

ALBAcheck® - BGS Monoclonal Control

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)
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use www.alivedx.com
	Manufacturer
	Rx only

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 blood grouping reagents, where referenced in the reagent IFU.

PRINCIPLE OF THE TEST

False positive test results are rarely seen with low-protein reagents. Unexpected reactivity may be exhibited due to the potentiators used in the formulation of Alba Bioscience Limited monoclonal blood grouping reagents. False positive agglutination may be due to a positive direct antiglobulin test

(DAT), cold agglutinins, or abnormal serum proteins. If false positive results are suspected, or local regulations require, and a control test for spontaneous agglutination is desired, ALBAcheck® - BGS Monoclonal Control (Z271U) may be substituted for the blood grouping reagent in the testing procedure. A negative reaction would serve as an appropriate control. If the control test gives a positive reaction, a valid interpretation of the results obtained in red blood cell testing cannot be made without further investigation.

INTENDED PURPOSE

ALBAcheck® - BGS Monoclonal Control is intended for use as a negative control in conjunction with Alba Bioscience Limited monoclonal blood grouping reagents (where referenced in the reagent IFU).

REAGENT DESCRIPTION

This reagent is formulated in a similar manner as Alba Bioscience Limited monoclonal blood grouping 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 contains material 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 Monoclonal Control should be substituted for, and used by, the recommended techniques for the monoclonal blood grouping 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 Monoclonal Control, this will invalidate the test result obtained when testing red blood cells with the respective Alba Bioscience Limited monoclonal blood grouping reagent.

PERFORMANCE LIMITATIONS

Unexpected reactivity 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 Monoclonal Control is tested by procedures to verify its intended use as a control for low protein blood grouping reagents.

Comparator Study Results

During comparator studies performed at Alba Bioscience Limited, blood samples were tested with ALBAcheck® - BGS Monoclonal Control as follows:

Monoclonal Control	Trial/Comparator Reagent	Comparator Reagent		
		Positive	Negative	Total
Trial Reagent	Positive	5	0	0
	Negative	0	100	100
	Total	5*	100	105
Positive Percentage Agreement				100.0
Negative Percentage Agreement				100.0

* Five DAT positive reagent red blood cell samples reported expected positive results following addition of AHG in IAT.

Reactivity with Spontaneously Agglutinating Samples

Positive reactivity has been observed with spontaneously agglutinating samples (both naturally occurring and simulated samples) and ALBAcheck® BGS Monoclonal Control using different test methods.

Test Method	Results from testing spontaneously agglutinating samples and ALBAcheck® BGS Monoclonal Control
Immediate Spin	Positive results with 12/13 samples
15 min, 18–24 °C	Positive results with 13/13 samples
15 min, 37 °C	Positive results with 7/9 samples
30 min, 37 °C	Positive results with 1/4 samples

BIBLIOGRAPHY

Technical Manual. 19th ed. Bethesda, MD: American Association of Blood Banks, 2017.

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