

# ALBACheck® - BGS Reagent Control for Anti-D

**REF** Z271U

**CAUTIONS: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER.**

## INTERPRETATION OF LABEL SYMBOLS



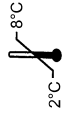
Batch code



Use by (YYYY-MM-DD)



Product code



Storage temperature limitation (2–8 °C)



*In vitro* diagnostic medical device



Consult instructions for use

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



Manufacturer

## INTRODUCTION

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

This reagent is designed to be used as a negative control in conjunction with Alba Bioscience Limited monoclonal Anti-D reagents.

## PRINCIPLE OF THE TEST

Certain tests performed on unwashed samples (e.g. cord), direct antiglobulin test positive samples, or samples stored and tested at 18 °C or below, may exhibit false positive reactions due to the potentiators used in the formulation of Alba Bioscience Limited Anti-D reagents. To control false

positive reactions, the reagent control should be substituted for the blood grouping reagent in the procedure chosen for use. If the control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made.

## INTENDED PURPOSE

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

## REAGENT DESCRIPTION

This reagent is formulated in a similar manner as Alba Bioscience Limited monoclonal Anti-D reagents. The reagent also contains EDTA and 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.

## 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% (w/v) sodium azide. Sodium azide may be toxic if ingested and 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.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.

**This product has components (dropper bulbs) containing dry natural rubber.** This reagent is for *in vitro* diagnostic 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. The reagent should be warmed to room temperature prior to use.

## INTERPRETATION OF RESULTS

If a positive result is obtained with ALBACheck® - BGS Reagent Control for Anti-D, this will invalidate the test result obtained with the respective Alba Bioscience Limited monoclonal Anti-D reagent and the red blood cells.

## 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.

## SPECIFIC PERFORMANCE CHARACTERISTICS

Prior to release, each lot of ALBACheck® - BGS Reagent Control for Anti-D is tested by FDA recommended methods against a panel of antigen-positive red blood cells to ensure negative reactivity.

## BIBLIOGRAPHY

Technical Manual, 18<sup>th</sup> ed. Bethesda, MD: American Association of Blood Banks, 2014.

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