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 DISCLAIMER
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 1 and ALBAsure QC Kit 2 are used to confirm the reactivity of anti-A, anti-B, anti-A,anti-B and D, and Rh Control (if tested). Testing of ALBAsure QC Kit 1 and anti-D at the anti-D antibody phase is used to confirm the reactivity of Anti-Human Globulin on Anti-IgG and IgG sensitized red blood cells. ALBAsure® QC Kit Antibody is used to confirm the reactivity of reverse grouping reagents (antibody and antibody screen reagents) 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. Both direct and indirect reacting antibodies and antigens are routinely used and detected, the kits allow 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 anti-antigen 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 Rb) human red blood cells at 2-3% in Modified Alsever’s Solution.

The ALBAsure® QC Kit antibody component contains dilute murine monoclonal IgG 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 chloride, citric acid, dextrose, sodium fluoride and the antibiotics, neomycin (0.13 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.

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

<table>
<thead>
<tr>
<th>Component of Kit</th>
<th>Reagent Under Test</th>
<th>Expected Test Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vial 1 – QC Kit Cell 1</td>
<td>All a</td>
<td>A</td>
</tr>
<tr>
<td>Vial 2 – QC Kit Cell 2</td>
<td>O Rh</td>
<td>Rh Control</td>
</tr>
<tr>
<td>Vial 3 – QC Kit Antibody</td>
<td>A cells</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>A cells</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>B cells</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Screening cell 1</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Screening cell 2</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td>Screening cell 3</td>
<td>+</td>
</tr>
</tbody>
</table>

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

*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 ABO 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 performance.

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 lot 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

3. 42 CFR 493.1256 Standard: Control Procedures

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