QUOTIENT

ALBAcheck® - BGS
AlbaSure
Sensitivity Control Kit

REF Z250

CE
1434

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

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
	Manufacturer
REF	Product Code

INTENDED USE

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit is intended for use as a qualitative sensitivity control of antiglobulin tests.

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

SUMMARY AND EXPLANATION

There are many variables that can affect the outcome of antiglobulin tests and consequently adequate control is a fundamental consideration. This product has been developed for use as sensitivity controls to confirm that the technique as performed is capable of detecting weak IgG antibodies.

PRINCIPLE OF THE PROCEDURE

Agglutination of reagent red blood cells known to be positive for the respective antigen type indicates a positive test result and that the Indirect Antiglobulin Test (IAT) system is capable of detecting weak Anti-S, Anti-K, Anti-c and Anti-E IgG antibodies. No agglutination indicates a negative test result. If no agglutination is observed with reagent red blood cells known to be positive for the target antigen, then this may indicate that further investigation is required before progressing to patient testing.

REAGENTS

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit Anti-K, Anti-c and Anti-E have been prepared from plasma collected from blood donors. Each individual donation contains IgG antibodies of the required specificity. Some donations may contain other IgG antibodies 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 main component of the Anti-S reagent is derived from the *in vitro* culture of the IgG secreting human/murine heterohybridoma P3S13JS123.

The diluent formulation contains bovine serum albumin (BSA), and all vials contain 0.1% (w/v) sodium azide.

Vial 1 - Anti-S (weak)
Vial 2 - Anti-K (weak)
Vial 3 - Anti-c (weak)
Vial 4 - Anti-E (weak)

WARNINGS AND PRECAUTIONS

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

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 of human/animal origin (murine and bovine), therefore care must be taken during use and disposal as there is a potential infection risk.

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.

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.

STORAGE CONDITIONS

Store at 2-8 °C.

MATERIALS

Materials provided

- ALBAcheck®-BGS AlbaSure Sensitivity Control Kit

Materials required but not provided

Refer to test procedures described in the Instructions for Use provided by the test system manufacturer.

PROCEDURE

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit has been validated for use in CAT test systems (manual Bio-Rad ID-System and Ortho BioVue). Strictly follow the test procedures described in the Instructions for Use provided by the test system manufacturer.

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

Suitability for use in techniques other than those listed in the Test Procedure has not been validated. Laboratories must validate the use of the product on other immunohaematology test systems 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.

SPECIFIC PERFORMANCE CHARACTERISTICS

ALBAcheck®-BGS AlbaSure Sensitivity Control Kit is released following satisfactory Quality Control testing by the manufacturer. This is performed using Bio-Rad ID-System and Ortho BioVue manual column agglutination techniques with materials selected appropriate for the attribute under test.

In performance evaluation studies ALBAcheck®-BGS AlbaSure Sensitivity Control Kit was tested against well characterised red blood cell samples from commercial panels. The performance of ALBAcheck®-BGS AlbaSure Sensitivity Control Kit showed 100% concordance with the expected test outcome based on the antigen profile of the red blood cells used when product was evaluated on the above platforms.

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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.

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