Point-of-Care Testing
Department of Clinical Laboratories
The Ohio State University Wexner Medical Center

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Approval and Acknowledgements
Refer to QPulse system and Document Details report for laboratory directors(s)' electronic signature approval, employee acknowledgment and effective date.

1.POLICY:

1.1. Point-of-Care tests are not considered as definitive. These tests are performed for continuing management of patients with known conditions, or for rapid detection of changes in condition which require frequent adjustments in patient treatment, where it would be impractical to obtain laboratory testing as frequently or rapidly as is required. The clinical usage and limitations are stated in each POCT policy.

1.2. POCT is defined as tests designed to be used at or near the site where the patient is located, that do not require permanent dedicated space, and that are performed outside the physical facilities of the clinical laboratories. Examples include kits and instruments that are hand carried or otherwise transported to the vicinity of the patient for immediate testing at that site or analytic instruments that are temporarily brought to a patient care location.

1.3. Specific tests, as authorized by the Clinical Laboratories, are performed as outlined in Point-of-Care Testing (POCT) Procedures, available in each patient care area by access to the Point of Care site on OneSource. Test results are confirmed by laboratory testing as specified in the Laboratory and nursing policies.

1.4. The POCT program follows manufacturer instructions for all test systems without modification.

1.5. Clinical uses of point of care test results are consistent with OSUWMC's policies and the manufactures' recommendations.

2.PURPOSE OF DOCUMENT

2.1. The purpose of this policy is to outline regulations, standards and expectations regarding POCT.

2.2. All areas performing near-patient testing will adhere to the point-of-care testing requirements as specified by CLIA, JCAHO, CAP or other accrediting agencies.

3.SCOPE OF DOCUMENT:

3.1. The following staff titles are authorized for point-of-care testing upon completion of initial training competency and may be authorized annually following successful completion of annual competency assessment: Anesthesia Technologist, Cardiac Rehab Specialist, Clinical Laboratory Technologist (MT, MLT), Emergency Medical Technician, Licensed Practical Nurse, Medical Assistant, Patient Care Associate/Patient Services Technician, Perfusionist, Phlebotomist, Registered Nurse/Patient Care Coordinator, Respiratory Therapist, Surgical Technologist, Radiologic Technologist, Radiographer, Physician, Licensed Nurse Practitioner.

3.2. The OSUWMC POCT program has a scope of service that includes waived and moderately complex (non-waived) testing.

4.DEFINITIONS:

4.1. FDA- The national, state, or provincial authority having jurisdiction over in vitro diagnostic test systems

4.2. Non-waived testing- Tests categorized as either moderately complex (including PPM), or highly complex by the FDA according to their scoring system.

4.3. Waived testing- A category of tests defined as "simple laboratory examinations and procedures which have an insignificant risk of an erroneous result", by the FDA. Laboratories performing waived tests are subject to minimal regulatory requirements.

4.4. CAP- College of American Pathologists is a comprehensive collection of Quality Management Tools strengthens a laboratory's knowledge of key laboratory processes, identifies quality improvement opportunities, and provides the information needed for effective laboratory management. The Quality Management Tools help laboratories deliver quality patient care and satisfy accreditation requirements and patient safety goals.

4.5. CLIA-Clinical Laboratory Improvement Amendments (CLIA) regulates laboratory testing and requires clinical laboratories to be certificated by their state as well as the Center for Medicare and Medicaid

Services (CMS) before they can accept human samples for diagnostic testing. Three federal agencies are responsible for CLIA: The Food and Drug Administration (FDA), Center for Medicaid Services (CMS) and the Center for Disease Control (CDC). Each agency has a unique role in assuring quality laboratory testing

4.6. TJC-An independent, not-for-profit organization, The Joint Commission accredits and certifies health care organizations and programs in the United States. Joint Commission accreditation and certification is recognized nationwide as a symbol of quality that reflects an organization's commitment to meeting certain performance standards.

4.7. Technical Consultant- Per CLIA and CAP, the technical consultant is responsible for the technical and scientific oversight of a laboratory performing moderate complex testing. This role is delegated to the Point of Care Coordinators, Point of Care Manager, Compliance Director, Division Directors and or Medical Director as applicable.

4.8. Per CLIA Regulations, the technical consultants have a BS in science and 2 years of experience in non-waived laboratory testing. Point of Care Coordinators (Technical consultants) are responsible for overseeing the training process of testing employees and annual competencies. Per laboratory policy observation of routine test performance, including patient identification and preparation, specimen collection, handling processing, testing, resulting, quality control and function checks may be performed by "super users" The Point of Care coordinators deem the "superuser" as competent to perform the observation elements of competence.

4.9. A "superuser" is chosen by the Point of Care Team. The Technical consultant also completes a separate competency assessment for the "superuser" to deem them competent to perform the observation tasks.

4.10. A "superuser" meets the necessary educational and experience requirements needed for the level of testing.

5. **RESPONSIBILITY**:

5.1. Laboratory Medical Director (name on CLIA Certificate):

5.1.1. The Laboratory Medical Director is responsible for establishing the Point-of-Care Testing policy.

5.1.2. The Laboratory Medical Director or designee identifies the staff responsible for supervising waived and non waived testing.

5.1.3. The Laboratory Medical Director approves all policies and procedures for point of care testing at the following times:

5.1.3.1. Before initial use of the test for patient testing

5.1.3.2. At least Biennially

5.1.3.3. When changes in procedures occur

5.1.4. The Point-of-Care Testing program is under the direction of the Laboratory Medical Director as specified on the CLIA certificate.

5.1.5. The Laboratory Medical Director establishes a written quality management plan applicable to point of care testing.

5.1.6. The Laboratory Medical Director establishes an Individual Quality Control Plan for applicable non waived testing.

5.1.7. The instruments and equipment in use are approved by the laboratory director or designee.

5.1.8. The laboratory director or designee must review QC data at least monthly. At OSUWMC, the clinical laboratories delegate this to the division directors / technical supervisors/coordinators.

5.1.9. The laboratory director or designee determines the limitations and clinical usage of each point of care test.

5.1.10. The laboratory director or designee determines when each waived and non-waived test can be used for monitoring, treatment and when follow up (confirmatory) testing is required.

5.1.11. The laboratory director approves all Point of Care competency assessments, content and all testing personnel competency assessments content.

5.1.12. The laboratory director evaluates each test for:

5.1.12.1. Clinical usage

5.1.12.2. Reagent stability

5.1.12.3. FDA approved manufacturers recommendations

5.1.12.4. Institutional experience

5.1.12.5. Currently accepted guidelines

5.2. Clinical Testing Departments:

5.2.1. The manager or designee for each department performing Point-of-Care testing is responsible for the following tasks, but not limited to:

5.2.1.1. Obtaining and maintaining documentation of the highest level of education (diploma or transcript) is required for all testing personnel of non-waived testing. For diplomas obtained outside of the United States, the diplomas must be reviewed and recorded to ensure that their training and qualifications are equivalent to CLIA requirements. The equivalency evaluations must be performed by a nationally recognized organization. CLIA provides two sources of third parties that perform this service: These may include such organizations as the National Association Credential Evaluation Services, Inc. (NACES) (http://www.naces.org) and the Association of International Credential Evaluators, Inc. (AICE) (http://www.aice-eval.org)

5.2.1.2. .Documenting and maintaining evidence of orientation, initial training, and use of maintenance of instruments, as applicable. In lieu of a diploma a nurse manager may contact HR for a copy of the PSV report. The report must document the nurse graduated from a college in the US.

5.2.1.3. The manager or designee maintains testing personnel files to include; job description, CE records, orientation records and other necessary documents required by Joint Commission.

5.2.1.4. Documenting and maintaining evidence of annual competency

5.2.1.5. Ensuring quality control is run and documented as required per technical procedure

5.2.1.6. Follow up of non compliance with critical value and quality control documentation

5.2.1.7. Ensuring availability and promoting staff awareness of all applicable policies, procedures, and package inserts

5.2.1.8. Ensuring all employees are notified of new policies and or policy changes. Making sure all employees know how to locate all policies and procedures

5.2.1.9. Maintaining an active, current personnel roster of staff authorized to perform testing

5.2.1.10. Assisting in competency annual or biannual evaluations

5.2.1.11. Completing corrective action and occurrence reports when problems are identified

5.2.1.12. Ensures the clinical use of the POC testing is following the manufacturer's guidelines and OSUWMC policies.

5.2.1.13. Purchasing new equipment for testing.

5.2.1.13.1. Complete and submit a Point of Care justification to add testing, a form is located on OneSource

5.2.1.13.2. Ensure the space will accommodate the instrument needs, electrical, IT, connectivity and humidity

5.2.1.13.3. If the reagents and supplies require temperature (refrigeration) requirements; ensure refrigeration and temperature monitoring systems can be accommodated.

5.2.1.13.4. Perform cost analysis – Testing departments that receive revenue must incur the following expenses

- Instrument purchase
- IT connectivity
- Reagents
- Service contracts

5.2.1.12.3 For moderate complex testing

- Obtain diplomas from all testing personnel, maintain in the employees file.
- Maintain a roster of all testing employees
- Perform Initial training, 6 month competency and annual competencies

5.2.2. The testing personnel are responsible for:

5.2.2.1. Understanding and following all regulations regarding proficiency testing and quality assessments

5.2.2.2. Completing initial training and maintain annual competency

5.2.2.3. Understanding and following the POC test procedures and manufacturer's guidelines

5.2.2.4. Reporting any instrument or testing issues to the POC department

5.2.2.5. Following manufacturer reagent storage requirements

5.2.2.6. Not using reagents beyond the expiration dates.

5.2.2.7. Following OSUWMC Infection control policy for portable and hand held devices
5.2.2.8. Understanding the POC result should not be used alone for clinical decisions.
5.2.2.9. Understanding the POC result must be in the medical record when a management decision related to the POC test is made.
5.2.2.10. Understanding they must initial or sign the POC test performed

5.2.3. Testing department compliance with laboratory regulations
5.2.3.1 Refer to the OSU Point of Care department service agreement
5.2.3.2 Each Moderate complexity POC testing location must agree and commit to compliance

5.3. Clinical Laboratories Point of Care Department
5.3.1. The POC department hours are 6:00 am to 4:30 pm Monday through Friday. POCT information is available on OneSource 24/7. The Point of Care department maintains paper package inserts for downtimes.
5.3.2. The Clinical Laboratory Point of Care Department is responsible for the following tasks, but not limited to:
5.3.2.1. Setting up and documentation of instrument method validation and Analytical Measurement Range (AMR) validation
5.3.2.2. Perform verification of test performance specifications.
5.3.2.3. Evaluating instruments and implementing test methods is the shared responsibility of the Test Utilization Committee and the Clinical Laboratories' Point-of-Care Testing department.
5.3.2.4. Performing correlations, calibrations, linearities, precisions, QC, and data management
5.3.2.5. Tracking and notifying clinical testing department with non compliance of documentation of critical values
5.3.2.6. Monitoring on going performance by tracking daily and monthly quality control results and maintenance records.
5.3.2.7. Ensuring QC is performed per regulation and manufacturers' guidelines
5.3.2.8. Tracking quality control failures and review of patient results for QC failure impacts.
5.3.2.9. Utilizing the "scorecard" to summarize the Critical call and QC tracking
5.3.2.10. Identify training needs, training employees and training a designee to train employees "superusers".
5.3.2.11. Educating clinical testing departments regarding standards for point of care testing.
5.3.2.12. The Coordinators are responsible for testing personnel competency assessments. The POCCs determine the best method to assess competency, establish the content, material learning assessment guides, learning assessment tests, acceptable criteria of the on line learning. The coordinators perform and document remediation.
5.3.2.13. Identifying and coordinating required proficiency testing and quality assessments.
5.3.2.14. Performing random audits for personnel file documentation. Required documentation: Diploma, transcript or equivalency, initial training and annual competency.
5.3.2.15. PSV may be used as a last alternative in lieu of a diploma for nursing employees hired after March 2014. The PSV report must be obtained and reviewed by POC. The PSV report must show the nurse graduated from a US college.
5.3.2.16. Moderate Complex POC laboratory personnel roster is audited annually by the technical consultants. The audits to include personnel hired within the last 12 months, all moderate complex testing locations, medical directors and technical consultants.
5.3.2.17. Updating procedures and notifying clinical testing department.
5.3.2.18. Reviewing and updating the procedures on QPulse and OneSource
5.3.2.19. Updating the procedures with the most recent manufactures package insert. Notifying clinical testing employees of changes
5.3.2.20. Working with personnel testing educators and managers to communicate to testing personnel updates, changes, issues and performance metrics
5.3.2.21. Updating, tracking and assisting with competency evaluations
5.3.2.22. Monthly rounding to POC sites, and periodic audits.
5.3.2.23. Preparing quality control and quality improvement reports

5.3.2.24. Resolve technical and IT problems and perform remedial actions.
5.3.2.25. Auditing laboratory regulations with monthly tracers
5.3.2.26. Monitoring maintenance and temperature logs
5.3.2.27. Assisting and overseeing testing personnel in completing occurrence reports
5.3.2.28. Retaining records on the Share Drive

6.POINT OF CARE STANDARDS AND EXPECTATIONS

6.1. CLIA Designations:

6.1.1. Laboratory testing is classified as highly complex, moderately complex (including provider performed microscopy- PPM), or waived under CLIA. The Food and Drug Administration (FDA) determines which tests are approved waived. The Centers for Medicare and Medicaid has designated an approved list of PPM testing.

6.1.2. Arterial blood gas, activated clotting time, INR, cooximetry, hemostasis, POC creatinine, Piccolo, EPOC, Rotem and Binax Malaria Ag assays are considered moderately complex according to CLIA.

6.1.3. The following waived point-of-care tests are designated as screening tests, which may be followed by confirmatory testing: Whole blood glucose, Urine HCG, Hemoglobin A1C, Urine Dipstick, Rapid Streptococcus A and Hemoglobin by HemoCue.

6.1.4. Provider-performed microscopy (PPM) procedures, fern test, urine sediment microscopy and vaginal wet mounts must be performed by a physician or midlevel practitioner under the supervision of a physician based upon their moderate complexity.

6.1.4.1. PPM tests are classified as moderately complex and are subject to all applicable CLIA regulations. All subparts, including proficiency testing, quality system, facility administration and personnel, apply to PPM testing.

6.2. General Point of Care Standards:

6.2.1. An appropriate NIST thermometric standard device of known accuracy is utilized to record room temperature and humidity. Temperatures are monitored for reagents stored in bulk.

6.2.2. Patient results, Quality control result records, test result records, and instrument records for waived/moderately complex testing are retained for at least two years

6.3. Hand off Communication:

6.3.1. Daily communication in the point of care department is done through the white board, path.glucose@ousmc.edu, emails, and the Hand off communication folder on the Share Drive.

6.4. Policies and procedures:

6.4.1. Must include the following elements:

6.4.1.1. Clinical usage and limitations of the test methodology
6.4.1.2. Need for confirmatory testing and result follow-up recommendations (for example, a recommendation to repeat the test when results are higher or lower than the reportable range of the test)
6.4.1.3. Specimen type, collection, and identification, and required labeling
6.4.1.4. Specimen preservation, if applicable
6.4.1.5. Instrument maintenance and function checks, such as calibration
6.4.1.6. Storage conditions for test components
6.4.1.7. Do not use a reagent after its expiration date per manufacture package insert or new expiration date due to reconstitution, storage changes or put in use. Do not use reagents beyond the expiration date that comes first.
6.4.1.8. Do not use reagents if proper storage conditions have not been met or integrity of the reagent has been compromised.
6.4.1.9. Quality control (including frequency and type) and remedial action.
6.4.1.10. Test performance
6.4.1.11. Result reporting, including not reporting individual patient results unless quality control is acceptable.
6.4.1.12. Test results are documented in the patients' medical record. Quantitative tests results are accompanied by reference intervals, ACT testing follows OSUWMC interpretative guidelines

6.4.1.13. Equipment performance evaluation

6.4.2. Current and complete policies, procedures, manufacture package inserts and charts are available via laboratory document control system and OneSource for use during testing to the person performing the waived/moderately complex test.

6.4.3. Discontinued policies are archived and are inaccessible to testing personnel.

6.4.4. OSUWMC establishes policies and procedures for each test based on the manufactures package insert and are enhanced to follow OSWUMC standards.

6.5. Quality Control

6.5.1. All testing:

6.5.1.1. Quality control results, including internal and external controls for testing are documented.

6.5.1.2. The results of controls are reviewed for acceptability before reporting patient results by testing personnel. Results are recorded in Telcor (QML) or on QC logs.

6.5.1.3. Quality control evaluation by Point of Care Department

6.5.1.3.1. All unacceptable quality control is reviewed.

6.5.1.3.2. Unacceptable QC is documented and corrective action is performed

6.5.1.4. Monthly Quality control reports are generated by the Point of Care department to include;

6.5.1.4.1. Raw data

6.5.1.4.2. Summary of unacceptable QC and corrective action

6.5.1.4.3. The corrective action for tests with an IQCP includes a statement as to whether further evaluation of the risk assessment and QC plan is needed.

6.5.1.4.4. Evaluation for trends and shifts

6.5.1.4.5. Acceptable criteria

6.5.1.4.6. Omissions in QC have an attached occurrence report

6.5.1.5. Monthly Quality Control reports are reviewed by the division director and designee

6.5.2. Waived testing:

6.5.2.1. For non-instrument-based waived testing, quality control checks are performed at the frequency and number of levels recommended by the manufacturer and as defined in technical procedures.

6.5.2.2. For instrument-based waived testing, 2 levels of quality control checks are performed on each instrument used for patient testing per manufacturers' instructions.

6.5.2.3. Controls results are documented for quantitative and qualitative tests, as applicable.

6.5.2.4. There is evidence of corrective action documentation when control results exceed defined acceptability limits.

6.5.3. When a licensed independent practitioner performs waived testing that does not involve an instrument and the test falls within his or her specialty, the OSUWMC use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to their scope of practice that he or she is authorized to perform.

6.5.3.1. OSUWMC applicable waived testing; Fecal occult blood testing, pH

6.5.4. Nonwaived testing:

6.5.4.1. Two levels of controls are run daily for quantitative and qualitative tests, where applicable

6.5.4.1.1. Quantitative: Low and High levels

6.5.4.1.2. Qualitative: Positive and Negative

6.5.4.1.3. IQCP process in place for Avox, Signature Elite (INR, ACT), ROTEM

6.5.4.2. Quality control data are evaluated daily to detect instrument or process failure.

6.5.4.3. Acceptable limits are defined for control procedure.

6.5.4.4. There is documentation of corrective action when control results exceed defined acceptability limits.

6.5.4.5. The laboratory director or designee (Division director) must review QC data at least monthly.

6.5.4.6. Control specimens are tested in the same manner and by the same personnel as patient samples.

6.5.4.7. The control results are reviewed for acceptability before reporting patient results.

6.5.4.8. If the laboratory/POCT program uses more than one instrument/method to test for a given analyte, the instruments/methods are checked against each other at least twice a year for correlation of results.

6.6. Calibration / AMR Verification
- 6.6.1. Waived testing:
  - 6.6.1.1. Follow manufacturer instructions for calibration, calibration verification, and related functions.
- 6.6.2. Nonwaived testing:
  - 6.6.2.1. Calibration, calibration (AMR) verification procedures and acceptable criteria are established for each test system and reviewed for acceptability.
  - 6.6.2.2. Test systems are recalibrated when calibration verification fails to meet the established criteria of the POCT program.
  - 6.6.2.3. The AMR range is defined and verified. The process and criteria is documented. Refer to individual procedures for more details.

6.7. Test Results
- 6.7.1. Test results are documented in the patient's medical record.
- 6.7.2. Test results in the medical record are accompanied by reference intervals (normal values), as applicable.
- 6.7.3. Records indicate (by initials, signature, etc.) who performed each test.
- 6.7.4. Result audits (tracers) are performed monthly for result instrument to EMR verification per calendar.

6.8. Confirmatory Testing and Critical Values
- 6.8.1. Critical results must be reported to nurses/physicians involved in the patient care. Tests will be referred to the Clinical Laboratories if necessary.
- 6.8.2. Critical Values Protocol
  - 6.8.2.1. Glucose: Results are documented in Telcor. Operator chooses appropriate comments on critical values including Notified RN, Notified MD, Lab Draw to Verify, RN only-Orders Present, Test on newborn (where applicable), Error Suspected and Will Repeat Test.
  - 6.8.2.2. Referring Policies: Laboratory Critical Result/Critical Value Policy; The Ohio State Wexner Medical center University Hospital/Ross Hospital/University Hospital East, division of nursing services Glucose Monitoring policy.
  - 6.8.2.3. Adult Glucose levels less than 50 mg/dl or greater than 400 mg/dl are considered a critical value. Infant glucose levels less than 40 mg/dl and greater than 200 mg/dl are considered a critical value.
- 6.8.3. Creatinine: for creatinine values greater than 10mg/dL the critical value form should be filled out and faxed to POC.
- 6.8.4. INR: If the INR value exceeds 3.0, a sample needs sent to the lab. A value of >4.9 is considered a critical value. The testing personnel documents the physician notified in the Complex Vitals flowsheet.
- 6.8.5. General Confirmatory Testing criteria:
  - 6.8.5.1. Confirmatory testing or followup testing is performed when:
    - 6.8.5.1.1. The test result is beyond the linearity (AMR) of the instrument
    - 6.8.5.1.2. An inconclusive test result is obtained.
    - 6.8.5.1.3. Quality control continues to fail
    - 6.8.5.1.4. An unusual result is obtained
    - 6.8.5.1.5. When results do not correlate with other clinical findings
    - 6.8.5.1.6. Per Physicians discretion
    - 6.8.5.1.7. For glucose, refer to: The University Hospital/Ross Hospital/University Hospital East, division of nursing services Glucose Monitoring policy.

6.9. Training
- 6.9.1. All initial POC testing must be coordinated through the POC office. A “super user” can be trained by the coordinators for each department when needed for POCT training.

6.9.2. Nova glucose initial training is approved by POC and is primarily completed at PCA orientation and nursing unit orientation.
6.9.3. After each initial training the testing personnel are assessed for competency. Record of training materials are maintained on the Share Drive.
6.9.4. The training checklist is specific for each test. Staff and licensed independent practitioners who perform testing that requires the use of an instrument have been trained on its use and maintenance, which is documented.
6.9.5. A licensed independent practitioner performs waived testing (Fecal Occult Blood/pH) that does not involve an instrument and the test falls within his or her specialty, OSU Wexner Medical Center use the medical staff credentialing and privileging process to document evidence of training and competency in lieu of annual competency assessment. In this circumstance, individual practitioner privileges include the specific waived tests appropriate to the scope of practice that he or she is authorized to perform.
6.9.6. Users of waived testing will have testing privileges removed if they do meet testing requirements.
6.9.7. Moderately complex testing training must be performed by a technical consultant delegated by laboratory medical director or per laboratory policy; training observation may be delegated to a point of care "superuser".

6.10. Competency Assessment
6.10.1. Initial: All patient care staff responsible for performing point-of-care testing will have documented evidence of competence. New testing employees will demonstrate competence of technical procedures for point-of-care testing during orientation or upon the job position requiring POC testing.
6.10.2. The competency encompasses pre-analytical, analytical and post-analytical steps of each test
6.10.3. Personnel files must contain initial qualifications including copies of diplomas/transcripts, licenses (where required), performance evaluations, and continuing education records.
6.10.4. Waived: Each person responsible for performing tests will have competency accessed after initial training and annually thereafter.
6.10.4.1. Competency for waived testing is assessed by using some of the following methods per person per test. The competency is presented in the form of computer based learning (CBL) curriculum. The curriculum includes the pre-analytical, analytical and post analytical phases of testing, specific to each test. Testing a blind sample or quality control is documented in the POC middleware and or the direct observation form.
6.10.4.1.1. Performance of a test on a blind specimen or proficiency test.
6.10.4.1.2. Periodic observation of routine work by the supervisor or qualified designee.
6.10.4.1.3. Monitoring of each user's quality control performance.
6.10.4.1.4. Review of training check off list and a written test specific to the test assessed.

6.10.5. Non-waived: For non-waived test systems, competency using all six elements described below must be assessed for each individual on each test system during annual and semi-annual assessments, unless an element is not applicable to the test system.
6.10.5.1. Competency must be assessed at 6 months and then annually thereafter. Elements of competency assessment include but are not limited to pre-analytical, analytical and post-analytical elements of each test. The POC computer based learning curriculum includes the pre-analytical, analytical and post analytical, troubleshooting, quality control and maintenance elements specific to each test. The direct observation is documented on the Direct Observation Competency form.
6.10.5.1.1. Direct observations of routine patient test performance, including, as applicable, patient identification and preparation; and specimen collection, handling, processing and testing.
6.10.5.1.2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results.
6.10.5.1.3. Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

6.10.5.1.4. Direct observation of performance of instrument maintenance and function checks, as applicable.
6.10.5.1.5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples
6.10.5.1.6. Evaluation of problem-solving skills.
6.10.5.1.7. Competency written test

6.10.6. Performance Assessment of Point of Care Coordinators (Technical Consultant)
6.10.6.1. The Laboratory ADM policy Employee Competency requires completion of the General Supervisor annual assessment competency form.

6.10.7. Assessment of Training and/or Competency Testing
6.10.7.1. A score of 85% is required on the test to be deemed competent.
6.10.7.2. An incorrect answer on the test requires corrective counseling by the POC team, manager or designee, review of learning assessment guide or paper test.
6.10.7.3. The manager/POC team or designee should document on the test "Incorrect results reviewed with technologist, employee deemed competent"
6.10.7.4. The designee deems the testing personnel competent. Once they are deemed competent they are approved to perform testing.

6.11. Method Validation
6.11.1. Waived: Methods defined as waived testing do not require method validation.
6.11.1.1. Each test is reviewed and evaluated for sound laboratory practices. A minimum correlation study is performed during training to show OSUWMC POC areas can perform the test per manufactures recommendations
6.11.2. Non-waived: All other test complexities require appropriate method validation, including accuracy, precision, and validation of reference ranges, interfering substances, linearity, and instrument correlations, as applicable. Method validations will be approved by the division director.
6.11.3. The director or designee reviews the validation study for performance of the method and its acceptability for patient testing

6.12. Proficiency Testing/Quality Assessment
6.12.1. Waived Testing: Per CLIA, Proficiency testing is not required for waived testing. A mechanism for assuring the overall quality of the testing will be performed at least two times per year. Quality Assessment is achieved by proficiency testing, blind samples, quality control, and/or correlation studies.
6.12.2. Correlation studies are performed biannually on Creatinine, Avox (Ross cath lab & UHE cath lab), INR, ACT, EPOC, Piccolo, and Blood gases.
6.12.3. Correlation studies are performed quarterly on whole blood glucose.
6.12.4. QC is reviewed monthly by coordinators, manager and division directors.
6.12.5. Internal QC is reviewed monthly for, Urine Dip and urine HCG assays.
6.12.6. The Health System is enrolled in the appropriate proficiency testing surveys for tests performed in the laboratory for which a survey is mandated per regulations. Proficiency testing is performed on the primary instrument.
6.12.7. Proficiency samples are integrated into the daily workload, are treated as patient samples, and are analyzed by technologists in that area for the day. Inter-laboratory communication about proficiency testing samples before submission of data to the CAP or other provider is strictly prohibited. Referral of proficiency testing specimens to another laboratory, even within The OSU Wexner Medical Center, is prohibited.
6.12.8. PT/QA results are reviewed by the Division Director and POC department manager. All unacceptable results are investigated and corrective action documented

7. SAFETY

7.1. All personnel handling laboratory specimens will adhere to all safety policies and procedures as required by The Ohio State University Medical Center, The Ohio State University - division of Environmental and Occupational Health and Safety, CAP, TJC, OSHA, EPA, and prevailing local and state regulations.

7.2. Food and Drink: Food and drink are prohibited in all laboratory work areas. Specimens containing a variety of pathogens are handled daily and stored in laboratory refrigerators. Food is not permitted in the laboratory refrigerators. Eating, drinking and food-storing refrigerators are restricted to the break room.

7.3. Cosmetics: Application of cosmetics in laboratory work areas is prohibited. Use of medical center-approved hand creams is allowed and recommended for employees performing frequent hand washing.

7.4. Eye and Face Protection:

- 7.4.1. Protective devices: safety glasses, facial shields, or other eye and face protectors must be worn when handling caustic or toxic materials. Protective devices must also be worn for splash protection when working with potentially infectious samples that can infect through mucous membranes or skin, or when splashing is likely to occur.
- 7.4.2. Contact lenses: will absorb solvents and therefore constitute a hazard during splashes or spills. In case of accidental splash, contact lenses should be removed immediately, eyes washed with water, and contact lenses decontaminated before wearing again.

7.5. Personal Protective Equipment

- 7.5.1. Gloves must worn when it can be reasonably anticipated that the healthcare worker will have contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin, or when handling contaminated items or surfaces. Gloves should be worn during vascular access procedures, including phlebotomy and finger or heel sticks.
- 7.5.2. Gloves should be replaced as soon as feasible if they become torn or punctured, or lose their ability to function as a barrier. Disposable gloves should not be washed or decontaminated for reuse because this will compromise the impermeability of the material. Gloves should be replaced between patient contacts.

7.6. Hand Washing: Standard Precautions - Hand HygienePhase II Standard precautions are used for point-of-care testing by testing personnel. The Ohio State Wexner Medical Center policy is located at https://onesource.osumc.edu/departments/Epidemiology/Pages/HandHygiene.aspx.

- 7.6.1. Hands should be washed frequently during the day. Wash hands before and after removing gloves, before and after contact with patients, and before eating or having any contact with mucous membranes.
- 7.6.2. Hands must be washed immediately after accidental contact with blood, body fluids, and contaminated materials.
- 7.6.3. Gloves must be worn during testing events and hand hygiene performed using an effective antimicrobial method.

7.7. Personal Safety

- 7.7.1. Report all injuries, however slight, to the appropriate charge person or safety officer. Get medical attention if required. Complete accident/incident report forms.
- 7.7.2. Employee Health maintains medical records on all employees for annual PPD skin test, current vaccinations (flu, Hepatitis) or other medical services which the employee may require.
- 7.7.3. Do not attempt to lift heavy objects or use inappropriate objects for climbing. Use carts or step stools when necessary.
- 7.7.4. Attend to accidental spills immediately according to nature of spill. Follow appropriate procedures.
- 7.7.5. Discard all sharps such as broken glass, needles, etc., in designated containers provided.
- 7.7.6. Use appropriate insulating or protective devices when handling extremely hot or cold items.
- 7.7.7. Do not recap needles unless using approved re-sheathing devices. Do not bend, break or manipulate needles by hand.
- 7.7.8. Use fume hoods when handling substances that produce toxic fumes.
- 7.7.9. Report unsafe practices to the laboratory leadership or safety officer as soon as possible so corrective action can be taken. Unusual incident reports are generally completed if there is a potential for legal concern (i.e. a patient was injured) or if equipment failure was involved.
- 7.7.10. Aisles and exits must be unobstructed. Do not block open self-closing doors.

7.8. Laboratory Equipment:

- 7.8.1. Hand held or portable devices:

7.8.1.1. Portable and hand held devices that enter patient's rooms are disinfected with an OSUWMC and manufacturer approved disinfectant after each patient use.

7.8.2. Centrifuges:

7.8.2.1. Do not operate centrifuges unless the cover is closed and secured.

7.8.2.2. All centrifuge tubes must be tightly capped to prevent aerosolization.

7.8.2.3. Ensure that the centrifuge is properly balanced and that all trunion rings are properly seated.

7.8.2.4. Never stop the centrifuge with your hand.

7.8.2.5. Clean centrifuges regularly with a 1:10 dilution of bleach or other approved disinfectant. Take a damp cloth and remove excess bleach solution, and dry the interior of the centrifuge completely.

7.8.3. Containers:

7.8.3.1. Label all containers to accurately identify contents, hazard warnings, and spill instructions

7.8.3.2. Never fill a container with anything other than the material identified on the label.

7.8.4. Safety Equipment: all personnel should know the location and instructions for use of the following safety equipment: fire extinguishers, safety showers, eye washes, spill kits, pull stations

7.9. Temperature and humidity requirements

7.9.1. Follow all manufacturers' instructions for handling and storing laboratory reagents or supplies according to their specific temperature and/or humidity requirements.

7.9.2. The storage requirements are documented in all moderate complex testing sites and all areas of bulk storage for waived testing.

7.9.3. Temperature and humidity are documented day in use on temperature logs. The logs are submitted to the POC department monthly for review

7.9.4. The temperature logs require the documentation of the minimum and maximum temperatures

7.9.5. Temperature logs are stored on the I Drive

7.9.6. Thermometers are replaced before the calibration expires

7.10. Restricted Laboratory Access.

7.10.1. The Point of Care department is locked during non-office hours.

7.10.2. All Point of Care devices have operator lock out features and require electronic approval to access the devices.

8. RESOURCES AND REFERENCES

8.1. CLIA Provider-performed microscopy (PPM) procedures, Center for Disease Control and Prevention. Sec 493.19

8.2. Code of Federal Regulations Title 42, Volume 3, Parts 430 to END (revised 10/1/97)

8.3. The Joint Commission Accreditation of Healthcare Organizations. JCAHO Waived Testing standards. Current version.

8.4. College of American Pathologists. Laboratory General Checklist and Point of Care Checklist. Northfield, IL 60093-2750. Current Version.

9. RELATED DOCUMENTS

9.1. Refer to QPulse System or Document Detail Report for related Laboratory Policies, Procedures, and Master Forms.