QUOTIENT

ALBAcheck® - BGS
SIMULATED WHOLE BLOOD CONTROLS

REF Z489

CE 1434

INTERPRETATION OF LABELLING 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 USE

ALBAcheck®-BGS Simulated Whole Blood Controls are intended to simulate whole blood samples. These qualitative controls have been prepared from red blood cells donated by blood donors. Each vial contains known ABO, Rh and K blood group antigens plus known ABO and irregular blood group antibodies. The product may, therefore, be suitable for use as controls on both manual and automated immunohaematology test platforms when validated by the user.

The product is intended for professional use in immunohaematology testing environments.

SUMMARY AND EXPLANATION

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.

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.

Simulated whole blood controls confirm the reactivity of the reagents used for ABO, Rh and K antigen typing plus the reagent red blood cells used for antibody screening and reverse grouping.

REAGENT DESCRIPTION

ALBAcheck®-BGS Simulated Whole Blood Controls have been prepared from red blood cells collected from blood donors. Each individual vial contains known ABO, Rh and K blood group antigens plus ABO and irregular blood group antibodies listed below.

Red blood cells are of human origin. ABO and Anti-D antibodies are of monoclonal origin and Anti-K antibodies are of polyclonal origin.

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.

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

WARNINGS AND PRECAUTIONS

For *in vitro* diagnostic use only.
Do not use if obviously discoloured or haemolysed. Slight discolouration in the supernatant is normal.
Do not use beyond the notified expiry date.

Do not transfer these reagents to another container as this could result in spillage or contamination.

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.

STORAGE CONDITIONS

Store at 2-8 °C. After opening the vial the product can be stored under proper storage conditions (2-8 °C) for 14 days.

TEST PROCEDURE

General Information

Laboratories must validate the use of the product on their selected immunohaematology test platforms and in their own laboratory environment.

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

MATERIALS

Materials provided

- ALBAcheck®-BGS Simulated Whole Blood Controls

Materials required but not provided

Please refer to device manufacturer's instructions.

QUALITY CONTROL

This is a quality control reagent. Users are responsible for determining the appropriate quality control procedures for their laboratory and for complying with applicable laboratory regulations.

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.

LIMITATIONS

Laboratories must validate the use of the product on their selected immunohaematology test platforms and in their own laboratory environment.

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

ALBAcheck®-BGS Simulated Whole Blood Controls are released following satisfactory Quality Control testing performed by the manufacturer. This is performed using a combination of manual tube serology and Column Agglutination Techniques (CAT). The CAT platform used is Bio-Rad ID-System with materials selected appropriate for the attribute under test.

Red blood cells donated by blood donors used as inputs to each vial have been 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.

REFERENCES

Milkins, C, Berryman, *et al*: Guidelines for pre-transfusion compatibility procedures in blood transfusion laboratories. 2013 23: 3-35.
Norfolk, D: Handbook of Transfusion Medicine, 5th ed. TSO, 2013.

DATE OF ISSUE

2023-08

For further information or advice please contact your local distributor.

EC REP

Emergo Europe B.V.
Westervoortedijk 60
6827 AT, Arnhem
The Netherlands

Alba Bioscience Limited
James Hamilton Way
Penicuik
EH26 0BF
UK

Tel No: +44 (0) 131 357 3333
Fax No: +44 (0) 131 445 7125
E-Mail: customer.serviceEU@quotientbd.com

 Z489PI/11

INSTRUCTIONS FOR USE
Instructions for Use are available on Quotient website at www.quotientbd.com or can be requested from your Local Distributor, by providing the relevant Product Code stated on product labels and Instructions for Use supplied with the product.

GEBRAUCHSANWEISUNG
Die Gebrauchsanweisung ist auch auf der Quotient Internetseite unter www.eu.quotientbd.com/ifu erhältlich oder kann bei Ihrem zuständigen Vertriebspartner angefordert werden. Hierfür geben Sie bitte die jeweilige Artikel-Nummer an, die sich auf den Etiketten und Gebrauchsanweisungen befindet, die mit dem Produkt geliefert werden.

FEUILLET TECHNIQUE
Le feuillet technique est disponible sur le site Web de Quotient à l'adresse www.quotientbd.com. Vous pouvez également le demander à votre distributeur local en renseignant le code produit concerné, qui est mentionné sur l'étiquette du produit et dans le feuillet technique fourni avec ce dernier.

ISTRUZIONI PER L'USO
Le istruzioni per l'uso son disponibili sul sito Web di Quotient, www.quotientbd.com, o possono essere
richieste al proprio distributore locale fornendo il codice del prodotto indicato sulle etichette del prodotto e nelle istruzioni per l'uso fornite con il prodotto.

ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
Οι οδηγίες χρήσης είναι διαθέσιμες στον ιστότοπο της Quotient στη διεύθυνση www.quotientbd.com ή μπορείτε να τις ζητήσετε από τον τοπικό διανομέα, παρέχοντας τον αντίστοιχο κωδικό προϊόντος που αναφέρεται στις ετικέτες του προϊόντος και στις οδηγίες χρήσης που συνοδεύουν το προϊόν.