DailyChek QC Kit

INTENDED USE
American Red Cross (Red Cross) DailyChek QC Kit is used in quality control of blood bank reagent red blood cells.

SUMMARY AND EXPLANATION
Quality control of blood bank reagents should be performed daily to ensure reagents are functioning properly. Reagent quality may deteriorate due to improper storage or contamination, or its performance impacted by faulty equipment or improper technique. Observation of a standardized daily control can confirm expected test results for reagent red blood cells used in reverse grouping and antibody detection.

PRINCIPLE OF PROCEDURE
Red Cross DailyChek QC Kit consists of Positive and Negative Controls used to evaluate reactivity with A<sub>1</sub>, A<sub>2</sub>, B reverse grouping and O antibody detection reagent red blood cells. The Positive Control can monitor performance of potentiators. Decreased or no agglutination with the Positive Control or a positive reaction with the Negative Control may indicate reagent deterioration, equipment failure or improper technique.

REAGENT
Each lot of Red Cross DailyChek QC Kit is a two-component kit consisting of two vials of Positive Control and one vial of Negative Control. The Positive Control is a blend of polyclonal and/or monoclonal antibodies in a bovine albumin diluent. The Negative Control contains a bovine albumin diluent that is nonreactive in standard serological tests.

Components under Test
Each lot is standardized for pH and protein concentration, and may contain sodium chloride and sodium or potassium phosphates. The bovine albumin component of this product is derived exclusively from United States sources of disease-free cattle, inspected and certified by the US Veterinary Services. This ruminant-based product is deemed to have low Transmissible Spongiform Encephalopathy (TSE) risk. The total protein concentration is 3-7%. The product contains sodium azide (final concentration of 0.1%) as a preservative.

Red Cross DailyChek QC Kit is supplied ready for use, no dilution or modification is required. No US standard of potency.

CAUTION: Do not pipette this product by mouth, as the absence of murine virus has not been determined. 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 test methods can offer assurance that products derived from human blood will not transmit infectious agents.

Caution: This Product Contains Natural Rubber Latex (Dropper Bulbs) Which May Cause Allergic Reactions.

Warning: Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. If discarded into sinks, flush with a large volume of water to prevent azide build-up.

STORAGE
Store at 1-8 C when not in use. Do not freeze.

Even though this product is clear following filtration, soluble lipoproteins may precipitate over the dating period.

Do not use beyond expiration date. The format for the expiration date is expressed as YYYY-MM-DD (year month day).

MATERIALS
Materials provided:
1. American Red Cross DailyChek QC Kit: containing Positive and Negative antiserum controls

Materials required but not supplied:
1. Reverse grouping reagent red blood cells (A<sub>1</sub>, A<sub>2</sub>, B, O cells)
2. Antibody detection reagent red blood cells
3. Potentiators (optional)
4. Test tubes, 10 x 75 mm or 12 x 75 mm
5. Test tube racks
6. Centrifuge
7. Isotonic saline (pH 6.0 – 7.5)

8. Incubating and support equipment
9. Anti-Human Globulin containing anti-IgG
10. Antiglobulin control cells (IgG sensitized red blood cells)
11. Timer

PROCEDURE
1) Inspect reagents under test for signs of contamination or deterioration (i.e., excessive turbidity, leakage, flocculation, hemolysis). Document manufacturer, lot number and expiration date of each reagent lot to be tested.
2) Add 1 drop of Red Cross DailyChek QC Kit Positive Control to an appropriately labeled test tube, one tube for each reverse grouping and each antibody detection reagent red blood cell to be tested.
3) Add 1 drop of Red Cross DailyChek QC Kit Negative Control to an appropriately labeled test tube, one tube for each antibody detection reagent red blood cell to be tested.
4) QC of reverse grouping reagent red blood cells
   a) Add 1 drop of reverse grouping reagent red blood cells to appropriately labeled tubes.
   b) Mix well and centrifuge* the tubes.
   c) Resuspend the red blood cells by gentle agitation.
   d) Read macroscopically for agglutination and record results.
   e) For weak or negative reactions with A<sub>1</sub>, A<sub>2</sub> and B cells (5 RT):
      i) Incubate the tubes at room temperature (18-28 C) for 5 minutes.
      ii) Mix well and centrifuge* the tubes.
      iii) Resuspend the red blood cells by gentle agitation.
   f) Read macroscopically for agglutination and record results.
5) QC of antibody detection reagent red blood cells
   a) Add 1 drop of antibody detection reagent red blood cells to appropriately labeled Positive Control tubes and appropriately labeled Negative Control tubes.
   b) Immediate spin phase (optional)
      i) Mix well and centrifuge* the tubes.
      ii) Resuspend the red blood cells by gentle agitation.
      iii) Read macroscopically for agglutination and record results.
   c) Incubate the tubes at 36-38 C for at least 15 minutes.
   d) 36-38 C phase (optional)
      i) Centrifuge tubes immediately*.
      ii) Resuspend the red blood cells by gentle agitation.
   e) Read macroscopically for agglutination and record results.
   f) Add Anti-Human Globulin containing anti-IgG according to the manufacturer's directions.
   g) Mix well and centrifuge* the tubes.
   h) Resuspend the red blood cells by gentle agitation.
   i) Read macroscopically for agglutination and record results.
   j) Add antglobulin control cells to all negative tests and centrifuge*. Agglutination of the antglobulin control cells confirms the presence of active anti-IgG. No agglutination of the antglobulin control cells may indicate the antglobulin reagent has been neutralized or omitted; these tests should be repeated.
6) QC of antibody detection reagent red blood cells with potentiator
   a) Follow manufacturer’s directions for potentiator used

   *Centrifuge for 15 seconds at 3400 rpm (900-1000 rcf) or 1 minute at 1000 rpm (100-120 rcf) or equivalent, as indicated by equipment quality control calibration.

   **rcf=0.00001118 x radius (cm) x (rpm)²

STABILITY OF REACTION
Tests should be read and recorded immediately following centrifugation. Delays can result in stronger reactions which could impact day to day comparison.

INTERPRETATION OF RESULTS
Hemolysis, if obtained, should not be interpreted as a positive result since the conditions for complement activation due to a red blood cell antibody-antigen reaction do not exist. Expected reactions are shown in the chart below. Reaction strength using the same lot of reagent red blood cells should be comparable from day to day. Unexpected reactions or significant decreases in reaction strength with any reagent red blood cell should be confirmed. Repeated failures to react as expected or decreases in reaction strengths warrant thorough investigation.

<table>
<thead>
<tr>
<th>DailyChek QC Kit Component</th>
<th>Reagent under Test</th>
<th>Phase</th>
<th>Expected Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Control Reverse Grouping</td>
<td>A&lt;sub&gt;1&lt;/sub&gt;, A&lt;sub&gt;2&lt;/sub&gt;, B cells</td>
<td>IS 5' RT</td>
<td>1-4+</td>
</tr>
<tr>
<td>Positive Control Reverse Grouping O cells</td>
<td>IS</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Positive Control Antibody Detection</td>
<td>IS 36-38 C IAT</td>
<td>1-4+ IAT*</td>
<td></td>
</tr>
<tr>
<td>Negative Control Antibody Detection</td>
<td>IS 36-38 C IAT</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

Key: IS = immediate spin, IAT = indirect antoglobulin test; RT = room temperature

*Reactivity may or may not be seen at IS or 36-38 C incubation.

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LIMITATIONS

All serological tests have limitations. To maximize success in obtaining valid results, follow the directions for use carefully. Deviations from manufacturer’s instructions without appropriate validation and controls may produce erroneous results.

- Red blood cells must be washed with adequate volumes of isotonic saline to avoid possible neutralization of Anti-Human Globulin reagent by residual serum proteins.
- Resuspend red blood cells in isotonic saline or other appropriate solution. The pH of saline may affect the stability of the reaction. It is recommended that the pH be 6.0 - 7.5.

Erroneous results may also be caused by:

- Red blood cells with a positive direct antiglobulin test
- Contaminated materials
- Bacterial or fungal contamination
- Improper storage of materials
- Omission of test reagents or addition to incorrect tube

DailyChek QC Kit is not designed to detect the following improper techniques:

- Incorrect centrifugation
- Addition of incorrect amounts of control reagent or test reagent
- Delay reading results
- Delay addition of Anti-Human Globulin (AHG) reagent
- Extended incubation time

The use of DailyChek QC Kit is only for evaluating the quality of blood bank reagent red blood cells.

SPECIFIC PERFORMANCE CHARACTERISTICS

Red Cross DailyChek QC Kit has been manufactured to provide a standardized reaction in blood bank procedures with reverse grouping and antibody detection reagent red blood cells.

For technical questions, contact the American Red Cross Diagnostic Manufacturing Division at 1-800-882-3737.

BIBLIOGRAPHY