Instructions for use – IgG Coated Cells

NHS Blood and Transplant

CE 0843

IVD

Reagent red cells
for use in the control of the anti-human globulin technique
for *in vitro* diagnostic use only
Product Code: PR092
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 for the control of negative anti-human globulin (AHG) tests and can also be used to monitor the washing efficiency of cell washing centrifuges.

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 4.0±0.2% suspension to be used directly from the vial.
These reagent red cells, prepared from non-remunerated blood donors, are leucodepleted, washed and suspended in a preservative solution – Modified Alsevers solution,which has been specially formulated to preserve 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, chloramphenicol 0.34g/L and neomycin sulphate 0.1g/L.

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
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.
Chloramphenicol is classed as a carcinogen, neomycin sulphate as an irritant.

Control of negative antiglobulin tests

Examination procedure
It is important to ensure that the anti-human globulin test worked correctly as a negative result could incorrectly be assigned where in fact the test mechanism failed

1. Add 1 drop of IgG coated cells to each negative antiglobulin test
2. Centrifuge at 1000rpm for 1 minute or for an equivalent speed and time
3. Read tests macroscopically

Interpretation of results
The IgG coated cells should give a macroscopic reaction with negative antiglobulin tests, when used as recommended
A macroscopic reaction (grade 2-3) indicates the anti human globulin has not been neutralised
All tests with IgG coated cells giving a negative of equivocal result must be considered invalid and the AHG test repeated.

Monitoring efficiency of cell-washing centrifuges

Examination procedure
It is important to ensure that the anti human globulin test is working correctly as a negative result could incorrectly be assigned where in fact the washing procedure has failed

1 Use one tube for each place in the centrifuge head and add to each 1 volume of the IgG coated cells plus 2 volumes of AB serum
2 Run the centrifuge through its normal cycle of 3 or 4 washes
3 Add 2 volumes of AHG reagent (or as recommended in the package insert) mix and centrifuge as per machine instructions
4 Read and record results

Interpretation of results
All tubes should show equal strength 2+ reactions or greater. Failure to do so indicates that the centrifuge is not washing corectly and should be taken out of service until the problem is corrected.

Performance characteristics
In both procedures an unequivocal 2-3 grade viewed macroscopically should be regarded as proof that test mechanism was working or that the centrifuge washing cycle was adequate for AHG test to work effectively.

Limitations of the examination procedure
If tests set up to control 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
Guidelines for the Blood Transfusion Services in the UK (current version)