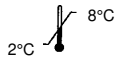




# ALBACheck® - BGS AB Serum (Human)

**REF** Z281



**IVD**



## INTERPRETATION OF LABELLING 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](http://www.quotientbd.com)



Manufacturer

**REF**

Product Code

## INTENDED USE

ALBACheck®-BGS AB Serum is intended for use as a diluent or inert control in immuno-haematology.

The product is intended for professional use in immuno-haematology testing environments.

## SUMMARY AND EXPLANATION

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.

## PRINCIPLE OF THE PROCEDURE

The procedures used with these reagents are based on the principle of agglutination. Normal human red blood cells will agglutinate in the presence of antibody directed against antigens on those red blood cells. No agglutination indicates the absence of the demonstrable antigen or antibody. This reagent does not contain any known blood group antibodies and should not lead to red blood cell agglutination.

## REAGENTS

This reagent has been prepared from plasma collected from blood donors. Conversion to serum was achieved by the addition of calcium chloride. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 0.1% (w/v) sodium azide.

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

## WARNINGS AND PRECAUTIONS

For *in vitro* professional use only.  
Do not use if turbid.

Do not dilute.

Do not use beyond the notified expiry date.

**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 contains 0.1% (w/v) 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.

## STORAGE CONDITIONS

The reagent should be stored at 2-8 °C.

## MATERIALS

### Materials provided

- ALBACheck®-BGS AB Serum (Human)

### Materials required but not provided

Materials dependent upon test to be performed. Refer to validated procedures and/or reagent instructions for use.

## PROCEDURE

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

When using automated blood typing test platforms, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

## QUALITY CONTROL

This is a quality control reagent. Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

## INTERPRETATION OF RESULTS

Agglutination	=	positive test result
No agglutination	=	negative test result

## LIMITATIONS

Laboratories must validate the use of the product on their selected immuno-haematology test platforms and in their own laboratory environment.

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.

## SPECIFIC PERFORMANCE CHARACTERISTICS

ALBACheck®-BGS AB Serum is released following satisfactory Quality Control testing by the manufacturer. This is performed using manual tube serology and Bio-Rad ID-System and Ortho BioVue manual column agglutination techniques with materials selected appropriate for the attribute under test to demonstrate that the product does not contain any known blood group antibodies and should not lead to red blood cell agglutination when used in these techniques.

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.

#### DATE OF ISSUE

2024-10

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 termékkód megadásával, mely a termék címkéjén és a termékhez mellékelte használati útmutatón található.