



Instructions for use - ABO Cells



Blood and Transplant

IVD

**Reagent red cells for use in ABO & RhD grouping
for in vitro diagnostic use only**
Product Codes: PR012, PR022, PR033, PR034 and PR044
Reagents, NHSBT Liverpool,
14 Estuary Banks, Liverpool L24 8RB
Tel 0151 268 7157

Intended use

These reagent red 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 blood 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 plasma or serum 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 A₁ rr, A₂ rr, B rr, O R₁r and B R₁r cells and are pooled where indicated on the label.

These reagent red cells are supplied as 3.0±0.2% suspension for the A₁ rr, A₂ rr, B rr, B R₁r and as a 3.2±0.2% suspension for the O R₁r to be used directly from the vial.

These cells may be washed and resuspended before use in phosphate buffered saline (PBS) pH 7 or in LISS to a concentration appropriate to the method involved, but must be discarded within 24 hours of preparation. The user is responsible for assuring the strength of cell suspension and the quality of PBS, LISS or any other suspension solution used, and care should be taken to ensure that appropriate serum to cell ratios are maintained in all test systems.

These reagent red cells, prepared from non-remunerated donor blood, are leucodepleted, washed and suspended in Modified Alsevers solution, which has been specially formulated to preserve red cell integrity and antigenicity, containing trisodium citrate (8 g/L), D-glucose (20.0g/L), citric acid monohydrate (0.5g/L) sodium chloride (4.2g/L), inosine (0.938g/L), ATP (0.4g/L), chloramphenicol (0.34g/L) and neomycin sulphate (0.1g/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.

The recommended conditions of storage and use must be rigidly applied.

Do not use if 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.

Chloramphenicol is classified as a carcinogen, neomycin sulphate as an irritant.

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

Tube centrifugation (spin) method

- 1 Add cells to test serum/plasma in 1:1 ratio
- 2 Mix, incubate at RT for 5 minutes then centrifuge
- 3 Read macroscopically and record results

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 cells has been determined using, wherever possible, at least 2 examples of 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 then 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 version of the Guidelines for the Blood Transfusion Services in the UK.