Instructions for Use - AB Serum

CE 1434 IVD

Reagent for use as a negative control in antibody detection.
For *in vitro* diagnostic use only
Product Code: PN061
NHSBT Reagents,
14 Estuary Banks, Liverpool
L24 8RB
Tel 0151 268 7157

NHS Blood and Transplant

Intended use
This reagent has been formulated as a negative control in antibody detection by antiglobulin and enzyme techniques.

Principles of the examination method
AB serum is incubated with red blood cells in a test system to show when testing unknown samples by direct or indirect methods.

Components
This reagent is provided as AB serum which has been sterile filtered and contains sodium azide as a bacteriostat at less than 0.1%.
This reagent has been prepared from a pool of human AB serum or defibrinated plasma and screened to ensure the absence of antibodies to major blood group antigens and rouleaux inducing properties at ambient temperature, at 37ºC papain techniques, by LISS tube and BioRad gel antiglobulin techniques.

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

Storage and shelf life 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 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 discoloured.
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.
This reagent should not be used in automated antibody quantitation systems.

Examination procedure
This AB serum can be used to control standard antiglobulin and enzyme techniques as described in the current 'Guidelines for the Blood Transfusion Services in the UK and in current BCSH Guidelines for compatibility procedures in blood transfusion laboratories.

Interpretation of results
The presence of agglutination indicates a positive result.

Performance characteristics
A positive result obtained with red cells against AB serum in a test system must be investigated.

Limitations of the examination procedure
If controls set up with the batch of tests fail to give the required results all tests must be repeated.
Repeated failure to obtain a negative reaction of AB serum versus test or control red cells must be investigated.
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
Quality First International OÜ,Laki 30,12915 Tallinn, Estonia