**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

* At completion of initial training
* 6 months after training on new method or processes
* 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 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 |
| **Step** | **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.
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| 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 TSL Leads, the Competency Coordinator is responsible for scheduling and administering competencies. |
| 3 | Working with the Quality/Compliance analyst and TS Manager, the Competency Coordinator will identify areas of competency assessment based on quality incidents. |
| 4 | Working with the TSL 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 an MLS Lead or TSL Manager for grading and evaluation. |
| **MLS/CLT Responsibilities**  |
| 1 | MLS/CLT are responsible for * Completing competencies on time
* Tracking competencies in the tracker
* Reviewing the direct observation checklists ahead of time
* Not copying answers from other staff
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| 2 | Peer direct observations* May be required to perform direct observation for annual competency
* Do not interfere or help the tech who is being observed during the competency
* Do not provide the direct observation checklist to the tech to use as reference
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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
* Microsoft Office
* Presentation to staff
* On-line materials
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| 2 | Direct Observations * Initial competencies must have direct observations with a Lead or assigned trainer.
* MLS staff who have at least 2 years of experience with high complexity testing in Blood Bank may be observers for 6 months and annual competencies.
* CLT staff who have at least 1 year of experience in Blood Bank may be observers for 6 month and annual competencies.
* Direct observation sign-off may only be performed by staff in areas which they maintain competency.
* Direct observations on reassessments and/or corrective actions must be with a Lead or assigned trainer
 |
| 3 | 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
* MLS 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.* Staff must pass competency with at least 80% score
* Steps identified as critical with Direct Observations will require a corrective action
* Final review of all training and competency documents
 |
| **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.
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| 2 | Corrective action will be determined by the TSL Manager:* Scope: number of staff
* Activity: re-training and re-assessment of competency
* Second Review: measurement of competency is met
 |
| 3 | TSL Manager or Lead will follow up with staff for re-training and reassessments |
| 4 | All staff will be provided an opportunity to review their competency paperwork once the review has been completed |
| **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:**

Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks. AABB Press, Bethesda, MD.

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