements of Directive 98/79/EC on in vitro diagnostic medical devices.

The recommendations contained in current version of the Guidelines for the Blood Transfusion Services in the UK.

BCSH Guidelines for compatibility procedures - current version.