Instructions for Use - ABO Grouping Cells in CellMedia

CE 0843

IVD

for use in ABO GROUPING
for *in vitro* diagnostic use only
Product Codes: PR015, PR036 and PR046
Reagents, NHSBT Liverpool,
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NHS Blood and Transplant

Intended use
These reagent red blood cells are intended to be used to test plasma/serum samples to determine ABO group (reverse or serum group). It is important to determine the ABO group correctly 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.

Principles of the examination method
An individual's ABO type is usually determined by testing their red cells with anti-A and anti-B to detect the presence of the A & B antigens and testing their serum or plasma with A and B cells to detect the presence of anti-A and anti-B. Plasma/serum samples are incubated with reagent red cells to determine the presence of agglutinins by direct methods.

Components
These reagents include A1rr, Brr and OR1r cells and may be pooled during manufacture where indicated on the label.
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 vialbility 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.
For use only in DG CellMedia Systems.
It is imperative to use accurate, properly calibrated volumetric pipettes in DG Gel systems to avoid variations which may affect the test outcome.
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 the red cells appear obviously discoloured or haemolysed.
Cells must not be pooled by user.
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 disease. 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 Systems – refer to the package insert of the cards being used; only this technique should be used. NHSBT Reagents ABO cells in CellMedia can be used in place of the DG Gel System reagents recommended in the package insert. Only red cells in CellMedia should only be used with DG Gel Systems.

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. If anomalous ABO results are found, the grouping should be repeated and include both O cells and auto controls.

Performance characteristics
The antigenic status of these red cells has been determined using, wherever possible, at least 2 examples of the antisera directed against that antigen.

Limitations of the examination procedure
If controls set up with the batch of tests fail to give the required results than all tests must be repeated. Deviations from these recommended methods must be validated by the user. If these reagent red cells are used in a proprietary system, the manufacturer's recommended method must be followed.

Literature references
These reagents comply with:
The requirements of Directive 98/79/EC on in vitro diagnostic medical devices.
The recommendations contained in the current Guidelines for the Blood Transfusion Services in the UK.