QUOTIENT

ALBAcheck® - BGS
High Titre Controls Kit

REF Z257 CE

INTERPRETATION OF LABELLING SYMBOLS

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

INTENDED USE

The kit is intended to be used as a qualitative control for the routine screening of blood donations for the presence of high titre Anti-A and Anti-B.

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

SUMMARY AND EXPLANATION

High titres of Anti-A, Anti-B and/or Anti-A,B antibodies can be found in blood products derived from group O donors. Haemolytic transfusion reactions can occur in non-group O patients when given these high titre products. As a result, screening for high titre donors should be routinely carried out within each donation testing laboratory.

The approach for performing high titre ABO antibody screening is determined by national and regional requirements and professional guidelines. The UKBTS guidelines recommend the use of high titre controls.

PRINCIPLE OF THE PROCEDURE

When substituted for donor plasma in the test system, these controls provide positive and negative reference points, representing donor samples with and without high titre ABO antibodies, respectively. Agglutination (clumping) of reagent red blood cells carrying A and/or B antigens by the positive control, when appropriately diluted, indicates that the test system is capable of identifying donor samples containing high titre ABO antibodies. Lack of agglutination by the negative control, diluted in the same manner, indicates that the test system is capable of not reacting with donor samples without high titre ABO antibodies.

REAGENTS

ALBAcheck®-BGS High Titre Controls Kit contains:
- High Titre Control POSITIVE (Z257A): 2 x 6 mL vials
- High Titre Control NEGATIVE (Z257B): 2 x 6 mL vials

The main components of this kit are derived from the *in vitro* culture of murine hybridomas LA2 and LB2, which secrete IgM Anti-A and IgM Anti-B, respectively.

The formulation also contains bovine serum albumin and 0.1% (w/v) sodium azide.

WARNINGS AND PRECAUTIONS

For *in vitro* professional use only.
Do not use if turbid.
Do not use beyond the notified expiry date.

This kit contains 0.1% (w/v) sodium azide. Sodium azide 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 (murine and bovine) care must be taken during use and disposal as there is a potential infection risk.

Contains material of murine origin; therefore, handle appropriately as the absence of murine viruses has not been determined.

Bovine serum albumin has been sourced from animals declared free from Bovine Spongiform Encephalopathies (BSE) disease and deemed to have low Transmissible Spongiform Encephalopathies (TSE) risk.

Harmful to aquatic life with long lasting effects. Avoid release to the environment. Dispose of contents/container in accordance with local/regional/national/international regulations.

STORAGE CONDITIONS

Store at 2-8 °C.
The reagent should be discarded within 14 days after opening.

REAGENT PREPARATION

Dilute material 1:128 in PBS, or equivalent dilution for platform in use.

MATERIALS

Materials provided

- ALBAcheck® - BGS High Titre Controls Kit

Materials required but not provided

- PBS pH 7.0 ± 0.2
- Reagent red blood cells A, B or AB

PROCEDURE

When used for the control of high titre Anti-A and Anti-B screening, the control reagent should be substituted for donor plasma and used in accordance with routine validated laboratory procedures.

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

Agglutination	=	positive test result
No agglutination	=	negative test result

LIMITATIONS

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

False positive or false negative results can occur due to contamination of test materials, improper reaction temperature, improper storage of materials, omission of test reagents and certain disease states.

THIS REAGENT SHOULD ONLY BE USED IN THE APPLICATION DESCRIBED AND IS NOT SUITABLE FOR ABO GROUPING

SPECIFIC PERFORMANCE CHARACTERISTICS

ALBAcheck® - BGS High Titre Controls Kit is released following satisfactory Quality Control testing by the manufacturer. This is performed using manual tube technique with materials selected appropriate for the attribute under test, to demonstrate that, when diluted 1:128 in PBS, the positive control will give a positive test result and the negative control will give a negative test result when tested against group A and B red blood cells.

Note: The negative control contains Anti-A and Anti-B which may be detectable at a 1:64 dilution in the manual tube technique, therefore in some techniques, a 1:128 equivalent dilution may yield positive results.

Potency is assessed by saline agglutination method; therefore, there may be requirement for laboratories to determine the appropriate equivalent dilution to yield expected results on their chosen test platform.

BIBLIOGRAPHY

Joint UKBTS/NIBSC Professional Advisory Committee. Guidelines for the Blood Transfusion Services in the United Kingdom. 8 ed. Norwich: TSO; 2013

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For further information or advice please contact your local distributor.

EC REP

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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.

INSTRUKCJA UŻYTKOWANIA

Instrukcja użytkowania jest dostępna na stronie internetowej firmy Quotient pod adresem www.quotientbd.com. Można ją też zamówić u lokalnego dystrybutora, podając odpowiedni kod produktu zawarty na etykietach produktów i w instrukcji użytkowania dostarczonej z produktem.

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