CLINICAL POLICY

Decentralized Lab Testing Program Scope

A. EFFECTIVE DATE :

January 19, 2021

B. PURPOSE :

The Decentralized Laboratory Testing (DLT) Program coordinates, oversees and regulates compliance to ensure that all waived /PPM (Provider Performed Microscopic) testing is performed in accordance with state, federal and independent regulatory agencies as proposed by Clinical Laboratory Improvement Amendments (CLIA). The DLT Program staff work collaboratively with nursing personnel and clinical staff to ensure quality patient care throughout all areas.

C. POLICY :

The overall responsibility for the decentralized lab testing (DLT) program is shared by the Department of Pathology and Laboratory Medicine, the Department of Nursing, and/or the department performing testing. The request for new testing must be authorized by the Lab Test Request committee.

D. SCOPE :

The scope of DLT performed is limited to Waived Testing and Provider-Performed Microscopy (PPM), as defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The Department of Pathology and Laboratory Medicine applies for and maintains the appropriate CLIA license.

E. DEFINITIONS :

None

F. MATERIAL(S) NEEDED :

None

G. PROCEDURE :

The DLT program establishes standards to ensure accuracy and reliability of test results. All locations performing testing must follow these quality standards.

1. New instruments and/or testing products for DLT must be evaluated and approved by the Dept. of Pathology and Laboratory Medicine prior to purchase and implementation.

2. The results of DLT are utilized for screening, monitoring, and diagnostic purposes in conjunction with patient history and/or clinical laboratory testing. Unanticipated results that are not within normal limits must be reported to the practitioner.

3. DLT procedures are available on each nursing unit/clinical area and can be used as a resource to staff. These procedures follow, at minimum, the manufacturer's recommendations.

4. Specimen collection and preservation is performed according to the DLT procedures in the Specimen Collection Manual available online http://nso-pathlab1/PathLab_PnPManager/main.aspx

5. The quality assurance data is reviewed by DLT program staff on an ongoing basis. Appropriate action is taken as necessary.

6. Noncompliance with quality indicators is communicated periodically in quality assurance reports compiled by DLT program staff.

7. New staff identified by their manager or designee will receive training on DLT patient test and associated quality control procedures. Training is provided specific to the job responsibilities of staff within their unit/department.

8. Skill and knowledge competency of DLT will be validated annually using at least two of the following methods:

a. Performance of a test on a blind specimen
b. Periodic observation of routine work by a qualified staff
c. Monitoring each user's quality control performance
d. Use of a written test specific to the test assessed

9. Competency validation will be done under the direction of DLT program staff, and will be consistent with best practices identified in the DLT Procedure Manual.

10. Documentation of orientation and competency validation will be maintained in the employee's personnel file in the Human Resource department. Copies are also retained in the Dept. of Pathology and Lab Medicine DLT office.

11. When a licensed independent practitioner performs noninstrument waived testing, and the test falls within his or her specialty, the medical staff credentialing and privileging process will be used to document evidence of training and competency.

H. ATTACHMENTS :

None

I. REFERENCES :

None

J. SEARCH WORDS :

Decentralized Lab Testing, DLT, Waived Testing, CLIA

K. ENFORCEMENT:

Violations of this policy or associated procedures may result in appropriate disciplinary measures in accordance with University By-Laws, General Rules of Conduct for All University Employees, applicable collective bargaining agreements, the University of Connecticut Student Code, other applicable University Policies, or as outlined in any procedures document related to this policy.

L. STAKEHOLDER APPROVALS :

On File

M. COMMITTEE APPROVALS :

None

N. FINAL APPROVAL :

1. Andrew Agwunobi, MD (Signed) 2/05/2021
Andrew Agwunobi, MD, MBA Date
UConn Health Chief Executive Officer

2. Anne D. Horbatuck (Signed) 1/28/2021
Anne D. Horbatuck, RN, BSN, MBA Date
Clinical Policy Committee Co-Chair

3. Scott Allen, MD (Signed) 1/29/2021
Scott Allen, MD Date
Clinical Policy Committee Co-Chair

4. Caryl Ryan (Signed) 2/02/2021
Caryl Ryan, MS, BSN, RN Date
VP Quality and Patient Service & Chief Nursing Officer

O. REVISION HISTORY :

Original approval by Nursing Administrative Council, 07/94 & Dept of Lab Medicine, 12/03
Date Revised: 07/90, 11/97, 10/00, 10/03, 07/12, 09/14, 05/15, 01/21
Dated Reviewed: 06/09, 11/17