



ALBAcheck® - BGS AlbaSure Sensitivity Control Kit

REF Z250 **CE**
1434

THIS REAGENT SHOULD ONLY BE USED IN THE APPLICATIONS DESCRIBED AND IS NOT SUITABLE FOR GROUPING PURPOSES.

INTERPRETATION OF LABEL SYMBOLS

- LOT** Batch code
- Use by (YYYY-MM-DD)
- Storage temperature limitation (2– 8 °C)
- IVD** *In vitro* diagnostic medical device
- Consult instructions for use
www.quotientbd.com
- Manufacturer
- REF** Product Code

INTRODUCTION

There are many variables that can affect the outcome of antiglobulin tests and consequently adequate control is a fundamental consideration. This product has been developed for use as sensitivity controls to confirm that the technique as performed is capable of detecting weak IgG antibodies.

INTENDED PURPOSE

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit is intended for use as a sensitivity control of antiglobulin tests.

REAGENT DESCRIPTION

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit Anti-K, Anti-c and Anti-E have been prepared from plasma collected from blood donors. Each individual donation contains IgG antibodies of the required specificity. Some donations may contain other IgG antibodies as minor contaminants. Conversion to serum was achieved by the addition of calcium chloride and, when required, thrombin. Excess calcium was removed by the addition of sodium oxalate. The main component of the Anti-S reagent is derived from the *in vitro* culture of the IgG secreting human/mouse heterohybridoma P3S13JS123. The diluent formulation contains BSA and all vials contain 1 g/L sodium azide.

- Vial 1 - Anti-S (weak)
Vial 2 - Anti-K (weak)
Vial 3 - Anti-c (weak)
Vial 4 - Anti-E (weak)

STORAGE CONDITIONS

The reagent should be stored at 2–8 °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 buildup.

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.

TEST PROCEDURES

General Information

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit has been standardised for use in Column Agglutination Technology (CAT) test systems. Suitability for use in other techniques cannot be guaranteed.

Test Procedure

Strictly follow the test procedures described in the Instructions for Use provided by the instrument/card manufacturer.

INTERPRETATION OF RESULTS

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.

SPECIFIC PERFORMANCE CHARACTERISTICS

In performance evaluation studies ALBAcheck®-BGS AlbaSure Sensitivity Control Kit was tested against well characterised red blood cell samples from commercial panels. The performance of ALBAcheck®-BGS AlbaSure Sensitivity Control Kit showed 100% concordance with the expected test outcome based on the antigen profile of the red blood cells used.

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For further information or advice please contact your local distributor.



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