

Instructions for use - ABO grouping cells in CellStab



IVD

Reagent red cells for use in ABO grouping
for *in vitro* diagnostic use only

Product Codes: PR014, PR035 and PR045

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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 are pooled where indicated on the label.

These cells are supplied as a 0.8±0.2% suspension to be used directly from the vial with BioRad ID cards, 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 – CellStab solution, which has been specially formulated to preserve red cell integrity and antigenicity, consisting of glycine buffered saline, containing sugars, trimethoprim and sulfamethoxazole as preservatives.

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.

For use only with BioRad gel cards.

It is imperative to use accurate, properly calibrated volumetric pipettes in BioRad 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

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 as control with BioRad ABO/Rh blood grouping cards – refer to the package insert of the cards being used; only this technique should be used. NBS Reagents ABO cells in CellStab can be used in place of the BioRad DiaCell reagents recommended in the package insert. Red cells in CellStab should only be used with BioRad gel cards.

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.