**Purpose**:

To describe the process for preparing, administering and reviewing competency testing in the Transfusion Service Laboratory.

**Policy:** Competency tests will be prepared and administered to all staff in TSL based on applicable regulations and job description. This includes but is not limited to twice in the first year of employment, 6 months after training in a new area or on significant procedural changes, and once annually in the second and subsequent years of employment.

**Process:**

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| **Step** | **Action** |
| **Competency Coordinator** |
| **1** | TSL Competency Coordinator will be selected by the TSL Manager. |
| **2** | The Competency Coordinator will serve a two year term.  |
| **3** | Selection will be by application of interest and interview with the TS Manager. |
| **4** | The Quality Coordinator, TS Manager, and Training Coordinator will serve as advisors. |
| **Regulations** |
| **1** | Competencies for technologists will include all of the following activities annually in order to comply with CLIA regulations:* Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.
* Monitoring the recording and reporting of test results
* Direct observation of performance of instrument maintenance and function checks
* Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventative maintenance records
* Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
* Evaluation of problem-solving skills

All six elements of CLIA will be assessed for CLIA-regulated tests which are;* ABO and Rh
* Antibody Screen
* Antibody Identification
* Crossmatch

Non- CLIA regulated tasks will have competency assessment based on written assessment and/or direct observation  |
|  | **Action** |
| **Regulations (continued)** |
| **2** | While CLIA regulations do not specify competency assessment for clinical laboratory technicians: * TSL will perform competency testing on the same schedule as technologists.
* Regulations applicable to the job description will be met where possible.
 |
| **3** | TS Manager review of competency testing will analyze aggregate competence assessment data for the purpose of identifying staff learning needs as required by Joint Commission. |
| **Competency Coordinator Responsibilities** |
| **1** | The Competency Coordinator is responsible for * Administering 6-month competencies for new hires and staff trained in a new area or on a new and/or revised task.
* Revising the existing 6-month competencies as needed for SOP revisions and job scope.
* Developing and administering annual competency assessment to TSL staff
* Developing and administering annual cGMP training.
* Maintaining records of competency performance and completion electronically
* Respecting the private nature of competency results
* Maintaining secrecy of competency contents prior to administration to applicable staff

Note: Annual compliance training is the responsibility of the Facility and is not included in TSL competency testing. |
| **2** | Working with the TS Leads, the Competency Coordinator is responsible for scheduling and administering competencies. |
| **3** | Working with the Quality Coordinator and TS Manager, the Competency Coordinator will identify areas of competency assessment based on quality incidents. |
| **4** | Working with the TS Safety Officer, the Competency Coordinator will identify safety issues to be covered in periodic competency assessment. |
| **5** | Working with personnel responsible for process implementation and revision, the Competency Coordinator will develop appropriate competency assessment. |
| **6** | The Training Coordinator will provide training completion dates for staff so the Competency Coordinator can schedule the competency assessment. |
| **7** | The Competency Coordinator is responsible for forwarding completed competencies to a CT Lead or TS Manager for grading and evaluation. |

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| **Competency Formats and Available Delivery Systems** |
| **1** | Competency formats are varied and should be explored by the Competency Coordinator for application to the topic. Formats might include but are not limited to:* Direct Observations
* Paper Exercises
* MTS reading and testing
* Catalyst testing
* Presentation to staff
* On-line materials

 |
| **2** | Utilization of on-line delivery systems should be coordinated with the TS Manager or Training Coordinator. |
| **Development** |
|  **1** | The Competency Coordinator will maintain confidentiality of topics to be covered in the competency and the contents of the competency exercise. |
| **2** | Request field testing of competencies prior to issue to appropriate staff. Field Testers are:* Quality Coordinator
* CT Leads
* Other staff as selected by the Competency Coordinator
 |
| **3** | The Competency Coordinator is responsible for preparing a key for the competency including acceptable answers and alternative answers. |
| **4** | The TS Manager is responsible for defining minimum acceptable performance. |
| **Review and Corrective Action** |
| **1** | * Review will be performed initially by the TSL Leads.
* Results will be tabulated and presented to the TS Manager prior to staff notification of results.
 |
| **2** | Corrective action will be determined by the TS Manager:* Scope: number of staff
* Activity: re-training and re-assessment of competency
* Second Review: measurement of competency is met
 |
| **Documentation of Competency Activity** |
| **1** | The Competency Coordinator will maintain records of competency performance and completion electronically. |
| **2** | The Training Coordinator is responsible for filing the competency paperwork in the employee’s training folder. |

**References:**

AABB Standards for Blood Banks and Transfusion Services, Current Edition

Technical Manual, Current Edition

“Regulations A to Z for Blood and HCT/PS”, 9th Edition, AABB Press

Code of Federal Regulations, 42 CFR and 21 CFR