INTENDED USE
The ALBAsure® QC Kit is intended for daily use to evaluate ABO and RhD 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-AB, and RhD (if needed). Testing of ALBAsure® QC Kit Cell 1 with anti-D at the antigenol 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 THE PROCEDURE
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 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 reagents, the anti-IgG component of anti-globulin 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.

MATERIALS
- known antibodies
- red blood cells of known types
- reagents
- test systems
- equipment

TEST PROCEDURE
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 10^8/mL)
2. ALBAsure® QC Kit Cell 2 (1 x 10^8/mL)
3. ALBAsure® QC Kit Antibody (2 x 10^8/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. Rh 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. Anti-D testing using ALBAsure® QC Kit Antibody.
5. Antibody screening using ALBAsure® QC Kit Antibody.

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

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>Anti-A</td>
<td>+</td>
</tr>
<tr>
<td>Vial 2 – QC Kit Cell 2</td>
<td>Anti-B</td>
<td>+</td>
</tr>
<tr>
<td>O Rh</td>
<td>Anti-A,B</td>
<td>+</td>
</tr>
<tr>
<td>Anti-D</td>
<td>Rh Control</td>
<td>0</td>
</tr>
<tr>
<td>Screening cell 1</td>
<td>A cells</td>
<td>+</td>
</tr>
<tr>
<td>Screening cell 2</td>
<td>A,B cells</td>
<td>+</td>
</tr>
<tr>
<td>Screening cell 3</td>
<td>B cells</td>
<td>+</td>
</tr>
</tbody>
</table>

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 or mix up 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

3. 42 CFR 493.1256 Standard: Control Procedures

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