Instructions for use - rr screening cells

CE 0843

IVD

NHS Blood and Transplant

Reagent red cells for the detection of red cell antibodies in patients who have received prophylactic Anti-D
For *in vitro* diagnostic use only
Product codes: PR106 and PR107
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 0.8±0.2% suspension to be used directly from the vial with BioRad 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 which has been specially formulated to preserve red cell integrity and antigenicity, consisting of glycine buffered saline, containing sugars, trimethoprim and sulfamethoxcazol as preservatives.

Reagent Preparation
Mix before use.

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.
This screening set must not be used for general antibody screening.
This screening cell set is intended for use with patients who have received prophylactic Anti-D as part of their antenatal care
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 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.

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. Incubating the patients serum/plasma and Reagents antibody screening cells in accordance with the BioRad ID package insert assists in this aim.

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 rr (PR106) 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 r'r and r"r subset (PR107) reagent red cells selected to be used for the detection of antibodies are negative for Wra with one of them being positive for Kpa unless otherwise 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
The recommendations contained in current version of the Guidelines for the Blood Transfusion Services in the UK.
BCSH Guidelines for compatibility procedures - current version.