QUOTIENT

ALBAcheck® - BGS
Anti-D 0.05 IU/mL
Human Polyclonal / Indirect Agglutinin

For Sensitivity Control of the Anti-Human Globulin Test

REF Z263

2°C–8°C IVD CE 1434

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 (0.05 IU/mL) can be used to evaluate the sensitivity of the antiglobulin test procedure performed in the laboratory.

INTERPRETATION OF LABELLING SYMBOLS

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

INTENDED PURPOSE

ALBAcheck®-BGS Anti-D (0.05 IU/mL) is intended for use as a sensitivity control of the 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 and when necessary thrombin. 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 buildup.

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

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

RECOMMENDED TECHNIQUES

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.

PERFORMANCE LIMITATIONS

R1r samples will exhibit a variable degree of RhD antigen expression. Due to weaker antigen expression some R1r cells may not react with ALBAcheck® - BGS Anti-D 0.05 IU/mL.

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.

SPECIFIC PERFORMANCE CHARACTERISTICS

In performance evaluation studies ALBAcheck®-BGS Anti-D (0.05 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.

DATE OF ISSUE

2024-02

For further information or advice please contact your local distributor.

EC REP

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