



Consult instructions for use



Manufacturer

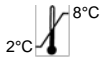


Product Code

ALBAclone® Anti-S

BLOOD GROUPING REAGENT Monoclonal / Indirect Agglutinin

REF Z182



INTRODUCTION

Anti-S and anti-s were described in 1947 and 1951 respectively and define a pair of alleles on the long arm of chromosome 4. The S/s locus is closely linked to the M/N locus and consequently, like the CDE antigens in the Rhesus System, the MNSs genetic contribution from each parent is inherited as a haplotype eg, MS, NS etc.

Ss antigens are carried on a red cell glycoprotein, glycoporphorin B, where they are characterised by a single amino acid substitution at position 29. Methionine is responsible for S antigen expression, threonine for s antigen expression.

Ss antigens are generally destroyed when red cells are exposed to papain, bromelain or ficin. Trypsin generally has no adverse effect.

The phenotype S-s- is extremely rare in whites but occurs in approx 1.5% of American blacks. Complexities within the MNS system also produce a number of phenotypes in which S/s expression may be modified.

INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2°C– 8°C)



In vitro diagnostic medical device

INTENDED PURPOSE

The Anti-S reagent is for the *in vitro* detection and identification of human S positive red blood cells by indirect agglutination.

REAGENT DESCRIPTION

The main component of this reagent is derived from the *in vitro* culture of the IgG secreting human/mouse heterohybridoma P3S13JS123.

The diluent formulation contains BSA and <0.1% sodium azide.

The volume delivered by the reagent dropper bottle is approximately 40µl; bearing this in mind, care should be taken to ensure that appropriate serum: cell ratios are maintained in all test systems.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

STORAGE CONDITIONS

The reagent should be stored at 2°C - 8°C. Do not use if turbid. Do not dilute. The reagent is stable until the expiry date stated on the product label.

PRECAUTIONS FOR USE AND DISPOSAL

This reagent contains <0.1% sodium azide. Sodium azide may react with lead and copper plumbing to form explosive compounds. If discarded into sink, flush with a large volume of water to prevent azide build-up.

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

This reagent is for *in vitro* professional use only

SPECIMEN COLLECTION AND PREPARATION

Specimens should be collected by aseptic technique with or without an anticoagulant. The specimen should be tested as soon as possible after collection. If testing is delayed, the specimen should be stored at 2°C - 8°C. Blood specimens exhibiting gross haemolysis or contamination should not be used. Clotted samples or those collected in EDTA should be tested within seven days from collection. Donor blood stored in citrate anticoagulant may be tested until the expiry date of the donation.

TEST PROCEDURES

This reagent has been standardised for use by the technique described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells suitable for the control of Anti-S
- Polyspecific anti-human globulin reagent
- 12 x 75mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUE

LISS, 37°C Indirect Antiglobulin

- Add 1 volume of blood grouping reagent to a 12 x 75mm glass tube.
- Add 1 volume of 5% LISS suspended cells.
- Mix the test well and incubate for 10 minutes at 37°C.
- Wash the test 4 times with a large excess of PBS pH 7.0 ± 0.2 (eg 4ml of PBS per 12 x 75mm tube).

NOTE: (i) allow adequate spin time to sediment the red cells.
(ii) make sure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.

- Add two drops of polyspecific anti-human globulin reagent to each tube.
- Mix thoroughly.
- Centrifuge at 1000g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

INTERPRETATION OF RESULTS

Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL

Quality control of reagents is essential and should be performed with each series of groups and with single groups. As a minimum a positive and a negative control should be used.

Ss red cells should be used as a positive control
ss red cells should be used as a negative control

PERFORMANCE LIMITATIONS

Tube tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

In tube tests it is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

The expression of certain red cell antigens may diminish in strength during storage, particularly in EDTA and clotted samples. Better results will be obtained with fresh samples.

Direct antiglobulin test positive samples will react by the indirect antiglobulin test irrespective of their S status.

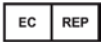
False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

UK frequencies: SS 11%; Ss 44%; ss 45%

DATE OF ISSUE

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For further information or advice please contact your local distributor.



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INSTRUCTIONS FOR USE

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