County of Los Angeles **Department of Health Services**

OLIVE VIEW-UCLA MEDICAL CENTER
POLICY & PROCEDURE

NUMBER: 220
VERSION: 4

SUBJECT/TITLE: **POCT-01: POCT-01 POINT-OF-CARE TESTING ADMINISTRATIVE POLICY/APPLICATION FOR NEW POCT**

POLICY: Under the direction, authority, jurisdiction, and responsibility of the Olive View-UCLA Medical Center Pathology Department Director, the hospital will maintain and administer an organized Point-of-Care Testing (POCT) Program.

PURPOSE: To provide a coordinated POCT program, involving both clinic and laboratory staff, which assures the quality of patient care by adherence to the standards of good laboratory practice. The program is designed to ensure quality POCT, adequate documentation, and compliance with all current federal, state, College of American Pathologists (CAP) and The Joint Commission requirements (TJC).

DEPARTMENTS: All

DEFINITIONS: **Point of Care Testing** is a clinical laboratory test performed outside of the main clinical laboratory, usually near or at the patient's bedside or location.

Waived test refers to a point of care test which has been designated under the Clinical Laboratories Improvement Amendments of 1988 (CLIA '88) as a test which employs methods so simple and accurate as to render the likelihood of erroneous results negligible, poses no reasonable risk of harm if the test were performed incorrectly, and which has been cleared by the Food and Drug Administration for home use.

Nonwaived test refers to tests categorized as either moderately complex including Provider-Performed Microscopy Procedure (PPMP) or highly complex by the US Food and Drug Administration (FDA), according to a scoring system used by the FDA.

PROCEDURE: The Point-of-Care Testing (POCT) Program is organized and administered as follows:

RESPONSIBILITY

Olive View–UCLA Medical Center POCT Advisory Committee comprised of Laboratory Director, Clinical Pathologist, Laboratory Manager, Clinical Laboratory Supervisors and POCT Coordinators.

1. Defines scope of POC testing and reviews petitions for added testing.
2. Defines requirements for the POCT program.
3. Presents recommendations for problem solving.
4. Refers unresolved problems to the Olive View-UCLA Chief Medical Officer, Hospital Administration.
5. The Laboratory Director designates POCT members which include POCT Supervising Clinical Laboratory Scientist I, Clinical Laboratory Scientist II and/or POCT Coordinators to review QC data, proficiency testing performance, competency assessment, test methodology performance studies, and biennial procedure review.

Olive View-UCLA Medical Center Department of Pathology:

1. Oversight of POCT quality control data and patient testing performed by clinic staff.
2. Development and maintenance of POCT procedure manuals.
3. Oversight of distribution of reagent and control solutions.
4. Validation of instruments (precision, accuracy, linearity, correlation) as required.
5. Assistance with instrument troubleshooting, non-routine maintenance, and provision of replacement instruments and instrument repair.

Olive View-UCLA Medical Center Clinic Departments (Department of Medicine, Department of Nursing, and Other Specified Ancillary Services) and Nurse Managers:

1. Direction/supervision of staff authorized to perform point-of-care testing and compliance with the Olive View-UCLA Medical Center POCT.
2. Performance of waived, provider-performed microscopic procedures, and selected non-waived POCT procedures.
3. Performance of quality control procedures (control solutions and reagent checks) and corrective action when applicable.
4. Appropriate reporting of test results to the ordering physician.
5. Documentation of test results on patient chart.
6. Patient education as needed.
7. Maintenance of training and competency assessment documentation for testing personnel at each testing site.
8. Maintenance of Proficiency Testing documents at each PPMP testing site.

Joint Responsibilities of Olive View-UCLA Medical Center Department of Pathology and Clinic Departments:

1. Orientation and training of personnel
2. Competency assessment of personnel

3. Proficiency testing

PROGRAM

I. CERTIFICATION

The POCT Program at Olive View-UCLA Medical Center is operated under a Center for Medicare and Medicaid Services CLIA Laboratory Certificate of Provider-Performed Microscopy Procedures for PPMP and waived testing, CLIA ID# 05D0872242, and is accredited by The Joint Commission for Glucose, Urinalysis, Urine Pregnancy, Eye pH and Fern Testing. For non-waived POC INR and ACT, the testing program is operated under Center for Medicare and Medicaid Services CLIA Certificate of Accreditation, CLIA ID#05D0558588, and is accredited by the College of American Pathologists (CAP).

II. ORGANIZATION

The Olive View-UCLA Medical Center Department of Pathology is accountable for oversight of POCT at Olive View-UCLA Medical Center.

The Director of the Olive View-UCLA Medical Center Department of Pathology serves as the POCT Laboratory Director at Olive View-UCLA Medical Center.

A. POCT Committee

1. Membership: Chaired by the Olive View-UCLA Medical Center Pathology Department Clinical Laboratory Scientist Administrative Coordinator (or designee). Committee members include representatives from Olive View-UCLA Medical Center Medical Administration, Hospital Administration, Medical Staff, Nursing Administration, and Department of Pathology.

2. Charge: Review deficiencies of monthly compliance reports submitted by POCT Coordinators and make recommendations for addressing/correcting these deficiencies.

B. POCT Administrative Team

1. Membership: Facilitated by the Olive View-UCLA Pathology Department Director and Clinical Laboratory Scientist Administrative Coordinator. Team members include the POCT Supervising Clinical Laboratory Scientist I & II, POCT Coordinators, and one Pathologist.

2. Charge: Responsible for the daily functioning of the POCT program and management of training, education, competency assessment, proficiency

testing program; and for monitoring QC, patient testing, instrument maintenance, assuring compliance with accreditation standards. The team also oversees the acquisition and maintenance of POCT supplies and reagents and the evaluation of new POCT equipment. The team updates and maintains POCT Procedure Manuals for all testing sites including procedures posted in the PPM. The team is also responsible for reviewing requests for expansion of existing POCT services, approving and implementing new POCT procedures and making recommendations concerning POCT policies.

III. SCOPE OF TESTING

A. Waived Testing

POC Glucose
POC Urine Chemistries
POC Urine Pregnancy
POC Eye pH

B. Nonwaived Testing

POC ACT
POC INR

C. Provider-Performed Microscopic Procedures

Fern Test – Amniotic Crystallization

IV. POINT-OF-CARE TESTING AND INSTRUMENTATION

A. POCT at Olive View – UCLA Medical Center is restricted to waived testing procedures (POC glucose, POC urine dipstick, POC urine pregnancy and eye pH), non-waived testing procedure (POC ACT and POC INR) and provider-performed microscopic procedures (fern test) at specified sites.

B. Requests for new POCT procedures and/or sites must be preceded by careful assessment of need including but not limited to improved patient care clinical outcomes. Requests must be submitted to the POCT Advisory Committee for review and approval. (See "Request for Point-of-Care Testing" form)

V. PERSONNEL TRAINING

A. Training

1. The POCT Administrative Team will provide training to trainers (test site managers and/or their designees) or POCT clinic personnel as needed. Routine quality control, patient testing, instrument maintenance, limited troubleshooting, and safety precautions will be included in training.

2. Documentation of training by the POCT Staff and Nursing Education Center will be provided to each test site manager. On-going training by site managers will be documented and records of training and competency assessment will be maintained at the test site. Original copy is sent to POCT Administrative Office.

3. Each manager will maintain a current list of personnel authorized and appropriately trained to perform POCT. The list will specify which tests every employee is authorized to perform.

B. Competency Assessment

1. Competency assessment will be overseen by the POCT Staff and conducted jointly with site managers. Competency assessment will include validation of test procedures and passing a competency test. A minimum score of 80% is required to pass competency assessment. POCT Administrative Team has the option to use competency tools provided by the manufacturer as test procedure validation (performance of QC material and patient tests performed) in addition to passing a competency test.

2. Competency assessment is required after initial training, 6 months, and annually thereafter.

3. Annual competency assessments are scheduled as follows and include all tests performed at each testing site:

    a. DEM – The month of October of each year
    b. Olive View Medical Center except DEM – The month of February of each year.

4. PPMP (Provider Performed Microscopy Procedures)

The Clinical Laboratory Improvement Amendment (CLIA'88) requires that competency of all personnel who are involved in the pre-analytic, analytic, and post-analytic phases of clinical laboratory testing must be evaluated for competency after initial training, 6 months, and annually thereafter. Methods used shall include, but are not limited to the following:

- Direct observations of routine patient test performance including patient preparation (when applicable), specimen handling, processing and testing;
- Monitoring of the recording and reporting of test results;
- Review of intermediate test results, and preventive maintenance records;
- Direct observation of performance of instrument maintenance and function checks;
- Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and,
- Assessment of problem solving skills for tasks requiring, judgment or interpretation.

For the Direct Observation Component, this occurs whenever there is a patient for testing. The Director of the PPMP is responsible for oversight of the direct observation component.

VI. PROCEDURE MANUAL

A. A current POCT Policy and Procedure Manual must be present in the testing area.

B. Procedures must include:
1. Specimen collection requirements
2. Specimen preservation requirements, if any
3. Quality Control Procedures
4. Quality control action limits
5. Step-by-step patient testing directions
6. Test performance requirements (acceptable limits, reference ranges, critical results, limitations of test procedures, result documentation to ordering or physician provider, etc.)
7. Trouble shooting and instrument maintenance
8. Corrective action procedure
9. Documentation of test results on patient chart

C. Procedures must be reviewed biennial by the Olive View-UCLA Medical Center Pathology Department Director and members of the POCT Administrative Team.

D. Documentation of receipt from testing personnel of all procedure revisions must be maintained by POCT Administrative Team and a copy provided to testing sites.

VII. REAGENTS

A. Reagents records will be checked periodically per site by POCT Administrative Team in conjunction with QC and Patients' review during monitoring site visits.

B. POCT Administrative Team and Supply Chain Operations will set-up with vendor sequestered lots, when applicable.

C. Reagents are ordered through Supply Chain Operations by individual testing sites according to tests performed.

VIII. QUALITY CONTROL (QC)

A. Quality control checks and appropriate corrective action steps must be documented.

B. Appropriate quality control records must be maintained at the test site and reviewed periodically by POCT Administrative Team staff.

C. POCT Administrative Team and Supply Chain Operations will set-up sequestered lots, if applicable.

D. QC samples are ordered through Supply Chain Operations by individual testing sites according to test performed.

IX. INSTRUMENT MAINTENANCE

A. Directions and schedules for proper maintenance including acceptable cleaning agents and disinfectants must be available at the testing area.

B. Instruments will be checked periodically for adherence to established maintenance procedures (daily, weekly or as needed maintenance) during monitoring site visits.

C. Records of maintenance performed by clinical staff as well as outside service providers must be available at the testing area.

X. PROFICIENCY TESTING (PT)

Proficiency testing participation will be established for non-waived and selected waived tests as well as provider performed microscopic procedures. Clinic personnel will perform testing on proficiency test samples. POCT Administrative Team staff

members will record results for submission on-line to CAP (College of American Pathologist), maintain records, and provide necessary feedback to test site supervisory and testing personnel. Hospital PT samples will be ordered annually by Department of Pathology QI/QA Coordinator.

POCT Coordinators will be responsible for submissions to CAP, maintain records and provide necessary feedback to the Pathologist member of POCT Administrative Team.

Investigation and corrective action for failed PT results will be the responsibility of the POCT Administrative Team. A copy will be sent to Department of Pathology QI/QA Coordinator and POCT Administrative Team.

XI. SAFETY POLICIES AND PROCEDURES

POCT Safety policies and procedures must include written procedures addressing procurement, handling, and disposal of all specimens with minimal hazard to personnel. Safety Data Sheets (SDS) will be included in each testing procedure manual. Refer to "Point of Care Testing Infection Control" and "Chemical Hygiene Policy" for details.

XII. SPECIMEN HANDLING

Specimen collection, handling and preservation are discussed in detail in each individual test's procedure.

XIII. RESULTS REPORTING

Periodic monitoring by POCT Administrative Team staff will include the following required items to ensure compliance with the JC standards, CAP, State of California and Federal regulations:

A. Test records must indicate by initials, Employee ID code, or other recognizable means of clinic staff who performed each test utilized in patient care.

B. Unique identification of specimens by FIN or pre-approved patient ID number by POCT Administrative Team must be used to minimize patient mix-ups.

C. Reference ranges must be available for review in the chart when results are documented. Abnormal and/or critical results must have documentation of notification to MD or Provider.

D. An adequate system for reporting results per Nursing guidelines must be followed.

References:	
Approved by: Bonnie Bilitch (Chief Nursing Officer), Holli Mason (Laboratory Director), Judith Maass (Chief Executive Officer), Rima Matevosian (Chief Medical Officer)	Date: 05/27/2020
Review Date: 05/27/2020	Revision Date: 02/25/2020
Next Review Date: 05/27/2022	
Distribution: Olive View Hospital-Wide Policies, Point of Care Testing	
Original Date: 01/21/2002	