

Instructions for use - Panel Cells in CellStab



Blood and Transplant

Reagent red cells for the identification of red cell antibodies

For *in vitro* diagnostic use only

Product codes: PR142, PR143, PR152 and PR153

Reagents, NHSBT Liverpool,

14 Estuary Banks, Liverpool L24 8RB

Tel 0151 268 7157

Intended use

These reagents red blood cells are intended to be used to test plasma/serum samples to allow identification 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 gel 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. It consists of glycine buffered saline, containing sugars, trimethoprim and sulfamethoxazol 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. Cells must not be pooled.

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.

For red cells that have been treated with the enzyme papain, the following antigens will 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 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.

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 patient's 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 NBS Reagents ID panel cells in accordance the BioRad instruction for use assist in this aim.

Refer to the instruction for use of the cards being used; only this technique should be used. NBS Reagents ID panels can be used in place of the ID-Diapanel reagents recommended in the package insert.

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. The pattern of reactions seen should allow identification of antibody present in sample when checked with the antigen profile for the lot of product used. Other confirmatory tests may be required to assign specificity to antibody 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.

The recommendations contained in current version of the Guidelines for the Blood Transfusion Services in the UK.

BCSH Guidelines for compatibility procedures – current version.