**ALBAcheck® - BGS Reagent Control for Anti-D**

**Caution:** The absence of all viruses has not been determined. This product has components (dropper bulbs) containing dry natural rubber.

**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. As monoclonal Anti-D reagents supplied by Alba Bioscience are formulated for use by slide techniques, a reagent control should be used. This reagent is designed to be used as a negative control in conjunction with the following Anti-D products: Z031U, Z036U, Z039U, Z041U.

**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 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 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: Z031U, Z036U, Z039U, Z041U). 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 DISPOSL**

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 build-up.

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, e.g. 20–30 °C, 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 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**


**DATE OF ISSUE**

13 May 2015

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