

ALBCheck® - BGS Reagent Control for Anti-D

REF Z271



Consult instructions for use



Harmful



Manufacturer



Product Code

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 and omission of test reagents.

DATE OF ISSUE

15 September 2013

INTENDED PURPOSE

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

REAGENT DESCRIPTION

This reagent is formulated in a similar manner as Alba Bioscience's monoclonal Anti-D reagents (Product No's: Z031, Z036, Z039, Z041). The reagent also contains EDTA and 1g/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°C - 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 (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. This reagent is for *in vitro* professional use only.

TEST PROCEDURES

General Information

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



INTRODUCTION

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

As some monoclonal Anti-D reagents supplied by Alba Bioscience are formulated for use by slide techniques it is essential to use a reagent control.

This reagent is designed to be used as a negative control in conjunction with the following Anti-D products: Z031, Z036, Z039, Z041.

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

For further information or advice please contact your local distributor.



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