1. **Principle**

Certain circumstances can affect the reactivity of reagents during shipment, storage and use in the TML. Quality control testing is performed to ensure that reagents will react as intended.

1. **Scope and Related Policies**
   1. All reagents shall be used and controlled according to the manufacturer’s written instruction.9.1
   2. For all reagents(including prepared in-house) and control materials records shall be kept of: 9.2
2. lot numbers
3. the date of receipt in the laboratory
4. the date the material is placed in service
5. expiration date
6. the date the material was taken out of service due to poor performance or quality issues (if applicable)
7. preparation date (if applicable)
   1. All reagents shall be marked with reagent name, date opened, reconstitution date (if applicable) / preparation date, expiry date, and technologist initials when prepared.
   2. All reagents must be stored according to manufacturer’s requirements and discarded when the expiry date is reached, unless exceptions are confirmed by the manufacturer, or controls indicate adequate performance.9.2
8. **Specimens – N/A**
9. **Materials**

**Reagents:** Anti- sera

Reagent red cells

1. **Quality Control**
   1. In this procedure quality control recommendations are summarized for blood grouping reagents and red cell reagents.
   2. In addition to these specific recommendations refer to the procedures for:

* Reading and grading serological reactions. See RT.001 – Reading and Recording Hemagglutination Reactions
  1. Documentation in this procedure includes:
* Visual inspection
* Reagent type and lot number
* Expiry date and lot number
* Date of testing
* Result obtained
* Individual performing the test
* Any follow-up action

1. **Procedure**

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| * 1. Upon receipt: | * + 1. A representative vial of each anti-sera reagent received must be visually inspected to ensure that cloudiness, turbidity and/or particulate matter are not present. See Procedural Notes 8.1. |
| * + 1. Each vial of reagent red cells when received should be allowed to settle. Once settled the supernatant in each vial must be visually inspected to ensure that hemolysis and/or discoloration is not present. Following gentle re-suspension of the cells the visual inspection is repeated to ensure discoloration is not present. |
| * + 1. The date of receipt and lot numbers of all reagents received must be documented. |
| * + 1. The results of the visual inspection must be documented. Document on form QCA 001 F1. |
| * + 1. If visual inspection is not acceptable quarantine shipment until the cause has been identified and corrected. |
| * + 1. IgG coated cells must be tested as a positive control for the IgG activity of the reagent; Unsensitised red cells must be tested as a negative control for each reagent and the results documented.9.1 |
| * + 1. C3d coated cells should be tested as a positive control for the C3d activity of a mono-specific anti-complement reagent. Unsensitised red cells must be tested as a negative control and the results documented. |
| * + 1. All QC results must be reviewed and the review documented by a supervisor. |
| * 1. Daily QC: | * + 1. Each vial of antisera must be visually inspected each day of use to ensure that cloudiness, turbidity and/or particulate matter are not present. See Procedural Notes 8.1. |
| * + 1. Each vial of reagent red cells must be visually inspected each day to ensure that hemolysis and/or discoloration is not present. |
| * + 1. The lot number and expiry date for each reagent that is used, the date of the testing and the individual performing the test must be documented. Document on form QCA.001F2. |
| * + 1. Date the vial when opened. Record on vial label. |
| * + 1. IgG coated cells must be added to all negative indirect antiglobulin tests which are performed by a tube procedure.9.1 If the reaction following the addition of the cells is weaker than expected, refer to the manufacturer instructions. |
| * + 1. An autocontrol or a direct antiglobulin test shall be performed in conjunction with patient red cell phenotyping that requires an indirect antiglobulin test.9.1 |
| * + 1. Phenotyping for antigens other than ABO/Rh are not usually performed on a routine basis therefore it is important to use appropriate positive and negative controls each time the reagent is used (per test or batch). Red cells used for a positive control should be heterozygous(single expression) for the antigen being tested.9.1 |
| * + 1. Document results on QCA.001F2 or in computer worksheet. All QC results must be reviewed and the review documented by a supervisor. |

1. **Reporting**
   1. Upon receipt document results on form QCA.001F1 or electronically.
   2. Review all results obtained on QCA.001F2 or electronically to ensure results are satisfactory and test results are reacting as expected.
      1. If repeated testing does not react as expected, quarantine the vial(s) until the cause has been identified and corrected.
      2. Corrective action must be documented.
   3. All quality control results must be reviewed by a supervisor. This review must be documented.
2. **Procedural Notes**
   1. If the potency of the anti-sera or red cell reagent has deteriorated, a false negative result may be obtained.

In many instances contaminated antisera, and deterioration of red cell reagents, can be detected by visual inspection.

* 1. False negative reactions with anti-IgG antiglobulin reagents can be easily detected by the routine addition of IgG coated cells to all negative antiglobulin tube tests. If the potency of the reagent has deteriorated the IgG sensitised cells will be non-reactive or give weaker reactions than expected. However weak or non-reactive IgG coated cells could also indicate inadequate washing or failure to add the reagent. Thus the test is controlled each time a negative reaction is obtained.

False positives can occur if the antisera become contaminated. In many instances contaminated antisera can be detected by visual inspection and all tests would appear positive thus alerting the technologist to a problem.

* 1. If a polyspecific reagent is used, anti-C3b is not controlled by the above procedure. Provided the reagent is stored under controlled conditions it is not necessary to retest the anti-C3b activity during routine use, as the C3b component is very stable.

1. **References**
   1. Standards for Hospital Transfusion Services Version 3 – February 2011. Canadian Society for Transfusion Medicine (5.3.1.1, 5.3.1.2, 5.3.4.2, 5.3.4.3)
   2. IQMH requirements. Version6.0, December 2013. (IV. 4; IV.4.2)
2. **Revision History**

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| **Revision Date** | **Summary of Revision** |
| September 1, 2015 | * Revised name of manual * Revised wording of section 2.0 * Revised and renumbered section 6.0 * Updated list of references to include most recent editions |