

Whole Blood Controls - Product Insert



IVD

National Blood Service



REAGENT RED CELLS

*For use as controls for routine immunohaematology tests
performed on automated Blood grouping Systems
or in vitro use only
Product Code PR051*

SPECIFICATIONS

- These reagents comply with the recommendations contained in the current Guidelines for the Blood Transfusion Services in the UK
- The materials used in this product may be pooled from two or more donations

PRESENTATION

These reagent red cells, prepared from non-remunerated donor blood, are leucodepleted and suspended in diluted plasma

The plasma is diluted using Modified Alsevers Solution which has been specially formulated to preserve red cell integrity and antigenicity

Modified Alsevers Solution – 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), chloramphenicol (0.34g/L) and neomycin sulphate (0.1g/L)

Warning: chloramphenicol is classed as a carcinogen, neomycin sulphate as an irritant.

- These reagent red cells are supplied as a set containing 2 vials of 5mL volumes of 33% (+/-3%) suspension
- Vial A will be group A, either RhD positive or negative and K+ or K- and will contain either anti-D or anti-K
- Vial B will be group B, either RhD positive or negative and K+ or K- and will contain either anti-D or anti-K

PRECAUTIONS

- For professional use only
- Store at 2° - 8°C
- Do not freeze
- Do not use if obviously discoloured or haemolysed
- Do not use beyond the notified expiry date
- Slight discolouration in the supernatant is normal

Caution: the donations used in this product have been tested at source and found negative for the mandatory microbiological tests required by the 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.

METHOD OF USE

This reagent has been validated for use as a laboratory control for laboratories performing routine immunohaematology tests on Diamed GelStation and Ortho Biovue automated blood group systems and therefore, its suitability for use by other technologies cannot be guaranteed. Users are advised to validate the reagent's suitability before using with alternative techniques.

LIMITATIONS

- Improper techniques may invalidate the results obtained with this product.
- False positive or false negative result can occur due to contamination of test material, incorrect reaction temperature, incorrect storage of materials and omission of test reagents

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