

PROTOCOL FOR: Decentralized Lab Testing: Program Scope, Responsibility and Competency Assessment/Validation

- POLICY:
1. Overall responsibility for the Nursing Department decentralized lab testing program is shared by the Nursing Department and the Department of Laboratory Medicine.
  2. At the unit level, the Nursing Manager in collaboration with the Clinical Nurse Specialist is accountable for the decentralized lab testing program.
  3. The scope of decentralized lab testing performed by the Nursing Department is limited to Waived testing and PPMP as defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA)<sup>88</sup>.
  4. The Department of Laboratory Medicine applies for and maintains the appropriate CLIA license.
  5. New instruments/testing products for decentralized lab testing must be evaluated and approved by the Department of Laboratory Medicine prior to purchase and implementation.
  6. The results of decentralized lab testing are utilized for screening and monitoring and diagnostic purposes in conjunction with patient history and/or clinical laboratory testing. Abnormal results are reported to the physician so that confirmatory tests may be ordered and sent to the Clinical Laboratory.
  7. Specimen collection and preservation is done according to the decentralized lab procedures in the Specimen Collection Manual located on each unit.
  8. A quality control system is implemented for each instrument and non-instrument testing which meets CLIA and JCAHO requirements.
  9. A quality assurance program is implemented for the decentralized lab program. Quality assurance reports are compiled by the Decentralized Lab Testing Office of Laboratory Medicine.
  10. The quality assurance reports are reviewed by the Laboratory Medicine Decentralized Laboratory Testing Office and Laboratory Medicine faculty on an ongoing basis. Appropriate action is taken as necessary.
  11. New Nursing Department staff receives training on decentralized lab testing and associated quality control procedures.

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12. Nursing Department staff who are responsible for decentralized lab testing are identified at the unit level by the Manager and/or Clinical Nurse Specialist.
13. Competency of all appropriate Department of Nursing staff in performing decentralized lab tests will be established by evaluating staff's skills and knowledge regarding both patient and quality control tests used on the units on which they work.
14. Competency assessment will be performed on a calendar year basis.
15. Nursing Department staff competence is evaluated at regularly defined intervals, determined by Educational Services. Competency requirements are based upon an annual assessment of testing frequency, complexity of the testing methodology, and consequences of an inaccurate result. Competency requirements are as follows:
  - a. Full and part-time Nursing Department Staff:
    - 1) Instrument Tests:
      - a) For new employees, competency will be assessed at the completion of orientation.
      - b) Annually after the first year of employment.
    - 2) Non-Instrument Tests: Competence is evaluated annually.
16. Cognitive/written decentralized lab examinations will be developed collaboratively by Educational Services with input from Nursing Managers, CNSs and the Decentralized Laboratory Testing Office of Laboratory Medicine.
17. Documentation of staffs' competency will be maintained on the unit until the time of their annual evaluation. The documentation will include the unit's decentralized lab competency checklist and/or orientation/annual competency checklist.

COMPETENCY VALIDATION PROCESS:

1. When assessing competency for non-instrument testing (i.e., pH Paper, Hemocult Slides) institutional guidelines will be followed. These will be centrally located on each unit in the Decentralized Lab Procedure Manual.
2. Competency validation for all testing will include observation of performance of patient test and quality control and written cognitive test.

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ORIENTATION OF

NEW EMPLOYEES: 1. The preceptor will validate competency by observing the orientee perform the patient and quality control decentralized lab tests. Performance assessment includes documentation, trouble-shooting and a written test.

APPROVAL: Nursing Administrative Council

EFFECTIVE DATE: 12/93

REVISION DATES: 7/94, 11/97, 10/00, 10/03

REVIEWED DATES: 6/09