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| **Microbiology/Virology Technical Competency Requirements and Instructions**  |
| **Purpose** | Competency assessment is a measurement of an individual’s ability to properly perform all the steps of a test procedure and related activities in full accord with the laboratory’s protocol. In the microbiology/virology laboratory, the ability to respond to unusual or critical microorganisms or results is crucial to good patient service. CLIA ’88 regulations has set standards of assessment that must be used to evaluate all individuals and demonstrate that they can perform all testing operations reliably to provide and report accurate results.New employees must demonstrate competency in performing test procedures twice during the first year of employment. Following the first year, an employee must demonstrate competency on an annual basis. If a new test procedure or a new instrument is added, each employee must demonstrate competency before reporting test results. Competency assessment is an opportunity to provide continuing education and performance feedback. If the employee does not meet all of the competency criteria, corrective action will be initiated. Corrective action may range from rereading the procedure to retraining. The employee will then be evaluated. If corrective action is required, it should be completed and documented within 30 days.Competency is assessed using the following 6 elements to meet CLIA minimal regulatory requirements: 1. Direct observation of routine patient test performance
2. Monitoring the recording and reporting of test results
3. Review of worksheets, QC records, PT results and preventive maintenance records
4. Direct observation of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external PT samples
6. Assessment of problem solving skills

Children’s Minnesota Laboratory utilizes StaffReady® software accessible from StarNet to document competency assessments.Competency is assessed for the following test systems:

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| * Processing
* Bacterial ID
* Kirby Bauer Susceptibility
* MicroScan Susceptibility
* Vitek ID/Susceptibility
* MALDI
* Occult Blood
* Gram Stain
* Clinical Microscopy
* Parasitology
 | * Shell Vial Culture
* Viral Cell Culture
* Viral Enzyme Immunassay
* Virology Referral
* Sofia Rapid Antigen
* Fluorescence
* Lateral Flow
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|  **Procedure**  | The following methods of evaluation will be used to establish competency: |
|  | 1 | **Initial Training Checklists**Initial Training checklists on paper must be completed prior to reporting patient test results. These checklists will become part of the employee’s permanent file. These checklist will include Computer (Sunquest/GUI and Cerner) training, Safety Policies, Location of Supplies, Equipment and Operations, General Lab Duties, Communication, Quality Control and Test processes and procedures for all tests and test systems. New employees will be assessed at 6 and 12 months in StaffReady® according to test system. Checklists are found on the G:drive,Lab,Microbiology, New Employee Training docs, MC1200-1231. |
|  | 2 | **Procedure/Policy Manual**Competency assessment is based on an employee’s knowledge of the procedures and the ability to follow protocols in the procedure manual. Within each procedure are many steps or tests that must be performed before a result is reported. These steps or tests may include ordering procedures, sample preparation and processing, direct microscopic exams, culture isolate identifications, antibiotic susceptibility testing, and reporting of test results. Also required is knowledge of the “critical values” or the corrective steps that must be taken when a procedure is “out-of-control”. Staff is responsible for annual review of policy and procedures.New employees complete a written exam reviewing procedures and policies with a passing score of 80%. New tests/procedures/revisions are reviewed by staff and documented on the check-off sheets or in MedTraining. |
|  | 3 | **Attends or Reads: Email notifications / Staff Meetings / Huddles** |
|  | 4 | **Continuing Education**12 CEU’s per year are required to meet performance criteria. Attending Grand Rounds, MIMA, and available workshops can satisfy CEU’s, reading related material, presenting a paper, audio conferences, etc. Documentation is managed by the Education Coordinator and is found on the G:drive under Continuing Education. |
|  | 5 | **Safety/Compliance**Each employee is required to participate in safety/compliance training and complete the hospital CHEX courses annually. Documentation of completion is tracked by the organization. |
|  | 6 | **Direct Observation of Routine Patient Test Performance**Direct observation is used to assess competency by observing the employee’s performance of specimen receiving, handling, processing and testing. Employees are assessed annually for each test system using StaffReady® CLIA Elements (EL) 1-4.Acceptability will be documented for each step of the respective checklist of the test system. |
|  | 7 | **Review of Completed Worksheets and Detection of Errors**Each employee will be required to review completed worksheets at the end of the shift for the testing that they have performed for clerical errors and significant analytical errors. Department supervisor or designee will monitor correction of errors and proper notification in a timely manner. Review of intermediate test results is assessed by observation of each test system in StaffReady® EL 1-4 by observing the reviewing of patient results.QC and preventative maintenance records are reviewed. Proficiency Testing is reviewed after results are received and documented in the PT Binder. |
|  | 8 | **Monitoring the Recording and Reporting of Results**Review of patient records will be monitored using the “Culture Review Report” by the department supervisor or designee. Patient records will be reviewed for appropriate test performance, organized and accurate records, timeliness, appropriate action (i.e. calling of “critical values”), proper reporting of results and clerical errors.Monitoring the Recording and Reporting for Results will also be assessed in the StaffReady EL 1-4 by observing the entry of patient results into the computer for each test system. |
|  | 9 | **Quality Control and Maintenance Records**QC and maintenance records will be reviewed for adherence to protocol and appropriate corrective action to resolve “out-of-control” or discrepant test results by the supervisor or designee. |
|  | 10 | **Direct Observation of Instrument Maintenance**Employees will be observed for performance of instrument maintenance and function checks in StaffReady® EL 1-4 of each test system. Appropriate documentation of corrective action is reviewed by the department supervisor or designee. |
|  | 11 | **Proficiency Testing**Employees are required to test and report one or more proficiency samples or a previously tested clinical sample for each test systems if performing testing in that area. Competency activity is recorded in the **Proficiency and/or Competency Binders**. Documentation is also located in the StaffReady® Lab Competency system (PT) for each test system.  |
|  | 12 | **Assessment of Problem Solving Skills**The ability of an employee to problem-solve can be assessed by documentation of occurrences that demonstrate problem-solving skills or by quiz. The problem may be an erroneous or questionable labeling, improper culture set-up, deviation from standard procedure, organisms that are unusual or difficult to identify, test results requiring further investigation, quality control failures, instrument trouble shooting, or order entry problems. Documentation of problem resolution can be by Sunquest mailbox, QA report form, or Safety Learning Report. The supervisor or designee will determine if the problem was adequately resolved by reviewing the forms. Problem Solving (PS) documentation is in StaffReady® for each test system.  |
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| **Historical Record** | **Version** | **Written/Revised by:** |  |  |
|  | 1 | Pat Ackerman | **Effective Date:** | **Summary of Revisions** |
| 1.1 | Pat Ackerman | 9/1/1993 | Initial Version |
| 1.2 | Pat Ackerman | 12/4/2002 |  |
| 1.3 | Pat Ackerman | 11/30/05  |  |
|  | 1.4 | Tina Gronquist | 1/6/14 | Reformatted into online format |
| 1.5 | Helen StefanBecky Carlson | 1/5/151/06/15 | Gram Stain Atlas no longer available- removed #7. Re- numbered: MC 109 to MC 1301.  |
| 2 | Becky Carlson | 4/4/2015 | Re-numbered from MC 1301 to MCVI 9.0 for CMS loading |
|  | 3 | Susan DeMeyere | 7/17/2017 | Added StaffReady website information and distinction by test system.  |