ALBAsure® QC Kit

Qualitative controls for the quality control of routine blood bank reagents

REF Z481U

- **2-3% Suspension** (red blood cell components only)
- **For Manual Techniques**
- **No U.S. standard of potency**
- **Do not freeze**
- **Discard if markedly hemolyzed** (red blood cell components only)
- **Preservatives:**
  - **chloramphenicol (0.349 g/L)**
  - **neomycin sulfate (0.103 g/L)** (red blood cell components only)
  - **sodium azide (0.1% w/v)** (antibody component only)

CAUTION: THE ABSENCE OF ALL VIRUSES HAS NOT BEEN DETERMINED. THIS PRODUCT HAS COMPONENTS (DROPPER BULBS) CONTAINING DRY NATURAL RUBBER

INTERPRETATION OF LABEL 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

REF — Product code

Consult instructions for use

Manufacturer

Harmful

INTENDED USE

The ALBAsure® QC Kit is intended for daily use to evaluate ABO, RhD and antibody screening reagents by manual blood grouping methods.

SUMMARY AND EXPLANATION

Day-of-use quality assurance allows the operator to assess the test system; reagents, test procedures and equipment operation.

The ALBAsure® QC Kit provides a means for laboratories to confirm the reactivity and performance of routinely used reagents on each day of use.

Using known antibodies and red blood cells of known types is an accepted form of quality control. ALBAsure® QC Kit Cell 1 and ALBAsure® QC Kit Cell 2 are used to confirm the reactivity of anti-A, anti-B, anti-A,B, anti-D, and Rh Control (if tested). Testing of ALBAsure® QC Kit Cell 1 with anti-D at the antiglobulin phase is used to confirm the reactivity of Anti-Human Globulin or Anti-IgG and IgG sensitized red blood cells. ALBAsure® QC Kit Antibody is used to confirm the reactivity of reverse grouping reagent red cells and antibody screen reagent red cells, as well as Anti-Human Globulin or Anti-IgG. Expected results indicate that reagents are reacting as expected.

However, if unexpected results are observed, the problem may be due to any one of a number of factors, which could include incorrect performance of the procedure, faulty equipment, or contamination or deterioration of reagents. The source of the problem must be identified and resolved before routine testing results can be reported.

PRINCIPLE OF USE

The procedures are based on the principle of agglutination (clumping of red blood cells). Normal human red blood cells will be agglutinated if the corresponding antibody is present. No agglutination indicates the absence of the antigen or antibody. As both direct and indirectly reacting antibodies and antigens are routinely used and detected, the kit allows both direct and indirect test systems to be checked.

The samples in the ALBAsure® QC Kit confirm the reactivity of the reagents used for ABO and RhD determinations, as well as the reverse grouping cells, the anti-IgG component of antiglobulin reagents, IgG sensitized cells and reagent red blood cells used in antibody detection tests.

REAGENT DESCRIPTION

The ALBAsure® QC Kit red cell components are prepared from red blood cells collected from blood donors. Each individual donation contains the appropriate ABO and RhD blood group antigens. The red cells are suspended in a preservative solution to retard bacterial contamination.

ALBAsure® QC Kit Cell 1 – Group AB RhD Negative (probable Rh genotype rr) human red blood cells at 2-3% in Modified Alsever's Solution.

ALBAsure® QC Kit Cell 2 – Group O RhD Positive (probable Rh genotype R_1r) human red blood cells at 2-3% in Modified Alsever's Solution.

The ALBAsure® QC Kit antibody component contains dilute murine monoclonal IgM anti-A and anti-B and also human/mouse monoclonal IgG anti-D and anti-c.

The red cell preservative solution has been specially formulated to preserve red cell integrity and antigenicity and contains the following components – trisodium citrate, citric acid, dextrose inosine and the antibiotics, neomycin sulfate (0.103 g/L) and chloramphenicol (0.349 g/L). 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.

PRECAUTIONS

Store at 2-8 °C.
Do not freeze.
Do not use if obviously discolored or hemolyzed.
Do not use beyond the notified expiry date.
CAUTION: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.

The antibody component of this kit contains 0.1% (w/v) sodium azide. Sodium azide may be toxic if ingested and 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.

As this reagent is of animal origin care must be taken during use and disposal as there is a potential infection risk.

This product has components (dropper bulbs) containing dry natural rubber. This reagent is for *in vitro* diagnostic use only.

TEST PROCEDURE

General Information

The procedures below are suggested protocols for manual testing. Laboratories may choose to design their own protocol for QC testing utilizing the ALBAsure® QC Kit. Laboratories must follow their approved validation procedures if using other methods.

Materials Provided

1. ALBAsure® QC Kit Cell 1 (1 x 10 mL)
2. ALBAsure® QC Kit Cell 2 (1 x 10 mL)
3. ALBAsure® QC Kit Antibody (2 x 10 mL)

Additional Materials Required

1. Test tubes (12 x 75 mm or 10 x 75 mm)
2. Incubator, 37 °C ± 1 °C
3. Centrifuge
4. Isotonic saline
5. Anti-Human Globulin
6. IgG sensitized cells
7. Rh control reagent if desired
8. Enhancement media if desired

An ALBAsure® QC Kit Worksheet can be found on the Quotient Biodiagnostics website:

http://us.quotientbd.com

Tube Technique

All tests should be performed according to the standard procedures contained within the Instructions for Use supplied with each reagent under QC testing. Mix reagent red blood cells prior to use.

Suggested tests:

1. ABO grouping using ALBAsure® QC Kit Cell 1 and QC Kit Cell 2.
2. RhD typing (including Rh Control if desired) using ALBAsure® QC Kit Cell 1 and QC Kit Cell 2.
3. Weak D testing using ALBAsure® QC Kit Cell 1.
4. Reverse grouping using ALBAsure® QC Kit Antibody.
5. Antibody screening using ALBAsure® QC Kit Antibody.

Individual laboratories may select the combination of test(s) to be performed based on local procedures, as well as local, state and federal regulations.

STABILITY OF REACTION

Test results should be read and interpreted immediately after centrifugation. Delays may cause dissociation of antigen-antibody complexes resulting in weak positive or false negative reactions.

INTERPRETATION OF RESULTS

The following table illustrates the expected results in tests with ALBAsure® QC Kit and routine blood bank reagents.

Component of Kit	Reagent Under Test	Expected Test Results*
Vial 1 – QC Kit Cell 1 AB rr	Anti-A	+
	Anti-B	+
	Anti-A,B	+
	Anti-D	0
	Rh Control	0
Vial 2 – QC Kit Cell 2 O R_1r	Anti-A	0
	Anti-B	0
	Anti-A,B	0
	Anti-D	+
	Rh Control	0
Vial 3 – QC Kit Antibody	A_1 cells	+
	A_2 cells	+
	B cells	+
	Screening cell 1	+
	Screening cell 2	+
	Screening cell 3	+

Note: The use of IgG sensitized cells is recommended for use with any negative Anti-Human Globulin test results.

***Discrepant results must be investigated further.**
Antibody screen expected test results listed are based on testing by indirect antiglobulin testing techniques. Negative or weak reactions are expected at the immediate spin phase of direct testing and as such are not considered to be discrepant.
Achieving expected test results in indirect antiglobulin tests confirms suitability of AHG reagents and/or enhancement media when used appropriately.

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

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

Individual laboratory procedures and use of enhancement media may affect the final reaction strength observed in tests performed with the ALBAsure® QC Kit.

ALBAsure® QC Kit antibodies are not suitable for blood grouping.

ALBAsure® QC Kit red blood cells are only to be tested with undiluted reagents.

ALBAsure® QC Kit red blood cells are not to be considered as auto controls for the ALBAsure® QC Kit antibodies.

The reactivity of the product may decrease during the dating period and, therefore, should not be used after the expiration date. The rate at which the antigen reactivity (e.g. agglutinability) is lost is partially dependent upon individual donor characteristics that are neither controlled nor predicted by the manufacturer.

SPECIFIC PERFORMANCE CHARACTERISTICS

The red blood cells in this kit have been shown to have a negative direct antiglobulin test, indicating that no human IgG or C3 complement components are detectable on the cell surface.

When properly stored and used according to standard procedures, these reagents will demonstrate the appropriate antigens / antibodies specified in the reagent description.

BIBLIOGRAPHY

1. Technical Manual. 18th ed. Bethesda, MD: American Association of Blood Banks, 2014.
2. Standards for Blood Banks and Transfusion Services. 29th ed. Bethesda, MD: American Association of Blood Banks, 2014.
3. 42 CFR 493.1256 Standard: Control Procedures

DATE OF ISSUE

24 April 2015

US Distributor

Quotient
301 S. State Street
Suite S-204
Newtown, PA 18940
USA

Customer Service Tel: 1-888-284-1901
Product Technical Support Tel: 1-888-228-1990
Customer Service Fax: 1-888-694-5208
E-Mail: customer.serviceUS@quotientbd.com
Web: www.quotientbd.com

Alba Bioscience
Ellen's Glen Road
Edinburgh
Scotland, UK
EH17 7QT

 Z481U/PI/01

QUOTIENT