

Instructions for use - AB Serum



IVD



Blood and Transplant

Reagent for use as a negative control in antibody detection
for *in vitro* diagnostic use only

Product Code: PN061

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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 37°C 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 2-8°C.

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 4°C 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 results.

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 then 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

BCSH Guidelines for compatibility procedures in blood transfusion laboratories-current version.