QUOTIENT

ALBAcheck® - BGS SIMULATED WHOLE BLOOD CONTROLS

REF Z489

CE 1434

INTERPRETATION OF LABEL SYMBOLS

LOT	Batch code
	Use by (YYYY-MM-DD)
2°C 8°C	Storage temperature limitation (2-8 °C)
IVD	*In vitro* diagnostic medical device
www.quotientbd.com	Consult instructions for use
REF	Product Code
	Manufacturer

INTENDED PURPOSE

ALBAcheck®-BGS Simulated Whole Blood Controls are intended for use as ABO and RhD controls for automated blood grouping systems. Also suitable for antibody screening controls.

INTRODUCTION

The purpose of daily quality assurance in the blood bank is to confirm the reliability of the test system. The test system includes reagents, test procedures and equipment. Testing known samples is an accepted method of quality control. If expected test results are observed, procedures are being performed accurately and reagents and equipment are performing properly. If unexpected results are observed, the problem may be due to improper test performance, faulty equipment, contamination or deterioration of reagents. The source of the problem should be determined and resolved before patient test results are reported.

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

PRINCIPLE OF THE PROCEDURE

The procedures used with these reagents are based on the principle of agglutination. Normal human red blood cells will agglutinate in the presence of antibody directed against antigens on those red blood cells. No agglutination indicates the absence of the demonstrable antigen or antibody.

The simulated whole blood controls provided in ALBAcheck®-BGS Simulated Whole Blood Controls confirm the reactivity of the reagents used for ABO, RhD and antibody screening and reverse grouping reagent red blood cells.

REAGENT DESCRIPTION

ALBAcheck®-BGS Simulated Whole Blood Controls have been prepared from red blood cells collected from blood donors. Each individual donation contains the appropriate ABO, Rh and K blood group antigens and also the appropriate ABO blood group antibodies and other irregular antibodies.

The concentration of red cells in each of the samples has been adjusted to 15±2%. The red cells are suspended in a preservative solution to retard haemolysis and bacterial contamination.

Vial 1 - Group A, R_1R_1, K positive containing anti-B.
Vial 2 - Group B, R_1R_2, K negative containing anti-A and anti-K.
Vial 3 - Group O, R_2R_2, K negative containing anti-A and anti-B.
Vial 4 - Group AB, rr, K negative containing anti-D.

PRECAUTIONS FOR USE AND DISPOSAL

The preservative solution has been specially formulated to preserve red cell integrity and antigenicity and contains the following components - trisodium citrate, citric acid, dextrose, inosine, neomycin sulphate (0.103 g/L) and chloramphenicol (0.349 g/L).

Chloramphenicol is classified as a carcinogen and neomycin sulphate is classified as an irritant.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2, ANTI-HCV AND SYPHILIS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS DISEASE. APPROPRIATE CARE SHOULD BE TAKEN IN THE USE AND DISPOSAL OF THIS PRODUCT.

This reagent is for *in vitro* diagnostic use only

STORAGE CONDITIONS

Do not transfer these reagents to another container as this could result in spillage or contamination. Store at 2-8 °C. Do not use if obviously discoloured or haemolysed. Do not use beyond the notified expiry date. Slight discolouration in the supernatant is normal. After opening the vial the product can be stored under proper storage conditions (2-8 °C) for 14 days.

TEST PROCEDURES

General Information

When using automated blood typing test platforms, follow the procedures that are contained in the operator's manual provided by the device manufacturer.

ALBAcheck®-BGS Simulated Whole Blood Controls are intended to simulate normal blood samples. The samples contained in the kit must be used at room temperature (18-25 °C) and should be tested by following standard procedures in accordance with the Instructions for Use accompanying each reagent used routinely.

ALBAcheck®-BGS Simulated Whole Blood Controls are suitable for use as controls for automated blood typing test platforms.

Materials provided

- ALBAcheck®-BGS Simulated Whole Blood Controls

Additional Material and Reagents Required

Please refer to device manufacturer's instructions.

QUALITY CONTROL

This is a quality control reagent and its satisfactory performance when used by the recommended techniques represents an adequate level of control.

INTERPRETATION OF RESULTS

The following table illustrates the expected results in tests with ALBAcheck®-BGS Simulated Whole Blood Controls and routine blood bank reagents.

Component of ALBAcheck®-BGS Simulated Whole Blood Controls	Reagent Under Test	Expected Test Results*	Reagent Under Test	Expected Test Results*
Vial 1	Anti-A	+	Anti-D	+
	Anti-B	0	Anti-C	+
	Anti-A,B	+	Anti-E	0
	A_1 cells	0	Anti-c	0
	A_2 cells	0	Anti-e	+
	B cells	+	Anti-K	+
	O cells	0		
	Screening cell 1	0		
	Screening cell 2	0		
	Screening cell 3	0		
Vial 2	Anti-A	0	Anti-D	+
	Anti-B	+	Anti-C	+
	Anti-A,B	+	Anti-E	+
	A_1 cells	+	Anti-c	+
	A_2 cells	+	Anti-e	+
	B cells	0	Anti-K	0
	O cells	0		
Dependent on antigen profile	Screening cell 1			
	Screening cell 2			
	Screening cell 3			
Vial 3	Anti-A	0	Anti-D	+
	Anti-B	0	Anti-C	0
	Anti-A,B	0	Anti-E	+
	A_1 cells	+	Anti-c	+
	A_2 cells	+	Anti-e	0
	B cells	+	Anti-K	0
	O cells	0		
	Screening cell 1	0		
	Screening cell 2	0		
	Screening cell 3	0		
Vial 4	Anti-A	+	Anti-D	0
	Anti-B	+	Anti-C	0
	Anti-A,B	+	Anti-E	0
	A_1 cells	0	Anti-c	+
	A_2 cells	0	Anti-e	+
	B cells	0	Anti-K	0
	O cells	0		
Dependent on antigen profile	Screening cell 1			
	Screening cell 2			
	Screening cell 3			

*Discrepant results must be investigated further.

PERFORMANCE LIMITATIONS

Improper techniques may invalidate the results obtained with this product.

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.

Individual laboratory procedures may affect the final reaction strength observed in tests performed with ALBAcheck®-BGS Simulated Whole Blood Controls.

SPECIFIC PERFORMANCE CHARACTERISTICS

Each cell sample is shown to have a negative direct antiglobulin test.

When properly stored and used according to standard procedures, these reagents will demonstrate the appropriate antigens / antibodies specified in the reagent description.

The Procedure and Interpretation of Results must be followed closely to ensure the accuracy of the test results. Each laboratory should have a program that will train personnel on the proper use and handling of the product.

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For further information or advice please contact your local distributor.

EC REP

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