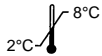




ALBAcheck® - BGS Reagent Control for Anti-D

REF Z271



IVD

CE
1434

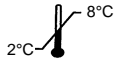
INTERPRETATION OF LABEL SYMBOLS

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



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, Z036, 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, Z036, 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

2019-12-23

For further information or advice please contact your local distributor.

EC **REP**

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