STANDARD OPERATING PROCEDURE FOR QUALITY CONTROL OF REAGENTS AND ANTISERA
TITLE: STANDARD OPERATING PROCEDURE FOR
QUALITY CONTROL OF
REAGENTS AND ANTISERA

1.0 Principle

1.1 The purpose of quality control is to confirm the reliability of the test system
(which includes reagents, test procedures and equipment) on each day of use.

1.2 The results of the quality control performed on the reagents and antisera must
demonstrate acceptable performance before patient test results are released. If
expected test results are observed, procedures are being performed accurately
and reagents and equipments are performing properly.

2.0 Scope and Related Policies

2.1 Quality control performed must focus on identifying problems which occur
during the shipment and delivery of the reagent (e.g. exposure to excessive heat
or cold); and contamination of the reagent which could occur during use in the
Transfusion Medicine Laboratory affecting the reactivity of these reagents.

2.2 If unexpected results are observed, the source of the problem should be
determined and resolved before patient test results are reported. Corrective
actions must be documented.

2.3 Table 1: Clauses from the CSA and CSTM Standards Related to
Quality Control of Reagents and Antisera

<table>
<thead>
<tr>
<th>Clause</th>
<th>Text</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSA 8.1.6</td>
<td>Reagents shall be used and controlled according to manufacturer’s recommendations.</td>
</tr>
<tr>
<td>CSTM 5.3.1.1</td>
<td>The Rh group shall be determined with anti-D typing reagent. A control system appropriate to the anti-D reagent being used should be included.</td>
</tr>
<tr>
<td>CSA 10.4.5</td>
<td>Each antiglobulin test that reads negative shall be controlled by the addition of IgG-sensitized red cells. All observed reactions shall be documented.</td>
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<tr>
<td>CSTM 5.3.5.4</td>
<td>All antisera shall be controlled using red cells known to be positive and red cells known to be negative for the specific antigen(s).</td>
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<tr>
<td>CSTM 5.3.4.2</td>
<td>Red cells with a single expression of the antigen should be used for positive controls.</td>
</tr>
</tbody>
</table>
2.4 A program of quality control shall be established that is sufficiently comprehensive to ensure that reagents, equipment and methods perform as expected.

3.0 Specimens N/A

4.0 Materials

**Reagents:**
- Reagent red cells
- Anti-sera
- Commercial QC system
- Anti-human globulin (AHG)
- IgG sensitized cells
- Potentiator, if used
- Isotonic saline

**Supplies:**
- Quality control data sheets
- Test tubes (10x75mm)
- Transfer pipettes
- Test tube rack

**Equipment:**
- Serological centrifuge
- Waterbath 37(±1)°C
- Cellwasher
- Interval timer

5.0 Procedure

5.1 **Upon Receipt:** Perform a visual inspection of all reagents upon receipt in the Transfusion Medicine Laboratory:

5.1.1 **Reagents red cells:** Each vial of red cells received should be allowed to settle and then visually inspected for hemolysis or discolouration.

5.1.2 **Antisera:** a representative sample of the antisera must be visually inspected for cloudiness, turbidity and/or particulate matter.

5.1.3 **Potentiators:** Each vial received must be visually inspected for cloudiness, turbidity and/or particulate matter.
5.2 Document:
   5.2.1 Reagent lot number.
   5.2.2 Reagent appearance.
   5.2.3 Date of receipt.
   5.2.4 Results of the visual inspection.
   5.2.5 Initials of the technologists performing the inspection.
      • Reagents that do not meet visual inspection must not be used for
testing. Quarantine shipment until the cause has been identified
and corrected.

5.3 Check the revision date on the package insert, received with the reagent to
ensure the package insert with the most recent date is placed in the file.

5.4 Daily Quality Control (QC): Perform daily QC using commercial QC system.
   5.4.1 Prior to performing daily QC testing, perform visual inspection of
reagents and anti-sera.

   Note: IgG coated cells must be added to all negative indirect antiglobulin tests
which are performed by a tube procedure. If the reaction following the
addition of the cells is weaker than expected (less than grade 2), the test must
be repeated.

5.5 Record test results, date and technologists initials on the QC data sheet.
   5.5.1 If expected results are obtained, results can be entered into the
Laboratory Information System (LIS) if applicable.
   5.5.2 If expected results are not obtained, repeat the test(s) using a new vial
of the reagent in question.

   NOTE: The date the vial is opened should be written on the vial label.
   5.5.2.1 If the results are corrected, discard the initial reagent vial.
   5.5.2.2 If the results are not corrected, investigate equipment and/or
technique.
   5.5.2.3 Corrective actions must be documented.

5.6 Quality control of non-routine antisera:
   5.6.1 Visually inspect the antisera for cloudiness, turbidity and/or particulate
matter.
   5.6.2 Phenotyping for antigens other than ABO/Rh are not usually
performed on a routine basis. For non- routine anti-sera (e.g. anti-JK²)
the appropriate positive and negative controls must be used each time
the reagent is used (per test or batch).
• The positive red cell control should be heterozygous for the antigen being tested and red cells known to lack the corresponding antigen for the negative control. Reagent red cells for the positive and negative controls can be selected from an identification panel or antibody screening cells.

5.6.3 Follow manufacturer’s instructions to perform testing for the selected antisera.

5.6.4 Document the following information on the laboratory worksheet.
- reagent type
- visual inspection results
- lot number
- results of the positive and negative control
- Technologists initials on the worksheet.

6.0 Reporting

6.1 Upon receipt document results of visual inspection on quality control worksheet.

6.2 Review all results obtained to ensure results are acceptable.

6.3 Corrective actions must be documented.

6.4 All quality control results must be reviewed by senior technologists or designate.

Procedural Notes

6.5 Following centrifugation, all tests should be read immediately and results interpreted without delay. Delays may result in dissociation of antigen-antibody complexes leading to false negative or weak positive reactions.

6.6 On rare occasions outdated antisera may have to be used. It is important that the Transfusion Medicine Laboratory have a policy and procedure in place if outdated antisera is used and that the procedure be approved by the medical director or designate.
6.7 False negative or false positive results can occur from:
- Bacterial or chemical contamination
- Inadequate incubation time or temperature
- Improper centrifugation
- Improper storage of materials
- Potency of the anti-sera or red cell reagent
- Omission of tests reagents.

6.8 Reactions obtained that are weaker than expected could be due to:
- Deterioration of the routine reagent under evaluation
- Suboptimal performance of test equipment such as washing devices and centrifuges
- Poor testing technique of the operator
- Failure of the QC reagents.

6.9 When the results of any QC test fails to meet expectations, the test should be repeated. Repeated failures require investigation to identify the cause and to eliminate it.

6.10 All laboratory equipment must be regularly maintained in accordance with manufacturer’s instructions.

7.0 Records Management
7.1 Reagent quality control records must be retained for 5 years.

8.0 References


8.5 Immucor Inc. corQC test system manufacturer’s instructions. Norcross, (GA) USA: Immucor Gamma; 2009.


