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| **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.

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| **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.
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| 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.
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| Laboratory Personnel | * Perform and review QC testing as scheduled or when indicated.
* Implement corrective action as required.
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| **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
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| 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
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| 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.
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| 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
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| 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
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| **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
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| 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
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| Blood Product Testing QC resultsUnacceptable 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
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| 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
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| Records | * Records of all QC activities are maintained in accordance with regulatory requirements.
 | * Quality Policy: Documents and Records Retention
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**References**

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

TANGO Optimo User Manual, Biorad Laboratories