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|  | **LABORATORY DEPARTMENT**  **POLICY AND PROCEDURES** | **Department: GENERAL** |
| **Number: 100-Prfi-gu-rev02/2013** |

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| **QUALITY IMPROVEMENT PLAN** |

**POLICY**:

The Clinical Laboratory Department’s Quality Improvement Plan is designed to:

1. Identify and eliminate sources of error, problems and complaints
2. Ensure the effectiveness of our policies and procedures
3. Ensure the adequacy and competency of staff
4. Provide a mechanism for corrective actions to ensure accurate, reliable, and prompt reporting of patient test results.

**PROCEDURE**:

1. Responsibility
   1. Quality Assurance Lead Technologist

1. Establishes and implements an annual Laboratory Quality Improvement program. The program will integrate the following into a system that will foster quality improvement in patient care

* + - 1. laboratory performance
      2. continuous quality improvement
      3. quality control activities
    1. Delegates responsibilities for monitoring, action, evaluation and reporting.
    2. Presents quality improvement activities to the hospital-wide Quality Steering committee.
  1. Laboratory Medical Director
     1. Ensures that the Quality Improvement plan is coordinated with other programs at this facility
     2. Will bring outcomes to physician committees within the facility
  2. Laboratory Staff
     1. Will complete and forward to the Clinical Lab Director, Situational Investigation reports to communicate concerns or complaints with respect to
        1. the quality of patient testing
        2. patient safety issues
     2. Will complete on-line in RDE occurrences that directly affect patient care.
     3. Are encouraged to voluntarily report device-related serious adverse patient events directly to the FDA. This information on how to do this is provided at <http://www.fda.gov/medwatch/report/hcp.htm>
     4. If a patient death has occurred, it is required to report the event to the FDA and the device manufacturer.
     5. If a serious patient injury has occurred, the report may be submitted to the manufacturer only.
     6. Reports must be submitted as soon as practicable but no later than 10 days from the time medical personnel became aware of the event.
     7. Issues that you think have not been appropriately addressed can be called into the College of American Pathology (CAP) hotline at 866-236-7212. The laboratory does not allow harassment of punitive action against an employee in response to a complaint or concern made to CAP or other regulatory organization regarding laboratory quality or safety.

1. Scope of Care
   1. Patient services are provided to both the inpatient and outpatient population and include
      1. Analytical chemistry testing to include therapeutic and abuse drug testing
      2. Hematological testing
      3. Coagulation studies
      4. Microbiological identifications
      5. Serology testing
      6. Blood Bank/Transfusion services to include immunological testing and transfusion of blood components
      7. Urinalysis testing
      8. Collection and reporting of data
      9. Quality control in all areas
2. Aspects of Care
   1. Pre-analytical
      1. Specimen collection
      2. Documentation of collection of specimens
      3. Distributing specimens to various work areas
      4. Completing paperwork as needed
      5. Providing complete and accurate information in the computer system
      6. Identifying patients appropriately
   2. Analytical-review testing within the lab by proficiency testing in areas such as
      1. Chemistry
      2. Urinalysis
      3. Hematology
      4. Blood Bank
      5. Serology
      6. Microbiology
      7. Coagulation
      8. Point of Care testing
   3. Post-analytical
      1. Producing and distributing laboratory reports to health care providers
      2. Reporting results in a timely manner
      3. Reporting accurate and complete results
      4. Directly contacting providers with test results as needed
3. Performance Measures
   1. Performance measures will be established as a means to systematically monitor identified aspects of care in an ongoing manner.
   2. Choosing Indicators
      1. All areas of the lab will have a Quality Assurance project at least once per year. The departments include:
         1. Chemistry
         2. Hematology/Coagulation
         3. Microbiology
         4. Serology
         5. Phlebotomy
         6. Urinalysis
         7. Safety
         8. Point of Care
         9. Blood Bank
         10. Send Outs
      2. Periodic review of Situational Investigation reports and looking for trends
      3. Periodic review of Occurrence Reports involving the Laboratory
      4. Provider complaints
      5. Staff concerns
      6. National benchmarks
   3. Indicators
      1. The lab will monitor a minimum of 5 indicators of patient care processes
      2. They will relate to the identified aspects of care and will be specific and measurable
      3. They will be structured to relate to both the processes and outcomes of patient care
      4. They will pertain directly to Clinical Laboratory practices
      5. They will be structured to focus on improvement in patient care
      6. They will use objective criteria that reflect current knowledge and clinical experience
   4. Thresholds
      1. Will represent pre-established levels that trigger a more intensive evaluation of the indicator or
      2. Benchmarks that have been identified by facility experience or other documentation
   5. Data Collection and Monitoring Methodology
      1. Will be performed with a frequency sufficient to identify potential problems
      2. An outline of actual aspects of care under review will include
         1. description of the frequency of monitoring each activity
         2. how it will be monitored
         3. where the data will be obtained from
      3. Data will be collected from a variety of sources to analyze patterns or trends. These include but are not limited to
         1. incident logs
         2. computer reports
         3. requisitions
         4. medical records
   6. Safety
      1. Employees experiencing occupational injuries or illnesses are required to complete a Situational Investigation form which is given to the Clinical Lab Director.
      2. All safety related Situational Investigation reports are reviewed on an ongoing basis.
      3. These are assessed in order to avoid recurrence.
4. Evaluation
   1. Identify opportunities for improvement in processes of patient care
   2. Conclusions will be drawn regarding evaluation of data presented with recommendations considered.
5. Action - the Clinical Laboratory will
   1. Take action to resolve identified problems
   2. Direct efforts to those areas which have the greatest potential for improving patient care
   3. Utilize hospital resources, committees and problem-solving techniques to resolve identified problems and improve patient care
6. Assessment of Effectiveness- the Clinical Laboratory will
   1. perform follow-up monitoring to assure actions taken are effective and that any progress is sustained
   2. use the same or similar criteria that was used to identify the problem
7. Documentation- Documentation includes
   1. Findings from monitoring activities
   2. Conclusions regarding identified opportunities for improvement
   3. Recommendations concerning potential actions
   4. Actions taken to effectuate change
   5. Outcome of action effectiveness
8. Communication of Information
   1. Post all QA outcomes on the QA board for staff to review
   2. Report outcomes to the hospital-wide Quality Assurance committee.
9. Annual Evaluation of Performance Improvement Program
   1. The Clinical Laboratory will evaluate the effectiveness of the performance improvement monitoring program at least on an annual basis
   2. The evaluation will be documented and forwarded to the appropriate reporting structure.
10. CAP Interim Self-Inspections
    1. CAP Interim Self-Inspections are held biannually opposite the years of the on-site CAP inspections.

1. The CAP will forward site specific inspection checklists to the Laboratory to complete a self-inspection, approximately one year prior to the Laboratory’s on-site inspection date.

1. The Clinical Lab Director will ensure the checklists are provided to the appropriate key personnel for the self-inspection.
2. A deficiency form will be completed by the Lead Technologist inspecting the section. It will list all deficiencies and include the name of the section and the signature of the inspector.
3. Once all documentation is completed a meeting will be set up with the Medical Lab Director and the inspector to review the deficiencies and the proposed corrections.
4. Once all documentation is completed the letter from CAP will be signed by the Medical Director and returned to CAP for completion of the self inspection.
5. The documentation will be placed in a notebook for review at the next on-site inspection.
6. A due date will be set to complete all the changes or write new policies.
7. 90 days prior to the due date, each Lead Technologist will be given time off to review the regulations.
8. All new policies or policies needing changes will be completed by the due date.

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| **REFERENCES:**   1. Clinical Laboratory Improvement Plan (2002). *Flagstaff Medical Center Laboratory Policies and Procedures* 2. Laboratory Quality Improvement Plan (2004). *Verde Valley Medical Center Laboratory General Laboratory Manual.* 3. A Plan for Implementation (1998). *COLA Laboratory Quality Assurance.* 1-1 to 1-5. 4. CAP Laboratory General Checklist (GEN.20371) 9/25/2012 |
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| **Prepared by/Title/Date:**  Karen McMullin QA/LIS Lab Coordinator  October, 2005  **Approved by/Title/Date:**  Signature on File in Lab | **Committee Approval/Date:**  Policy & Procedure \_\_\_\_\_\_ | **Dates Reviewed/Revised:**  4/09  12/09  12/12  2/2013 |