








ALBAcheck® - BGS Reagent Control for Anti-D

This insert refers to product code 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)
	Storage temperature limitation (2°C–8°C)
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Harmful
	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.

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 (eg 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 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.

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% (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, 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

Technical Manual. 16th ed. Bethesda, MD: American Association of Blood Banks, 2008.

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