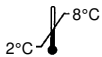




# ALBAcheck® - BGS Reagent Control for Anti-D

**REF** Z271



**IVD**

**CE**  
1434

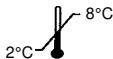
## INTERPRETATION OF LABEL SYMBOLS

**LOT**

Batch code



Use by (YYYY-MM-DD)



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

**IVD**

*In vitro* diagnostic medical device



Consult instructions for use

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



Manufacturer

**REF**

Product Code

## INTRODUCTION

As some monoclonal Anti-D reagents are potentiated for use, it is essential to use a reagent control. This reagent is designed to be used as a negative control in conjunction with the following Quotient Anti-D products: Z031, Z039, Z041.

## INTENDED PURPOSE

ALBAcheck®-BGS Reagent Control for Anti-D is intended for use as a negative control in conjunction with Quotient monoclonal Anti-D reagents.

## REAGENT DESCRIPTION

This reagent is formulated in a similar manner to Quotient monoclonal Anti-D reagents (Product No: Z031, Z039, Z041). The reagent also contains EDTA and 1 g/L 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.

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 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.

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

## TEST PROCEDURES

### General Information

ALBAcheck®-BGS Reagent Control for Anti-D should be substituted for, and used by the recommended techniques for the monoclonal Anti-D reagent being controlled.

### QUALITY CONTROL

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

### SPECIFIC PERFORMANCE CHARACTERISTICS

In performance evaluation studies ALBAcheck®-BGS Reagent Control for Anti-D was tested against well characterised red blood cells.

The performance of ALBAcheck®-BGS Reagent Control for Anti-D showed 100% concordance with the expected test outcomes.

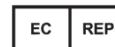
## PERFORMANCE LIMITATIONS

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

2024-05

For further information or advice please contact your local distributor.



**Emergo Europe B.V.**  
Westervoortsedijk 60  
6827 AT, Arnhem  
The Netherlands



Alba Bioscience Limited  
James Hamilton Way  
Penicuik  
EH26 0BF, UK

Tel No: +44 (0) 131 357 3333  
Fax No: +44 (0) 131 445 7125  
E-Mail: [customer.serviceEU@quotientbd.com](mailto:customer.serviceEU@quotientbd.com)

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Z271P1/08

## 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.

## ISTRUZIONI PER L'USO

Le istruzioni per l'uso son disponibili sul sito Web di Quotient, [www.quotientbd.com](http://www.quotientbd.com), o possono essere richieste al proprio distributore locale fornendo il codice del prodotto indicato sulle etichette del prodotto e nelle istruzioni per l'uso fornite con il prodotto.

## ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ

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