



# ALBAcheck® - BGS AB Serum (Human)

**REF** Z281



## INTERPRETATION OF LABEL SYMBOLS



Batch code



Use by (YYYY-MM-DD)



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



*In vitro* diagnostic medical device



Consult instructions for use

[www.quotientbd.com](http://www.quotientbd.com)



Manufacturer



Product Code

## INTRODUCTION

AB Serum has various applications in blood group serology. This product can be used as a diluent in certain procedures or as an inert control.

## INTENDED PURPOSE

ALBAcheck®-BGS AB Serum is intended for use as a diluent or inert control in immunohaematology.

## REAGENT DESCRIPTION

This reagent has been prepared from plasma collected from blood donors. Conversion to serum was achieved by the addition of calcium chloride and where necessary thrombin. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 1 g/L 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 2-8 °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

AB Serum has various applications in blood group serology. Users are advised to carefully confirm reagent suitability before use in specific procedures.

## SPECIFIC PERFORMANCE CHARACTERISTICS

In performance evaluation studies ALBAcheck®-BGS AB Serum was tested against well characterised red blood cells from commercial panels. The performance of ALBAcheck®-BGS AB Serum showed 100% concordance with the expected test outcomes.

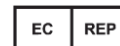
## PERFORMANCE LIMITATIONS

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

## DATE OF ISSUE

2019-12-17

For further information or advice please contact your local distributor.



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## INSTRUCTIONS FOR USE

Instructions for Use are available on Quotient website at [www.quotientbd.com](http://www.quotientbd.com) or can be requested from your Local Distributor, by providing the relevant Product Code stated on product labels and Instructions for Use supplied with the product.

## HASZNÁLATI ÚTMUTATÓ

A használati útmutatók elérhetők a Quotient honlapján, [www.quotientbd.com](http://www.quotientbd.com), illetve igényelhetők a helyi forgalmazótól a vonatkozó termék kód megadásával, mely a termék címkéjén és a termékhez mellékelt használati útmutatóban található.