Instructions for Use – Screening Cells

CE 0843

IVD

NHS Blood and Transplant

Reagent red cells for use in antibody detection
For *in vitro* diagnostic use only
Product codes PR101, PR121 and PR124
NBS 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 screen plasma/serum samples for presence of red cell antibodies by serological means.

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.

Components
These cells are supplied as a 3.2±0.2% suspension to be used directly from the vial.
These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative solution – Modified Alsevers solution,which has been specially formulated to preserve red cell integrity and antigenicity, containing trisodium citrate 8g/L, D-glucose 20/0g/L, citric acid monohydrate 0.5g/L, sodium chloride 4.2g/L, inosine0.938g/L, ATP 0.4g/L, chloramphenicol 0.34g/L and neomycin sulphate 0.1g/L.

Reagent Preparation
Mix before use.
These cells may be washed and resuspended before use in phosphate buffered saline (PBS) pH7 or in LISS to the concentration appropriate to the method involved. However they must then be discarded within 24 hours of preparation.The user is responsible for assuring the strength of these cell suspensions, quality of suspension used and ensuring that an appropriate serum:cell ratio is maintained in the test system.

Storage and shelf life after first opening
Store at 2º- 8ºC.
Do not freeze.
Do not use beyond the notified expiry date.

Warnings and precautions
For professional use only.
For red cells that have been treated with the enzyme papain the following antigens wil 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. Chloramphenicol is classed 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
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
Tube method
1. Add 2 volumes of test serum to a labelled tube
2. Add 1 volume of supplied product cells
3. Mix thoroughly and incubate at 37ºC for 45 minutes
4. Wash the cells at least three times
5. Add 2 volumes of anti-human globulin reagent
6. Centrifuge and observe for agglutination

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 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 medical devices
Guidelines for the Blood Transfusion Services in the UK (current version)
BCSH Guidelines for compatibility procedures - current version.