Instructions for Use - Weak Anti-D Control

CE 1434 IVD

For use in controlling antiglobulin tests for *in vitro* diagnostic use only
Product Code: PN046
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NHS Blood and Transplant

Intended use
This reagent has been formulated to contain weak anti-D with a value of 0.09iu ±0.01 suitable for the control of antiglobulin tests.
This reagent can be used to assure the effectiveness of each batch of laboratory tests designed to detect clinically significant red cell antibodies.
This reagent is not suitable for use as an anti-D grouping reagent.

Principles of the examination method
Reagent containing a weak red cell antibody is incubated with red blood cells known to exhibit the appropriate antigen in a test system to show that the system at that time is capable of detecting an antibody/antigen reaction when testing unknown samples by direct or indirect methods.

Components
This reagent is provided as weak anti-D control reagent.
This reagent has been prepared using a diluent containing 30g/L bovine serum albumin from a BSE free source and sodium azide as a bacteriostat at less than 0.1%.

Reagent preparation
Mix before use.
Use reagent as supplied, without addition or dilution.

Storage and shelflife after opening
Store at 2-8ºC.
Do not freeze.
Do not use beyond the notified expiry date.
Protect from contamination.

Warnings and precautions
For professional use only.
The reagent has not been absorbed to remove ABO alloagglutinins.
The reagent may contain weak anti-C and/or E which maybe active in systems using enzyme treated cells.
The recommended conditions of storage and use must be rigidly applied as storage at a temperature significantly above 4ºC may result in a reduction in its efficacy as a control reagent.
The reagent should not be used if turbid, or if a precipitate, gel or particles are present.
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.

Examination procedure
This reagent has been tested using antiglobulin tube and column techniques.

Interpretation of results
The presence of agglutination indicates a positive result. Weak anti-D control must, when used undiluted, give grade 2-4 reaction results with red cells with homozygous antigen expression, otherwise results obtained in that batch of tests are invalid.

Performance characteristics
The absence of other blood group antibodies has been assured using a panel of red cells which bear the following antigens: Le^a, Le^b, K, Kp^a, P_1, C^w, M, N, S, s, Lu^a, Jk^a, Jk^b, Fy^a, Fy^b.
Negative reactions with this panel also exclude the presence of antibodies to antigens having a prevalence of greater than 99%.
Antibodies to low incidence blood group antigens may occur as contaminants and may, on rare occasions, give rise to false positive results.
Group O D+ positive red cells which have been found to be direct antiglobulin test negative should be used with this reagent.

Limitations of the examination procedure
This reagent is not suitable for use as an anti-D grouping reagent or for ensuring that any washing step used in an antiglobulin technique has been adequate. If assurance of a washing phase is needed then a volume of AB serum must be added to the test tube or microplate well containing the anti-D.
Heterozygous D positive cells e.g. R1r may give weaker or occasionally negative reactions against weak anti-D reagents.
Failure to obtain a positive reaction against homozygous D positive cells must be investigated and that batch of tests must be repeated.
Suitability for use in other techniques must be validated by user.
The precise conditions for red cell suspension, ratio, incubation and reading must be identical to those of the batch of tests being controlled.

Literature references
This reagent complies 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
BSH Guidelines for compatibility procedures in blood transfusion laboratories-current version.

EC REP
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