[](http://depts.washington.edu/labweb/index.htm)

|  |  |  |
| --- | --- | --- |
| **University of Washington,**  **Harborview Medical Center**  **325 9th Ave. Seattle, WA, 98104**  **Transfusion Services Laboratory**  **Policies and Procedures Manual** | **Original Effective Date:**  **June 24, 2011** | **Number:**  **1500-3** |
| **Revision Effective Date:**  1/15/14 | **Pages:**  **3** |
| **TITLE: QSE Process Control**  **Quality Policy: Quality Control (QC)** | | |

**Policy:**

The Harborview Medical Center Transfusion Service has developed goals, policies, processes, and procedures relating to the quality of laboratory testing in accordance with regulatory requirements and accepted standards of practice.

**Purpose:**

To describe the Harborview Medical Center Transfusion Service Laboratory program for quality control of reagents, equipment, and methods.

|  |  |
| --- | --- |
| **Role** | **Responsibilities** |
| Medical Director | * Overall quality of testing. * Administrative review of QC performance results via annual Quality Plan review. * Oversight on corrective actions taken as a result of performance review. |
| Manager | * Selection of appropriate Quality Control material and procedures based on regulatory requirements. * Review and/or sign-off of QC results. * Ensure that corrective action is taken when required. * Prepare QC performance report for annual Quality Plan review. |
| Laboratory Personnel | * Perform and review QC testing as scheduled or when indicated. * Implement corrective action as required. |

|  |  |  |
| --- | --- | --- |
| **QC Element** | **Description** | **Supporting Documents** |
| Proficiency Testing (PT) | * HMC Transfusion Service Subscribes to any available CAP surveys that are specific to HMC testing methods. | * Proficiency Testing Survey Process |
| Reagent Quality Control | * QC samples are tested in the same manner and by the same personnel as patient or donor samples. * All Reagent Red Cell and Antisera lot numbers are tested with appropriate quality control material before being placed into use. * This quality control includes a check against known positive and negative cells or antisera * All regulatory requirements for quality control are followed per CAP, AABB, and FDA. * All manufacturer’s recommendations for quality control are followed. * All reagents are used within their indicated expiration date, with the following exceptions: * Rare antisera or cells which are unique, or difficult to obtain. * Unusual circumstance when delivery of new shipments of reagents is delayed through causes not in control of the laboratory. * Any time reagents are used beyond expiration date in the above described instances, reactivity will be compared for acceptability with appropriate quality control material at each use. | * Daily Quality Control for Manual Testing * TANGO Daily QC and Maintenance * TANGO Validation of Control Results |
| Selection of QC Material | * QC material is evaluated at selection and run per manufacturer’s recommendations. * Any QC material that lacks a manufacturer’s expiration date, is evaluated after testing and compared to previous results. |
| Schedule for QC testing | Frequency of Quality Control testing is determined by the following:   * Regulatory requirements * Accepted standards of practice * Manufacturer’s instructions, where applicable. | * Quality Control Testing and Review Schedule * Monthly QC Review Form |
| Review of QC | * Review of QC results is documented, and reviewed for acceptability before the release of patient results. * Documented corrective action is taken when |
| **QC Element** | **Description** | **Supporting Documents** |
|  | * examination of QC results are unacceptable. * The laboratory has established action limits for quality control performance, when action is required. | * Monthly QC Review Form |
| Patient Testing QC results Unacceptable or missing | * When patient testing QC results are not acceptable: * Patient results are not released. * The laboratory corrective action plan for this circumstance will be followed. * All actions will be documented, and attached to QIM. * All patient testing since most recent acceptable QC results must be repeated. * Any test result changes are corrected per policy * Should patient testing QC results be found missing after results are released: * Any un-transfused products issued from those test results are retrieved immediately. * All patient testing since most recent acceptable QC results is repeated. | * Daily Quality Control for Manual Testing * Handling Failed QC Results on TANGO * Using the QIM Form * Quality Improvement Monitor Form * Quality Policy: Result Reporting and Post-Analytic Processes |
| Blood Product Testing QC results  Unacceptable or missing | * When blood product testing results are not acceptable, blood products are not distributed. * If unacceptable or missing results are found after distribution: * All products involved are Non-conforming products. * All un-transfused products are retrieved immediately. * All actions will be documented and attached to QIM * Manager will follow FDA reporting requirements. | * Quality Process: Recall of Nonconforming Products * FDA-CBER Biological Deviation Reporting * Using the QIM form * Quality Improvement Monitor Form |
| Review of Performance | * Reviews of all QC activities are monitored on a regular basis. * Documented corrective action is taken as required. * Review and any resulting corrective action taken are documented with QIM form. | * Daily Quality Control for Manual Testing * Using the QIM Form * Quality Improvement Monitor Form |
| Records | * Records of all QC activities are maintained in accordance with regulatory requirements. | * Quality Policy: Documents and Records Retention |

**References**

AABB Standards for Blood Banks and Transfusion Services, Current Edition.

TANGO Optimo User Manual, Biorad Laboratories