Instructions for use – Whole Blood Controls

CE

IVD

NHS Blood and Transplant

Reagent red cells for use as controls on automated blood grouping systems
For *in vitro* diagnostic use only
Product Code: PR051
Reagents, NHSBT Liverpool,
14 Estuary Banks, Liverpool L24 8RB
Tel 0151 268 7157

Intended use
The reagent is intended for use in the control of routine immunohaematology tests on automated grouping and antibody screening systems.

Principles of the examination method
The product has been designed to replicate a patient's sample and so should be run through the system as a routine sample.

Components
These reagent red cells are supplied as a set containing 2 vials.
Vial A will be group A, either Rh D positive or negative and K+ or K- and will contain either anti-D or anti-K.
Vial B will be group B, either Rh D positive or negative and K+ or K- and will contain either anti-D or anti-K. The supplied vials will contain anti-D and anti-K in each lot.
The cells in this product are supplied as 33±3% suspension to be used directly from the vial.
The reagent red cells, prepared from non-remunerated blood donors, are leucodeleted, washed and suspended in Modified Alsevers solution, which has been specially formulated to preverse 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, inosine 0.938g/L, ATP 0.4g/L, chloramphenicolo 0.34g/L, neomycin sulphate 0.1g/L and appropriate antibody.

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.
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.

Examination procedure
This reagent has been validated for use as a control for laboratories performing routine immunohaematology tests on BioRad and Ortho Biovue systems. Its suitability for use by other technologies cannot be quaranteed.

Interpretation of results
Review results obtained against product profile. This product is designed as a control and so only provides an indication that the system is detecting types as given on the profile.

Performance characteristics
The antigenic status of these cells has been determined using, wherever possible, at least two examples of antisera directed against that antigen.

Limitations of the examination procedure
Improper techniques may invalidate the results obtained with this product.
If these reagents red cells are used in a proprietary system, the manufacturer's recommended method must be followed.
Users are advised to validate the reagent's suitability before using with alternative techniques.
False positive or false negative results can occur due to contamination of test material, incorrect reaction temperature, incorrect storage of materials and omission of test reagents.

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**.**