



ALBAcheck® - BGS Anti-D <0.1 IU/mL Human Polyclonal / Indirect Agglutinin

For Sensitivity Control of the
Anti-Human Globulin Test

REF Z262



IVD



THIS REAGENT SHOULD ONLY BE USED IN THE APPLICATIONS DESCRIBED AND IS NOT SUITABLE FOR GROUPING PURPOSES.

INTRODUCTION

Described in 1945 by Coombs, Mourant and Race, the Coombs, or anti-human globulin technique, remains one of the most important and widely used techniques in blood group serology. A multiplicity of variables can affect the outcome of antiglobulin tests and consequently it is good laboratory practice to employ a procedure which can be used to indicate the sensitivity and limitations of a test system. This Anti-D (0<0.1IU/mL) can be used to evaluate the sensitivity of the indirect anti-human globulin test procedure performed in the laboratory.

INTERPRETATION OF LABELLING SYMBOLS

LOT

Batch code



Use by (YYYY-MM-DD)



Storage temperature limitation (2– 8 °C)

IVD

In vitro diagnostic medical device



Consult instructions for use

www.quotientbd.com



Manufacturer

REF

Product Code

INTENDED PURPOSE

ALBAcheck®-BGS Anti-D (<0.1 IU/mL) is intended for use as a sensitivity control of the indirect anti-human globulin test.

REAGENT DESCRIPTION

This reagent has been prepared from plasma collected from blood donors. Some donations may contain IgG antibodies other than anti-D as minor contaminants.

Conversion to serum was achieved by the addition of calcium chloride. Excess calcium was removed by the addition of sodium oxalate. The formulation also contains 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.

This reagent complies with the requirements of Directive 98/79/EC on *in vitro* Diagnostic Medical Devices and the recommendations contained in the Guidelines for Blood Transfusion Services in the United Kingdom.

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 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.

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.

CAUTION: SOURCE MATERIAL FROM WHICH THIS PRODUCT IS DERIVED WAS FOUND NON-REACTIVE FOR HBsAg, ANTI-HIV 1/2 AND ANTI-HCV. 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* professional use only.

TEST PROCEDURES

General Information

This reagent has been standardised for use by the techniques described below and therefore its suitability for use in other techniques cannot be guaranteed.

ADDITIONAL MATERIALS AND REAGENTS REQUIRED

- PBS pH 7.0 ± 0.2
- LISS
- Reagent red cells
- Polyspecific Anti-Human Globulin / Anti-Human IgG
- 10 x 75 mm or 12 x 75 mm glass test tubes
- Pipettes
- Centrifuge

RECOMMENDED TECHNIQUES

LISS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a glass test tube.
- Add 2 volumes of 1.5-2% LISS suspended cells.
- Mix the test well and incubate for 15 minutes at 37 °C.
- Wash the test 4 times with a large excess of PBS pH 7.0±0.2 (e.g. 4 mL of PBS per 12 x 75 mm tube).

- NOTE:** (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.
- Add two drops of anti-human globulin reagent to each tube.
 - Mix thoroughly.
 - Centrifuge at 1000 g for 10 seconds or at a suitable alternative g force and time.
 - Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

NIS, 37°C Indirect Antiglobulin

- Add 2 volumes of blood grouping reagent to a glass test tube.
- Add 1 volume of 2-3% NIS suspended red cells.
- Mix the test well and incubate for 45 minutes at 37 °C.
- Wash the test 4 times with a large excess of PBS pH 7.0±0.2 (e.g. 4 mL of PBS per 12 x 75 mm tube).

- NOTE:** (i) allow adequate spin time to sediment the red cells.
(ii) ensure that most of the residual saline is removed at the end of each wash to leave a 'dry' cell button.
- Add two drops of anti-human globulin reagent to each tube.

- Mix thoroughly.
- Centrifuge at 1000 g for 10 seconds or at a suitable alternative g force and time.
- Gently shake the tube to dislodge the cell button from the bottom and observe macroscopically for agglutination.

Bio-Rad ID Micro Typing System

Additional Materials and Reagents Required

- ID card "LISS/Coombs"
- ID Diluent 2 - modified LISS
- ID centrifuge
- ID Dispenser
- ID Pipettor
- ID Pipettor tips
- Tubes for cell suspensions
- ID working table
- ID incubator

Test Procedure

- Prepare cell suspension - 12.5 µL packed cells + 1.0 mL ID Diluent 2.
- Add 50 µL cells to the appropriate microtubes.
- Add 25 µL of the Anti-D control to each microtube.
- Incubate for 15 minutes at 37 °C in the ID incubator.
- Centrifuge in the ID centrifuge for 10 minutes.
- Read reactions.

ORTHO BioVue® System

Additional Materials and Reagents Required

- Anti-IgG,-C3 cassettes
- ORTHO BLISS
- ORTHO BioVue Centrifuge
- ORTHO BioVue Incubator
- ORTHO BioVue Pipette
- ORTHO BioVue pipette tips
- ORTHO BioVue Workstation
- ORTHO Optix™ Reader
- Tubes for cell suspension

Test Procedure

- Prepare cell suspension – 10 µL packed cells + 0.8 mL BLISS.
- Add 50 µL of test cells to appropriate microtubes.
- Add 40 µL Anti-D control to each microtube.
- Incubate for 15 minutes at 37 °C in ORTHO BioVue incubator.
- Centrifuge in ORTHO BioVue centrifuge for 5 minutes.
- Read reactions.

INTERPRETATION OF RESULTS

Agglutination = positive test result
 No agglutination = negative test result

QUALITY CONTROL

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

SPECIFIC PERFORMANCE CHARACTERISTICS

In performance evaluation studies ALBAcheck®-BGS Anti-D (<0.1 IU/mL) was tested against well characterised red blood cells from commercial panels. These studies demonstrated the suitability of this product as a sensitivity control for the detection of weak IgG antibodies.

PERFORMANCE LIMITATIONS

R1r samples will exhibit variable degrees of RhD antigen expression.

Driblocks and waterbaths promote better heat transfer and are recommended for 37 °C tests, particularly where the incubation period is 30 minutes or less.

Tube tests should be read by a 'tip and roll' procedure. Excessive agitation may disrupt weak agglutination and produce false negative results.

In tube tests it is important to use the recommended g force during centrifugation as excessive centrifugation can lead to difficulty in resuspending the cell button, while inadequate centrifugation may result in agglutinates that are easily dispersed.

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.

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For further information or advice please contact your local distributor.



Quotient Suisse S.A.
 Unit B1 Terre Bonne Business Park
 Route de Crassier 13
 Eysins 1262, Switzerland



Alba Bioscience Limited
 James Hamilton Way
 Penicuik
 EH26 0BF

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

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