Instructions for Use - Panel Cells in CellMedia

CE 0843

NHS Blood and Transplant

Reagent red cells for the identification of red cell antibodies
For *in vitro* diagnostic use only
Product codes: PR162, PR163, PR172 and PR173
Reagents, NHSBT Liverpool,
14 Estuary Banks, Liverpool L24 8RB
Tel 0151 268 7157

Intended use
These reagent red blood cells are intended to be used to test plasma/serum samples to allow identification of red cell antibodies by serological means in the DG Gel system.

Principles of the examination method
Plasma/serum samples are incubated with reagent red cells to determine the presence of agglutinins by direct and/or indirect methods. It is important to detect the presence of clinically significant red cell antibodies in a patient's 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 2-8ºC. Do not freeze.
Do not use beyond the notified expiry date.

Warnings and precautions
For professional use only. Cells must not be pooled.
For use only with DG Gel System..
It is imperative to use accurate, properly calibrated volumetric pipettes in DG Gel Systems to avoid variations which may affect the test outcome.
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 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.
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 in DG Gel System, refer to the package insert of the cards being used; only this technique should be used. NHSBT Reagents ID panels can 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. The pattern of reactions seen should allow identification of antibody present in sample when checked with the antigen profile for the lot of product used. Other confirmatory tests may be required to assign specificity to antibody seen.

Performance characteristics
The 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 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 mendical 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.