OLIVE VIEW-UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY & PROCEDURE

NUMBER: 1971
VERSION: 2

SUBJECT/TITLE: POCT-02 POINT OF CARE TESTING OPERATIONAL POLICY/COMPLIANCE & CORRECTIVE ACTION GUIDELINES

POLICY: Point-of-Care Testing will be performed in accordance with this policy.

PURPOSE: To ensure quality patient care through accurate Point-of-Care Testing (POCT) performed in a manner consistent with Federal, State of California, Joint Commission (JC), and College of American Pathologist (CAP) regulatory standards.

This document defines the scope of Point-of-Care Testing (POCT) at Olive View-UCLA Medical Center (OVMC), POCT training and competency assessment, patient results including critical (life-threatening) test result confirmation and reporting, quality control testing, monitoring, proficiency testing and special studies, compliance and corrective action guidelines, and record keeping.

DEPARTMENTS: PATHOLOGY

DEFINITIONS:

PROCEDURE:

I. SCOPE OF TESTING:

Point-of-Care Testing at Olive View-UCLA Medical Center consists of Clinical Laboratory Improvement Amendment (CLIA) Waived, Non-Waived testing, and Provider Performed Microscopy Procedures (PPMP) as follows:

WAIVED TESTS:

POC Glucose Determination by Nova StatSrip Glucose Meter
POC Urine Pregnancy by QUIDEL® Quickvue® + One Step hCG
POC Urine Pregnancy by Siemens Clinitest® hCG by Clinitied STATUS® +
POC Urine Chemistries by Siemens Multistix® 10 SG by Clinitek STATUS®+
POC Eye pH

NON-WAIVED TESTS:

POC INR by Coaguchek® XS Pro
POC ACT by Hemochron® Signature Elite

PPMP:

Fern Test – Amniotic Crystallization

Addition and/or deletion of testing requires notification to TJC by Department of Pathology, Laboratory QA/QI Coordinator.

II. PERSONNEL:

Point-of-Care testing is performed by Olive View-UCLA Medical Center physicians, nurse practitioners, registered nurses, licensed vocational nurses, certified nursing assistants, clinical laboratory scientists, and other staff members who satisfy California State and CLIA requirements for testing personnel and who have been trained and authorized to do such testing.

LVNs must have, in addition to IV Therapy certification, a Blood Withdrawal certification to perform skin puncture.

III. TRAINING AND COMPETENCY ASSESSMENT:

Purpose: To ensure that Point-of-Care Testing staff are properly trained and competent in performing test procedures and reporting tests results promptly, accurately, and proficiently for quality patient care.

Policy: All POCT personnel must be properly trained and evaluated for competency prior to performing and reporting any patient results. Initial training provided by Point-of-Care Testing Operations Management Team and Nursing Education Center includes routine quality control, patient testing, instrument maintenance and limited trouble-shooting, safe work practices including names and contact numbers for reporting concerns and issues with POCT quality and safety. The Point-of-Care Testing Operations Management Team will provide training to trainers (test site managers and/or their designees) or other clinical personnel as needed.

Documentation of training and competency by the POCT Operations Management Team will be provided to the Nursing Manager or Supervisor, Department Head and Health Center's Laboratory Director at each point-of-care testing site. On-going training and/or competency by designated trainers will be documented at each POCT site with the original copy sent to POCT Department. The Nursing Manager or Supervisor, Department Head and Health Center's Laboratory Director will maintain documentation of training and competency assessment for testing personnel at test site.

Each test site Nursing Manager or Supervisor, Department Head and Health Center's Laboratory Director will maintain a current list of personnel authorized and appropriately trained to perform testing. The list should specify which tests each individual is authorized to perform.

Competency assessment will be overseen by the POCT Operations Management Team

and conducted jointly with Nursing Manager or Supervisor, Nursing Education Center, Department Head and Health Center's Laboratory Director and test site staff. The procedures for evaluating the competency of the staff may include, but are not limited to, the following:

- Direct observation of QC and routine patient test performance, including patient preparation, if applicable, and specimen handling, processing, and testing
- Monitoring test result recording and reporting
- Review of test results or worksheets, quality control records, proficiency testing 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 same
- Assessment of problem solving skills

Competency assessment is required twice during the first year of testing and annually thereafter or whenever a methodology changes. Failure on competency evaluation will result in exclusion from test performance until retraining and/or retesting is completed satisfactorily.

IV. TEST ORDER and PATIENT IDENTIFICATION:

All requests for POC test must have a doctor's order. POC tests may be performed based on diagnosis as defined by Nursing protocols.

To properly identify patients for POC test, 2 patient identifiers are used. Refer to POCT-05 "Blood Specimen Collection by Skin Puncture" for details.

V. SPECIMEN COLLECTION, HANDLING and PRESERVATION:

Specimen collection, handling and preservation are discussed in detail in the individual test procedure. For finger and heel sticks procedure, see POCT-05 "Blood Specimen Collection by Skin Puncture ".

VI. LABORATORY SAFETY:

Patients and staff will adhere to established safety policies and procedures in the testing sites. Nursing Manager or Supervisor, Department Head and Health Center's Laboratory Director will be responsible for review and implementation of safety policies.

Product Recalls:

Employees who become aware of any laboratory instrument and reagents which has or may have contributed to serious injury or death to an employee or patient shall immediately notify their Nursing Manager or Supervisor and Department Head. Refer to Olive View – UCLA Medical Center Policies 803 and 804 for details.

VII. PATIENT RESULTS AND REFERENCE RANGES:

Purpose: To ensure that results are documented properly.

Policy: All patient results must be documented on the chart including the electronic chart, flow sheet, or a log sheet provided by POCT department. Interfaced POC Test results are posted on the Hospital Information System (Cerner).

Reference Ranges:

Instrument:	Test Menu	Reference Ranges
Nova StatStrip	**POC Glucose**	• Fasting 65 – 99 mg/dL • Random 65 – 139 mg/dL
CLINITEK STATUS+ **Siemens Multistix 10 SG**	**POC Urine Dipstick** Protein Glucose Ketones Bilirubin Blood Nitrite Leukocyte Esterase PH Specific Gravity Urobilinogen	• Protein Negative • Glucose Negative • Ketones Negative • Bilirubin Negative • Blood Negative • Nitrite Negative • Leukocyte Esterase Negative • PH 6.0 – 8.0 • Specific Gravity ≤ 1.005 – 1.030 • Urobilinogen < 2.0 EU/dL
Quidel Quickvue+ One Step hCG	**POC Urine Pregnancy**	• Negative • Positive
CLINITEK STATUS+ **Siemens Clinitest® hCG**	**POC Urine Pregnancy**	• Negative • Positive
Coaguchek® XS Pro	**POC INR**	**Therapeutic Range:** • **2.0 – 3.0** Venous thromboembolism; pulmonary embolism; bioprosthetic heart valve in the aortic position. • **2.5 – 3.5** Mechanical heart valve in the mitral position
Hemochron® Signature Elite	**POC ACT test**	**Therapeutic Ranges:** **Baselime: 160 seconds** **Target: 250 – 350 seconds**
Microscope	**Fern Test:**	• Fern Test Positive for Amniotic Fluid • Fern Test Negative for Amniotic Fluid
Visual	**Eye pH**	**pH - 7.0 (Neutral)**

The following information must be available before a test result can be reported:

- QC results within acceptable range

- Patient's Name – Last Name, First Name if applicable
- FIN – 10 digit FIN or other ID format pre-approved by POCT department
- Date test was performed
- Internal QC results, if applicable
- Electronic checks, if applicable
- Temperature check, if applicable
- Test Result – documentation of repeat testing if indicated
- Notification to Providers including date and time if indicated
- Initials of the person who performed the testing
- Reference range
- Comments – if any

Results must be visually verified for accuracy and reviewed for clerical errors. **Result's assessment is the responsibility of the trained operator who performed the test.**

Any result outside the Analytical Measurable Range (AMR) must be verified by repeat testing if clinically indicated and a specimen sent to the Olive View – UCLA Medical Center's Core Laboratory for confirmation, if applicable.

Results that do not match patient's clinical picture or an error occurred in the testing process are not reported. Results with instrument driven Error Codes must be repeated and verified. A sample may be sent to Core Laboratory for confirmation, if applicable. Document what action was taken, if indicated.

Reference ranges must be available on the chart for review by clinical staff. POC glucose, POC hemoglobin, POC urine dipstick, POC urine pregnancy POC INR, POC ACT and PPMP tests' reference ranges and are available in individual test procedure. POC hemoglobin, POC glucose, POC urine dipstick and POC INR results outside of the reference range require documentation of notification to MD or Provider. If clinically indicated, results can be verified by repeat testing and/or specimen sent to Core Laboratory for confirmation.

Olive View Medical Center Clinical Laboratory established the ranges based on the patient population served, test methodology, age and sex, if applicable and approved by the Laboratory Director. Any change in instrumentation or methodology may or may not require changes in reference ranges. Department of Pathology will inform all concerned testing sites of any change in reference ranges through Laboratory Updates.

Cerner Results (Electronic Health Record):

POC Glucose, POC Urine Dipstick, POC Urine Pregnancy (Clinitest® hCG) and POC INR are resulted in the EHR (Electronic Health Record) through TELCOR interface system. POC Urine Pregnancy (Quidel Quickvue+ One Step hCG) and POC ACT results are seen in Powerchart in the EHR system.

Incident Report / Corrected Report:

Whenever a result was reported to the provider or released to the EHR requiring a

correction, an Incident Report will be initiated by POCT Department.
The Incident Report form must be completed and investigated by the originating site. Both results (original and corrected) must appear on the report as "Reported **as ____ and corrected to ___ "**. Copies of the original result and corrected report must be included. A PSN Report must be filed by the originating site.

Send completed form to Department of Pathology Quality Improvement Coordinator and a copy to POCT Department.

VII. CRITICAL VALUES:

Purpose: To ensure that the physician/caregiver is informed of critical (life-threatening) test results immediately upon verification of result's accuracy.

Policy: All critical values are to be verified when clinically indicated prior to reporting. The result verification procedure is described in the Test Procedure and may include, as necessary, repeat testing including criteria for acceptable repeats, obtaining an additional sample for testing, confirmation of acceptable control value results for that run, or duplicate samples sent to the Olive View-UCLA Medical Center Clinical Laboratory.

Unusual findings should be verified as above and the section manager or supervisor notified.

The requesting provider must be notified immediately of all critical values and unusual/abnormal findings. Documentation of provider notification is recorded in the instrument data management system (NOVA StatStrip Meter thru NovaNet and Telcor, HemoCue Hb 201 DM, Coaguchek XS Pro and Clinitek Status+) or instrument print-out.

Critical ranges are established by General Laboratory.

Critical Ranges:

Instrument:	Test Menu	Critical Ranges
Nova StatStrip	**POC Glucose**	• 0-1 month: <41 - >199 mg/dL • 1 month to 16 yrs: <41 - >249 mg/dL • >16 yrs to Adult: <41 - >449 mg/dL
Coaguchek XS Pro	**POC INR**	• >3.9

VI. QUALITY CONTROL:

Purpose: To ensure quality patient care through precise and accurate testing to yield test results which may be used by clinicians to make diagnoses and/or decisions regarding the care of the patient.

Policy: Quality Control (QC) guidelines as described in the Test Procedures are to be implemented and practiced by all POCT and clinical staff at all times.

Frequency of Control Testing:

Quality Control must be performed each day of patient testing. Additional QC are required for POC INR and POC ACT test reagents and controls. (Exception: As per manufacturer's recommendations external quality control on QUIDEL® Quickvue® + One Step hCG urine pregnancy test is performed with each new box; internal quality controls are read with every test.) All controls must be treated in the same manner as patient samples.

At least two levels of controls are run. Control results must be assessed prior to testing of patient samples. **Assessment is made by the trained personnel performing the quality control testing.**

Definition of Out-of-Control:

"Out of control" occurs when the expected test results are not obtained:

- Positive instead of negative
- Negative instead of positive
- Greater or lesser than the expected defined value
- Color other than the expected defined color

Patient results must not be released until control problems are resolved.

Quality Control testing is performed as described in each written test procedure. At a minimum, quality control requirements are established which satisfy manufacturer recommendations and California State/Federal regulations. Results of quality control tests are recorded manually on the patient log or electronically in the instrument computer system.

Corrective Action:

Whenever the controls are out-of-range or non-compliant with expected results, the following steps must be taken:

- No patient testing is to be performed/no patient results are to be reported.
- The Nurse Manager or Supervisor, and Department Head must be notified.
- All information regarding the controls must be documented on the problem and corrective action section of the test log.
- Patient testing must be repeated when the problem(s) is(are) resolved and the control results are within acceptable limits.
- If QC continues to fall outside the expected range, testing must cease and provider/supervisor or designee must be notified immediately. If a back up instrument is needed, call POCT department for a replacement. Perform QC and instrument maintenance on the back-up or replacement instrument as required.

QC results must be within range before patient testing can be performed.

Corrective action must be documented on the corrective action log, if applicable, whenever QC fails to fall within the expected range. Documentation should include all trouble shooting performed but not limited to verifying control lot numbers and expiration dates and performing instrument maintenance. Document with date and time all communications with vendors and POC staff, repeat testing results and instructions given to correct the problem.

Nurse Managers or Supervisors, POC staff, and Department Head will review the adequacy of actions taken and decide whether patient's samples should be sent to Olive View – UCLA Medical Laboratory for testing or re-testing.

If QC was discovered to be out-of-range with patient testing results already reported, notify POCT department, Nurse Manager or Supervisor, and Department Head. POCT department will notify the site to submit a corrective action including but not limited to notifying providers and/or re-testing of patients affected. Completed corrective action must be sent to POCT Department and Department of Pathology Quality Improvement Coordinator.

VII. MONITORING:

Purpose: To ensure that patient test, quality control, instrument maintenance, and reagent handling and storage procedures are performed and documented appropriately to meet regulatory requirements and provide quality patient care. During monitoring site visits, any reported concerns about quality and safety will be assessed and evaluated for necessary corrective actions.

Policy: Quality control, patient test, and maintenance records as well as reagent use and storage conditions at the test sites are periodically monitored by POCT staff from the Olive View-UCLA Medical Center (OVMC) Pathology Department as required by regulatory agencies to ensure compliance with all POCT policies and procedures. Chart reviews, peer check and QI Indicators are also used to improve accuracy and quality of test results.

A bi-weekly or monthly (on-site visits occur quarterly) report is prepared by POCT staff indicating compliance issues as well as total compliance with all POCT policies and sent to Nurse Managers or Supervisors, and Department Head or designees. A bi-weekly or monthly corrective action is **not** required but may be used as a tool to prevent additional deficiencies.

A monthly Quality Assurance compliance report summarizing policy and test procedure compliance problems and total compliance score is prepared by OVMC Pathology Department POCT staff and distributed to section Nurse managers or Supervisors, and Department Head at each testing sites. Monthly corrective action is taken to address any compliance issues and is due two weeks from date of notice. Documentation including

bi-weekly corrective action, if any, is maintained by the Nursing Manager or Supervisor, and Department Head at each testing sites, and original copies are forwarded to POCT staff at the Olive View-UCLA Medical Center Pathology Department, Room 1A116.

Patient, quality control test, and maintenance records for POC urine pregnancy, POC ACT, POC INR, POC Rom and Fern test are maintained at the test site for three years. Nova StatStrip, HemoCue 201 DM, Clinitek® STATUS+ and Coaguchek XS Pro data logs are computer retrievable in POCT department thru Telcor middleware.

Monitoring Codes:

Reagent Check:

- **R1** No open date on reagent strip/cuvette/unit vial/box/bottle or open expiration date.
- **R2** Reagent strip/cuvette/unit vial/box/bottle expired including expired from open date.
- **R3** Reagent strip/cuvette vial/box/bottle unsealed/uncapped.
- **R4** No documentation of reagent strip/cuvette vial/box/bottle's lot number and expiration date or wrong lot number used.

Quality Control Check:

- **QC1** No open date on QC samples or open expiration date.
- **QC2** QC samples expired including expired from open date.
- **QC3** QC samples uncapped.
- **QC4** Failed QC, no documentation of action taken.
- **QC5** "Procedure Error" was not documented (glucose meters only).
- **QC6** No QC results (or incomplete results).
- **QC7** No Internal Control (POC urine pregnancy test) or Electronic QC and Temperature Verification Check (POC ACT)
- **QC8** No documentation of QC lot number and expiration date (or wrong QC lot number used).
- **QC9** No documentation of QC ranges (or wrong QC ranges used).

Patient/Data Logs:

- **PL1** No MRUN (or incorrect ID# used to identify patients).
- **PL4** Critical result, no documentation of action taken.
- **PL5** No patient's name (or incomplete name used to identify patients).
- **PL6** No test result (or incomplete results)
- **PL7** No operator's initials performing the test.
- **PL8** No documentation of test result in Cerner (POC INR only)
- **DM** No documentation of daily maintenance or instrument found dirty.
- **MR /DR** No documentation of Nurse Manager or Supervisor, Department Head or designee's <u>daily</u> review.

Note: PL2 and PL3 were used previously and does not apply to current monitoring process.

Chart Review:

Charts are periodically monitored by POCT staff from Olive View-UCLA Medical Center (OVMC) Pathology Department as required by regulatory agencies to ensure compliance with all POCT policies and procedures.
Charts of patients with POC tests performed during monitoring site visits are reviewed. Some low volume sites may or may not have patient tests and charts available during site visits. Charts are reviewed per site or per instrument used.

Results on patient testing logs, instrument print outs, meter's patient data are compared with results in Cerner or on patient's charts including electronic charts, if indicated.

Corrective action is required to address any compliance problems and documentation are maintained by the section Nurse Manager or Supervisor, and Department Head at the testing site with copies forwarded to POCT staff at the Olive View-UCLA Medical Center Pathology Department.

Quality Improvement Indicator (QI):

Point-of-Care Testing Pathology Department chose critical results documentation as the department's QI indicator. Critical results are monitored weekly and checked for proper documentation. A monthly report is sent to the Department of Pathology Quality Improvement Coordinator for review. A corrective action from the selected sites is required if threshold is not met at 90%.

POCT Department in conjunction with Olive View Medical Center's POC Advisory Committee may recommend addition and deletion of site(s) and/or change indicators to be monitored.

Temperature Checks:

For optimum operation all POC instruments, reagents with temperature storage and performance requirements, testing sites and storage rooms/areas, the temperature will be monitored and documented by nursing staff daily.

VIII. PROFICIENCY TESTING:

Purpose: Proficiency testing determines how well a POC results compare with those of other POC instruments with the same methodologies. Such testing can identify performance problems not recognized by internal mechanisms.

Policy: The POCT department participate in an approved proficiency testing program that meets regulatory requirements for variety, frequency of testing and

satisfactory performance criteria for regulated analytes. Yearly enrollment is the responsibility of the Department of Pathology.

Proficiency testing participation is established for following:

CLIA ID Number 05D0872242:	Olive View Medical Center, whole blood glucose, and PPMP
CLIA ID Number 05D0558588:	Anticoagulation Clinic, POC INR and Catherization lab, ACT test

Note: Quality cross check for whole blood glucose are done at Olive View Medical Center. Proficiency testing is not required for waived tests.

Assessment and corrective actions, when necessary, are the responsibilities of the Nurse Manager or Supervisor or designee, POCT Department staff and pathologist assigned to PPMP program.

Proficiency samples are performed 2-3 times a year by certified operators at testing sites along with regular patient testing, if applicable. It is tested in the same number of times that patient samples are routinely tested. The individual testing the sample must attest to the routine integration of samples into the regular patient testing, if applicable. POCT and Nursing department staff, must refrain from communicating with each other regarding test results until after data have been submitted to the proficiency testing provider. Proficiency samples must be performed at authorized testing sites only. Referral to another testing site or facility is strictly prohibited.

Documentation of test handling, processing, including testing and reporting of results and review of evaluations are kept in the Department of Pathology, 1A116. Copies are also available at the Department of Pathology Quality Improvement Department.

Corrective Action:

Results outside the acceptable range as well as results that, although acceptable, show bias or trends suggesting a problem should be treated as an opportunity to identify and correct problems, educate personnel and improve quality of testing provided.

POCT Department, Nurse Managers or Supervisors, and Department Head or designee will investigate using "Documentation of Unacceptable PT Results/Investigation" form available at the POCT Department, 1A116 and should include the following:

- the specific reason for the unacceptable result
- actions taken to reduce the likelihood of recurrence
- record of in-service/discussion of the unacceptable result and corrective action taken
- must be completed within time frame indicated by Department of Pathology, Quality Improvement Coordinator and not to exceed one month from the time Proficiency testing results were received.

The report is then reviewed, signed and dated by the appropriate site Supervisor,

Department Head, Health Center's Laboratory Director, Nurse Manager or designee. The original copy of the completed report is sent to Department of Pathology, Quality Improvement Department with a copy kept at the origination site. POCT Department will keep a copy for at least two years.

IX. SPECIAL STUDIES:

Purpose: To ensure that POC instruments are working properly and results are accurate.

Linearity Studies: A 5-level linearity studies are performed on all **new** POC glucose meters with acceptable results. If linearity studies include low, midpoint and high values that are near the stated AMR (Analytical Measurable Range) and results are acceptable, the instrument's AMR has been validated. Glucose linearity kits are available from the manufacturer. Linearity studies are performed on replacement meters/instruments, when applicable.

Correlation Studies: Correlation studies are performed on all new POC instruments or after a major instrument repair or maintenance. Correlation studies may be used to trouble-shoot instruments' questionable patient results against Clinical Laboratory results. An initial correlation study must include at least 20 acceptable results between the POC instrument and General Laboratory instrument. General Laboratory's result is the gold standard.

Acceptable correlation studies are as follows:

- POC Glucose by Nova Statstrip meters - $\leq$ 20%
- POC INR by Coaguchek XS Pro - $\leq$ 12%
- POC Urine Dipstick - one grade below or above analyte value
- POC ACT by Hemochron® Signature Elite - $\leq$12%
- POC Urine Pregnancy by Clinitek – equivalent result

POC INR's correlation studies with Core Laboratory are checked twice a year. A minimum of five finger stick samples are tested on the POC instrument and venipunctured blue top tubes are sent to General Lab for PT INR test.

POC ACT's correlation studies between devices are checked twice a year. A minimum of five samples are tested on the POC instrument.

Correlation studies are performed on replacement meters/instruments, when applicable.

Precision/Reproducibility Studies: POC INR by Coaguchek® XS Pro and POC ACT by Hemochron® Signature Elite requires accuracy studies on new instruments. Acceptable % CV is 14% or less.

Corrective Action:
POCT department will notify the Nurse Manager or Supervisor, and Department Head or designee of the unsatisfactory results. Failed Linearity, Correlation and/or Precision/Reproducibility studies will result in removal of the affected instrument from

the testing site. POCT department will provide a replacement through Vendor if back-up instrument is not available.
Nurse Managers or Supervisors, Department Head, POCT staff, will review the adequacy of actions taken and decide whether patient's samples should be sent to Olive View – UCLA Medical Center Clinical Laboratory for testing.

X. DOWNTIME PROCEDURE

Purpose: To provide guidelines for recording, transmission and data entry of patient's POC results in events of power and/or information systems failures.

Policy: Downtime procedure for POCT are to be implemented for POC devices which includes the following:

- Nova Statstrip – POC Glucose
- Clinitek Status®+ – POC Urine Dipstick
- Clinitek Status®+ – POC Urine Pregnancy
- Coaguchek® XS Pro – POC INR

Scheduled Downtime where a scheduled maintenance is involved. FIN number provided by Registration will be used for POC testing. When system comes back up, FIN numbers used should merge thru Registration's recovery process and post to patient's electronic health record.

Unscheduled Downtime where systems are not available due to an unplanned event such as test results are not posting on patient's electronic health record.

Nova Statstrip – POC Glucose

The meter displays "Data Transfer Complete and Meter Ready For Use" after patient testing and docking the meter. If the meter continues to display "Data Transfer and Connecting to Server", check the connection and dock the meter again. If the meter doesn't display "Data Transfer Complete and Meter Ready For Use", results are not transferring to patient's electronic health record. Call POCT at x73684 or x73153 or the NOVA technical support at 800-545-NOVA.

Clinitek Status®+ – POC Urine Dipstick and Urine Pregnancy

The instrument menu on the upper left should have no X. If there's an X patient results are not transferring. Call POCT at x73684 or 73153 or the Siemens Tech support at 1-877-229-3711 press 13 then 2.

Coaguchek® XS Pro – POC INR

The device is configured to transfer results once it's docked. If patient results are

not posted electronically call POCT at x73684 or x73153 or the Roche Tech support at 1-800-428-4674

On weekends and holidays where results are not transferring from the POC devices, manually entering results electronically should be the last resort for physician to view. Results entered should be correct because once the system comes back up duplicate results will post in patient's electronic health record. Results entered not matching with transferred results from the meter should have an SI report.

XI. COMPLIANCE AND CORRECTIVE ACTION GUIDELINES:

Policy: Compliance with regulatory and accreditation agency standards must be maintained and will be enforced as follows:

1. **Target compliance score is ≥ 95%.** [TJC Score 1 (Substantial compliance. "The organization consistently meets all major provisions of the standard and intent")]. Point-of-Care Testing laboratory staff periodically monitors Point-of-Care testing sites, quality control data, patient test logs, reagents and instrument maintenance. A monthly compliance score for each test site is calculated based on this monitoring. A mid-month compliance score may be sent to help those sites with a greater possibility of falling below the 80% monthly compliance score.

2. **Compliance Scores of 80% - 94%** [TJC Score 2 (Significant Compliance. The organization meets most of the provisions of the standard and intent")] will result in: Point-of-Care laboratory staff will work with Nursing, etc. to assist in resolution of compliance problems. Assistance may include retraining if applicable.

   Corrective Action: Corrective action required for the following compliance issues:
   a. Total Monthly Compliance Score less than 95%
   b. Individual Indicators less than 80% (reagent dating, QC compliance (in range), abnormal or critical result documentation).
   c. No QC or QC failures with patient testing.
   d. Use of expired controls and reagents with patient testing.
   e. Or as required by Point-of-Care laboratory staff.

3. **Compliance Scores ≤ 79%** [TJC Score 3-5 (Partial, Minimal, Non-compliance)] will result in:

   a. First month, issuance of a letter of warning to site managers requiring the submission of corrective action plan to the Department of Pathology and advising site managers that the failure to bring the score to ≥ 80% compliance will result in withdrawal of testing privileges/instruments.

   b. Second month,

i. Issuance of a "second warning" letter referencing failure to comply the previous month and stating that failure to bring the score to ≥ 80% will result in withdrawal of testing privileges/instruments.
ii. Notification to Chief Executive Officer (and Executive Committee), to Medical Director (and Medical Executive Committee) and to Health Care Quality Board of impending withdrawal of privileges/instruments.
iii. Corrective action plan to be administered by Executive Committee and Medical Executive Committee

c. Third month,

i. Notification by Executive Officer (and Executive Committee) and Medical Director (and Medical Executive Committee) of revocation of testing privileges/instruments.
ii. Withdrawal of testing privileges/instruments.

Petition to reinstate testing privileges must be submitted to Executive Officer an Medical Director. Petition must include justification of test privilege re-instatement and documented resolution of previous compliance issues.

OLIVE VIEW – UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POINT-OF-CARE TESTING

FAILURE TO COMPLY, SCORE < 79%

FIRST WARNING

Date: _____

TO: _____

Nurse Manager

FROM: Holli Mason, M.D., Chief, Department of Pathology

RE: Failure to comply with Point-of-Care Testing Privileges

This letter serves to inform you that _____(Testing Site)_____ has failed to comply with established guidelines for Point-of-Care Testing. In _____(Month)_____, __(Year)_____ your compliance score was _____ (≤ 79%). Please submit a corrective action plan to the Department of Pathology.

Failure to submit a corrective action plan and improve compliance (score ≥ 80%) within one month of the date of this notice will result in a second letter of warning. Continued violation may result in revocation of testing privileges/instruments.

OLIVE VIEW – UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POINT-OF-CARE TESTING

FAILURE TO COMPLY, SCORE < 79%

SECOND WARNING

Date: _____

TO: _____

Nurse Manager

FROM: Holli Mason, M.D., Chief, Department of Pathology

RE: Failure to comply with Point-of-Care Testing Privileges

This letter serves to inform you that ____(Testing Site)_____has failed to comply with established guidelines for Point-of-Care Testing for a period of at least two months. Your compliance scores were_____(≤ 79%) for the month of ___(Month)_____, ___(Year)___and _____ (≤ 79%) for

the month of __(Month)_____, ___(Year)___ Please submit a corrective action plan to the Department of Pathology.

Failure to submit a corrective action plan and improve compliance (score ≥ 80%) within one month of the date of this notice may result in revocation of testing privileges/instruments and as enforced by Chief Executive Officer and Executive Committee, Medical Director and Medical Executive Committee and Health Care Quality Board.

cc: Judith Maas, Chief Executive Officer, OVMC Executive Committee
Rima Matevosian, M.D., Medical Director, OVMC Medical Executive Committee
Bonnie Bilitch, Director of Nursing, OVMC, Health Care Quality Board

OLIVE VIEW – UCLA MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POINT-OF-CARE TESTING

NOTIFICATION OF REVOCATION OF TESTING

PRIVILEGES / INSTRUMENTS

Date: _____

TO: _____

Nurse Manager

FROM: **Holli Mason, M.D., Chief, Department of Pathology**

RE: **Revocation of Point-of-Care Testing Privileges/Instruments**

This letter serves to inform you that due to continued failure to comply with established guidelines for Point-of-Care Testing for a period of at least three months, testing privileges/instruments for _____ are hereby revoked.
Testing Site

A petition to reinstate testing privileges may be submitted to the Chief Executive Officer and Medical Director. Petition must include justification of testing privileges/instruments reinstatement and documented resolution of previous compliance issues.

Noted and Approved:

_____Date:_____
Judith Maass
Chief Executive Officer, Olive View – UCLA Medical Center

Noted and Approved:

_____Date:_____
Rima Matevosian, M.D.
Medical Director, Olive View – UCLA Medical Center

References:	
Approved by: Holli Mason (Laboratory Director)	Date: 05/07/2020
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