LOS ANGELES COUNTY DEPARTMENT OF HEALTH SERVICES
HARBOR-UCLA MEDICAL CENTER

SUBJECT: POINT-OF-CARE TESTING **POLICY NO.** 365

CATEGORY: Provision of Care	**EFFECTIVE DATE:** 3/96
POLICY CONTACT: Rasoul Koupaei	**UPDATE/REVISION DATE:** 6/22
REVIEWED BY COMMITTEE(S): Clinical Laboratory Committee	

PURPOSE:
The purpose of point-of-care testing is to give immediate results for a limited number of laboratory tests so that clinicians may utilize these results for patient care as defined in the policy. The purpose of this policy is to ensure quality patient care through accurate Point-of-Care Testing (POCT) performed in a manner consistent with Federal, State of California, College of American Pathologists (CAP) and other regulatory standards. Additionally, this policy delineates the categories of personnel that will be trained, competency assessed, and monitored in the performance of Point-of-Care Testing**.**

DEFINITION:
Point of Care Testing (POCT) or bedside testing is defined as laboratory testing at or near the site of patient care using a portable device that does not require a dedicated or permanent space.

POLICY:
At Harbor-UCLA Medical Center, the Department of Pathology is responsible for oversight of the point-of-care testing performed by Department of Nursing personnel or any other groups performing POCT testing. This oversight includes:

- Scope of point-of-care testing
- Selection of methods and reagents
- Selection and maintenance of equipment
- Review of competency, quality control, and quality assurance

Point-of-Care tests and equipment are selected by the Department of Pathology and approved by the Clinical Laboratory Committee at Harbor-UCLA Medical Center.

Areas requesting point-of-care testing and/or new tests added to their test menu must submit an application for POC testing to the Laboratory for preliminary evaluation and recommendation to the Clinical Laboratory Committee.

REVISED: 3/99, 1/07, 3/10, 5/14, 4/15, 6/16, 6/19, 6/22
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APPROVED BY:

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Harbor-UCLA Medical Center Department of Pathology shall:

- Ensure compliance with licensing and accreditation requirements by administering a program that monitors and documents the quality of point-of-care testing.
- Determine the clinical appropriateness and utilization of test results prior to authorization of:
    1. New test to institute
    2. Expanded point-of-care testing location
- Develop a Quality Management program that addresses the following elements:
    1. Evaluation, selection, and validation of device or reagent kit to be instituted.
    2. Testing Personnel Qualification:
        - Point of care tests designated by the FDA as “non-waived” are only done by registered nurses and physicians after receiving appropriate training and a current competency assessment.
        - Point of care tests designated by the FDA as “waived” may be done by any person after receiving appropriate training and/or a current competency assessment
        - Training program
        - Competency Assessment
    3. Policy and procedure for the testing in which include:
        - Testing procedure/Equipment operation
        - Quality assurance procedures include equipment preventive maintenance and troubleshooting
        - Reagent storage and handling
        - Quality control solution storage and handling
        - Specimen collection, handling, and preservation (if applicable)
        - Result interpretation and documentation
    4. Quality Assessment:
        - Staff compliance with the policies in place
        - Staff competency
        - Proficiency Testing
        - Pathology staff is responsible for collecting and maintaining all required records of quality control and patient testing, except the results recorded directly on the patient's medical record.

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) REGISTRATION:
POCT at Harbor-UCLA Medical Center is under the CLIA registration and the direction of the main Clinical Laboratory, Department of Pathology.

RESPONSIBILITY:
Department of Laboratories and Pathology
Administration
Attending Staff
House Staff
Mid-Level Providers
Nursing Staff

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PROCEDURE:

A. Utilization of Point-of-Care Testing

Point-of-care testing in this facility is used for three purposes:

1. Screening: When used for screening, abnormal values are confirmed by submitting duplicate specimens to the Main Laboratory, if clinically indicated.
2. Patient assessment: When used as part of an overall patient assessment, the follow-up of abnormal results with specimens sent to the Laboratory is determined by the physician and is evaluated on a case-by-case basis.
3. Following a patient's response to therapy, such as insulin or a transfusion: Any unexpected value may be cause for submission of a duplicate specimen to the Main Laboratory for verification if clinically indicated.

The most significant use of point-of-care testing in the hospital setting is for the immediate clinical assessment and efficiency in the management of seriously ill patients.

Point-of-care tests include waived and non-waived tests. As defined by CLIA, waived tests are simple tests with a low risk of an incorrect result. On the other hand, Non-waived testing is the term used to refer collectively to moderate and high complexity testing. Both types of the waived and non-waived tests POCT tests are done in Harbor-UCLA Medical center are done under the Department of Pathology's main Clinical Laboratory's CLIA registration.

All personnel performing Point of care must be trained initially, and then perform satisfactorily on annual competency assessments thereafter. Training and competency assessment documentation will be kept in the employee files, maintained by Pathology Department. The following POCT testing may be used for patient care in Harbor-UCLA Medical Center. When clinically indicated, duplicate specimens for confirmation may be sent to the Laboratory for confirmation.

- Dipstick urinalysis: Screening and assessment.
- Hemoglobin: Screening, assessment, or following therapy.
- Blood glucose: Screening, assessment, or following therapy.
- Urine pregnancy tests: Screening and assessment.
- Electrolytes, chemistry panels, lactate, blood gases by I-STAT: Screening, assessment, or following therapy.
- Activated clotting time: Following therapy.
- Whole blood prothrombin time: Following therapy.
- HbA1c: Screening, assessment, or following therapy.
- Amniotic fluid Rupture of Membranes Test: Screening and assessment.

Note 1: This list is reviewed and approved by the Clinical Laboratory Committee when designated and/or when new point-of-care tests become available.

Note 2: Any point-of-care test exceeding the linearity limit of the instrument or any other situation defined under the standard operating procedure will require a specimen sent to the Main Laboratory for confirmation. Additionally, duplicate tests may be sent to the main lab for confirmation when clinically indicated.

B. Methods and Equipment

Methods and equipment are selected by the laboratory. Test procedures, including quality control, proficiency testing, and record-keeping are written by the Department of Pathology, in accordance with the Joint Commission (JC), College of American Pathology, and State of California standards. The content of competency training and testing is specified by the Department of Pathology's Laboratory Director. The Point-of-Care section, in collaboration with the Nursing Department and other POCT user groups, will perform the competency training and testing. Records of each nurse's competency will be kept with their other competency records in the Point-of-Care section. No employee may perform a point-of-care test unless their competency certification is current.

All testing will be done in accordance with written procedures provided by the Department of Pathology which are kept, at all times, with the test materials and equipment. The area POCT user Manager is responsible for keeping the procedure manual, the appropriate supplies, and reagents in designated areas, and for maintaining the testing and quality-control records until they are picked up for review by the laboratory. Any unexpected results or issues regarding reagents, devices, or testing procedures should be communicated with the POCT group in the Department of Pathology.

No other testing outside of the main laboratory is authorized under the laboratory license maintained by the Department of Pathology.

C. Safety

The point-of-care testing personnel in this facility follow hospital policies:

1. Standard precautions are used for point-of-care testing.
2. Only auto-disabling single-use finger stick/heel stick lancing devices are used for assisting in the monitoring of blood glucose and the other point-of-care testing.
3. The hospital's infection control policy is to prevent the transmission of infection via portable or handheld testing devices.

D. Availability to Point-of-Care Testing:

An area requesting the ability to perform point-of-care testing or to add a new test to their menu obtains an application for POC testing from the POCT section supervisor at (424) 306-6266. Information to be included on the application is the approved budgetary source for the equipment and supplies as well as the identification of the qualified personnel to perform and maintain the new test. The clinical departments, the Nursing Department, and any other user groups submitting their requests by filling the "Requests for Point-of-Care Testing" form for any new or additional testing with adequate clinical justification. The Attending Physician or Resident in the area can complete the application, however, the form needs to be reviewed and signed by the medical and nursing director before submission. The forms will be reviewed by the POCT section for feasibility, regulatory issues, and standardization with DHS and then will be further reviewed and assessed, and approved by Clin Lab Committee and, if necessary, the DHS POCT Committee for new tests.

REFERENCE

Federal Register/Vol.57, No. 40, February 28, 1992: 42 CFR Section 405, et al.
California Business and Professions Code: Division 2, Chapter 3, Sections 1200-1327
California Code of Regulations: Title 17, Chapter 2, Subchapter 1, Group 2
College of American Pathologists (CAP): Standards for Laboratory Accreditation

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PROCEDURE DOCUMENTATION
Point-of-Care Testing Procedure Manual
Laboratories and Pathology Policy and Procedure Manual

Reviewed and approved by:
Medical Executive Committee 06/2022

Beverley A. Petrie

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