



ALBAcheck® - BGS High Titre Controls Kit

REF Z257

INTRODUCTION

ALBAcheck®-BGS is a registered trademark for a group of products manufactured by Alba Bioscience for use as controls in blood group serology tests.

High titres of anti-A, anti-B and/or anti-A, B antibodies can be found in blood products derived from group O donors. Haemolytic transfusion reactions can occur in non-group O patients when given these high-titre products. As a result, screening for high-titre donors should be routinely carried out within each donation testing laboratory. The UKBTS guidelines recommend the use of high-titre controls. These controls should give positive and negative reference points when diluted in the same test system as donor samples. ALBAcheck®-BGS High Titre Controls Kit contains two positive and two negative controls.

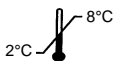
INTERPRETATION OF LABEL SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)



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

IVD

In vitro diagnostic medical device



Harmful



Consult instructions for use

INTENDED PURPOSE

The kit is intended to be used as a control for the routine screening of blood donations for the presence of high titre anti-A and anti-B.

REAGENT DESCRIPTION

The main components of this kit are derived from the *in vitro* culture of mouse hybridomas LA2, that secretes IgM anti-A and LB2 that secretes IgM anti-B.

The formulation also contains 1g/l sodium azide.

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

STORAGE CONDITIONS

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

PRECAUTIONS FOR USE AND DISPOSAL

This kit contains 0.1% sodium azide (EC No.247-852-1) and is classified as harmful. R22 Harmful if swallowed.

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.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.

This reagent is for *in vitro* professional use only.

TEST PROCEDURES

General Information

When diluted 1:128 in PBS, the positive control will give a positive test result and the negative control will give a negative test result when tested against group A, B and AB red blood cells.

Note: The negative control contains anti-A and anti-B which may be detectable at a 1:64 dilution in the manual tube technique, therefore in some automated techniques, a 1:128 equivalent dilution may yield positive results.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- Reagent red cells A, B or AB

RECOMMENDED TECHNIQUES

When used for the control of high titre anti-A and anti-B screening, the control reagent should be substituted for donor plasma and used in accordance with routine validated laboratory procedures.

INTERPRETATION OF RESULTS

When used by the methods described above:

Agglutination = positive test result
No agglutination = negative test result

QUALITY CONTROL

This is a quality control reagent and its satisfactory performance when used by the recommended techniques represents an adequate level of control.

PERFORMANCE LIMITATIONS

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.

The reagent should be discarded within 14 days after opening.

THIS REAGENT SHOULD ONLY BE USED IN THE APPLICATION DESCRIBED AND IS NOT SUITABLE FOR ABO GROUPING

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For further information or advice please contact your local distributor.



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