LB.61 The Blood bank and transfusion services develop a system for reagents quality control.

LB.61.1 Policies and procedures ensure performance of reagents quality control on each day of use.

LB.61.2 Policies and procedures ensure anti-sera are checked against known positive and negative cells.

LB.61.3 Policies and procedures ensure reagent Red Blood Cells are checked against known positive and negative anti-sera.

LB.61.4 Policies and procedures ensure results are checked against predefined acceptable results.

LB.61.5 Policies and procedures ensure results are reviewed and reagents are approved before use for patient testing.

LB.61.6 Corrective actions are taken for unacceptable results.

Standard Intent:

Quality control (QC) of blood bank reagents must be performed on each day of use. QC performance expectations and acceptable results should be defined and readily available to staff so that they will recognize unacceptable results and trends in order to respond appropriately. QC results should be documented concurrently with performance, and unacceptable QC results must be investigated and corrective action must be taken, if indicated, before releasing donor or patient results. If products or services were provided since the last acceptable QC results were obtained, it may be necessary to evaluate the conformance of these products or services. The review of quality control data must be documented and include follow-up for outliers, trends, or omissions that were not previously addressed.

Unless manufacturer instructions state otherwise, one vial of each reagent lot each day of testing are subjected to the following:

1. Typing sera (Anti-A, Anti-B, Anti A, B and Anti-D) are checked for reactivity and specificity against known positive and negative cells.
2. Typing cells (A and B cells) are checked for reactivity and specificity against known positive and negative antisera.
3. Each cell used for antibody detection (Screening Cells) are checked for reactivity of at least one antigen using antisera of 1+ or greater avidity.
4. Other typing sera (Anti-K, Anti-Fy(a), Anti- M etc.) are checked at every use for reactivity and specificity against known positive and negative cells.

Anti-IgG (Antiglobulin) reagents reactivity are checked during antibody screening and crossmatching through the use of IgG-coated red blood cells.