Office of Origin: Medical Center Clinical Laboratories

I. PURPOSE
To ensure that point-of-care (decentralized) laboratory testing is high quality and cost-effective, in order to contribute to optimal patient care.

II. REFERENCES

III. DEFINITIONS

Point of Care Testing: Laboratory testing, at any complexity level, that is performed and documented within the hospital organization at sites of immediate patient care (e.g. clinic, nursing unit, ED), where the results of the test are used for clinical decision making (see Appendix A for a list of such sites). It does not pertain to histologic or cytologic assessments or to testing performed in settings outside of those associated with immediate patient care.

NOTE: Point-of Care Testing may also be referred to as decentralized testing, ancillary testing and bedside testing. Based on Clinical Laboratory Improvement Amendment (CLIA) criteria, point-of-care testing is generally divided into two categories of complexity (waived and non-waived testing; see below) in addition to provider-performed microscopy (PPM).

Waived Testing: Non-critical tests which have been approved by the FDA for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or pose no reasonable risk of harm to the patient if performed incorrectly. Waived test lists are constantly updated and can be viewed on the web at http://www.phppo.cdc.gov/clia/waived.asp and http://cms.hhs.gov/clia/waivedtbl.pdf

Non-Waived Testing:

Moderately Complex Testing: Tests which require minimal scientific and technical knowledge and training to perform accurately, operational steps are either automatically executed or easily controlled, and minimal interpretation and judgment are required.

Highly Complex Testing: Tests which require specialized scientific and technical knowledge, training and experience to perform accurately, operational steps require close monitoring or control, and extensive independent interpretation and judgment are required.

Provider-Performed Microscopy (PPM): Amended by SB585 on 7/99; tests performed by a provider on patients in his or her own medical practice, including a group practice of which the provider is a member.
IV. POLICY

Any laboratory testing, including testing that is performed outside of the Clinical Laboratories by non-clinical laboratory personnel, must conform with state and federal regulations. The Point-of-Care Testing Committee establishes standards for Point-of-Care Testing, monitors all Point-of-Care Testing sites for compliance & proficiency as required, reviews for approval all requests to establish Point-of-Care Testing, arranges for evaluation of all POC test devices/kits by central laboratory and approves all such devices/kits before they are put into service. All sites performing Point-of-Care testing must be authorized to do so by the POCT Committee for each test performed.

Questions about the implementation of these guidelines should be addressed to the POC Specialist in the Clinical Laboratory. Further questions can be addressed to Risk Management.

V. IMPLEMENTATION / PROCEDURES

A. Point-of-Care Testing Committee

1. The Point-of-Care Testing Committee is chaired by the Clinical Laboratory Director and includes the following people or their designees; Chief Medical Officer, Medical Nursing, Surgical Nursing, Ambulatory Administration, Quality Improvement, Purchasing, Risk Management and Medical Center Administration. Representatives from Pathology, and others as necessary are invited to participate, on an ad hoc basis.

2. The Committee meets at least quarterly with conclusions, recommendations, and actions documented in the minutes. The Committee Chair reports annually to the Clinical Performance Improvement Committee.

3. The Committee:
   a. Reviews for approval all requests for Point-of-Care testing, taking into consideration the following issues:
      1) Medical need for immediate turnaround time
      2) Procedure complexity
      3) Appropriate CLIA certification for requested testing (e.g. waived, moderately complex, PPMP, etc.)
      4) Ongoing testing proficiency
      5) Cost
   b. Assigns Point-of-Care testing oversight to the appropriate laboratory staff.
   c. Reviews reports of performance for all areas performing laboratory testing and recommends corrective action as necessary.
B. Guidelines

1. Any proposal to establish decentralized testing must be referred to the Point-of-Care Testing Committee for approval. See Appendix E: Request for Approval Form.

2. Clinical Laboratory personnel are assigned to assess technology available for the requested decentralized testing. Vendors who market laboratory test kits, reagents, and instruments will be referred to the laboratory. The Clinical Laboratory evaluates and recommends items to the Point-of-Care Testing Committee before purchase is approved.

3. The Point-of-Care Testing Committee assigns oversight of the testing to the appropriate clinical laboratory staff. The department performing the testing ensures that testing complies with all pertinent accrediting agencies and state and federal standards, including ongoing renewals for CLIA registrations or certificates and payment of the applicable fees, if a separate license is required.

4. Test procedures are written in standard format that is clear to the user and meets all regulatory requirements. Procedures are reviewed at least annually and signed by the director of record (or designee) and as required by change of law or practice.

5. The Clinical Laboratory POCT staff monitors test systems (equipment and reagents) and testing techniques. A Quality Control procedure is established and data collected in the routine course of the performance of laboratory testing by those personnel producing the results in the patient care setting. The Clinical Laboratory regularly reviews Quality Control (QC) data.

6. Internal and external proficiency testing is established when appropriate, with results monitored by the Clinical Laboratory. Sub-optimal performance on proficiency testing is brought to the immediate attention of the Point-of Care Testing Committee, which determines corrective action.

7. A training program ensures that testing personnel meet regulatory requirements and provides regularly scheduled review of training and techniques. Personnel who are to perform the testing are identified individually, and only those individuals who demonstrate competency perform the testing.

8. Preventative maintenance is performed and documented in accordance with manufacturer's instructions and regulatory standards.

9. Clinical Laboratory personnel provide continuing review of all documentation, provide feedback to the appropriate responsible authority in
that testing area, and present reports of performance to the Point-of-Care Testing Committee.

10. Disregard for these standards will be recognized as contrary to the best interest of patient care and result in termination of the testing opportunity.

11. Units, clinics or sites may not borrow POCT kits, supplies, or devices for testing unless the site is already approved by the POCT Committee to perform the test(s) involved.

VI. APPENDICES
   A. POCT Locations
   B. Waived Tests Performed
   C. Non-Waived Tests Performed
   D. Provider Performed Microscopy Procedures
   E. POCT Request form

VII. HISTORY OF POLICY

APPENDIX A: POCT LOCATIONS
APPENDIX B:
LIST OF WAIVED TESTS PERFORMED AT MEDICAL CENTER HOSPITALS AND CLINICS

This appendix defines the testing methods that are classified as waived tests and the conditions under which they will be performed at the patient's bedside or in the Ambulatory practice setting in accordance with federal law and regulations. The following elements are defined:
1. The tests and the extent to which the test results are used in an individual's care (definitive or used only as a screen);
2. The individuals responsible for test performance;
3. The individuals responsible for direction/supervision of the testing activity;
4. Orientation and specific training, and competency testing of those individuals performing the tests;
5. Location of written policies and procedures regarding performance of the test. These policies and procedures describe specimen collection and preservation, instrument calibration, quality control and remedial action, equipment performance evaluation and test performance;
6. Quality control checks; and
7. Quality control and test record maintenance.

1. Waived Tests Performed at Lab X POCT

<table>
<thead>
<tr>
<th>Test</th>
<th>Use of result</th>
<th>Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood glucose monitoring</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Urine dipstick</td>
<td>Screening</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Fecal occult blood</td>
<td>Screening</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Gastric occult blood</td>
<td>Screening</td>
<td>Hospital</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Hemoglobin A1c</td>
<td>Definitive</td>
<td>Ambulatory practices</td>
</tr>
<tr>
<td>Urine pregnancy</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>pH determination by pH paper/strip</td>
<td>Screening</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>RSV</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Strep A</td>
<td>Definitive</td>
<td>Ambulatory practices</td>
</tr>
<tr>
<td>Influenza</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
<tr>
<td>Prothrombin time</td>
<td>Definitive</td>
<td>Ambulatory practices</td>
</tr>
<tr>
<td>Lipid analysis</td>
<td>Definitive</td>
<td>Ambulatory practices</td>
</tr>
<tr>
<td>Creatinine</td>
<td>Definitive</td>
<td>Hospital, Ambulatory practices</td>
</tr>
</tbody>
</table>

2. Individuals Responsible for Test Performance

Within the hospital only licensed individuals (MD, CLS, RN, NP, PA, Nurse Midwife, Respiratory Tech, Licensed Radiology Tech, and Perfusionist) may perform point of care testing.

Within the Ambulatory practices, Medical Assistants may perform waived point of care testing in addition to the above personnel categories.
Point of Care Testing

3. Individuals Responsible for Direction/Supervision of Testing Activity:

Overall direction of waived testing activity is provided by the Clinical Laboratory QA/POCT & Regulatory Compliance Section. The QA/POCT & Regulatory Compliance section and Laboratory Director appoints the Specialists of POC Testing. All POC testing is approved through the POCT Committee.

The Nurse Manager or Ambulatory practice Manager of each individual area is responsible for the supervision of waived testing on that unit. The actual orientation and competency monitoring may be delegated to a specially trained RN.

4. Orientation, Specific Training and Competency Testing:

a. All appropriate staff are trained in waived test procedures at time of orientation.

b. Staff is assessed for competency on an annual basis.
1) Initial orientation and training consists of acquisition of theoretical knowledge concerning the test as demonstrated by a score of 80% or better on the post-test, and practical demonstration of technique to an authorized evaluator.

2) Ongoing annual competency assessment will consist of at least two of the following: attaining a score of 80% or better on a written exam, practical demonstration of technique to an authorized evaluator, electronic documentation of successful quality control or test performance annually.

3) Authorized evaluators are defined according to test complexity:
   - Waived tests: A licensed individual competent to perform the test
   - Moderate complexity: A person meeting or exceeding the CLIA ’88 requirements for a Technical Supervisor (in general a licensed Clinical Laboratory Scientist)

4) Physician competency:
   - Not required for: visual endpoint tests
   - Required for: device or instrument based tests
   - Required for: Physician performed microscopy (PPM)

c. Documentation of training and competency validation is maintained in the employee’s unit-based personnel file.

5. Location of Written Policies and Procedures Regarding Performance of the Test:

a. Procedures pertaining to waived testing are found in the following location:

"Type your file access information here"

1) Lab X POCT - Waived Test Procedures manual:
   - Blood Glucose Determination Using the Accu-Check Inform Meter®
   - Fecal Occult Blood (ColoScreen®)
   - Gastric Occult Blood and pH (Gastrocult®)
   - Urine Dipstick (Siemens Multistix & Uristix)
   - Hemoglobin Determination Using the Hemocue Hemoglobin Photometer®
   - Urine Pregnancy Using IM Confirm II ®
Point of Care Testing

- Prothrombin time with CoaguCheck®
- Lipid analysis with Cholestech®
- HgbA1c with DCA 2000®
- pH determination (pH paper, pH strip)
- Strep A (Signify Strep®)
- Influenza (QuickVue Influenza®)
- RSV (Binax Now RSV Test®)
- Creatinine (iSTAT®)

6. Quality Control:

   Quality control requirements for each individual test are found in the individual test procedures.

7. Record Maintenance:

   a. Each unit maintains ongoing records to ensure that staff is trained and competent to do waived testing.
   b. Completed records are maintained for a minimum of 3 years.
APPENDIX C:
LIST OF NON-WAIVED TESTS PERFORMED AT LAB X POCT

This appendix defines the testing methods, which are classified as moderate complexity, and the conditions under which they will be performed at the patient’s bedside in accordance with federal law and regulations. All testing sites must get the approval of the POC Advisory Committee prior to beginning testing. The following must be in place before testing begins.

1) Laboratory Director must be determined and a CLIA Certificate obtained (493.1403 Condition)
2) Personnel (493.1407 E 11 Standard)
   a) Identified
   b) Qualifications Documented
   c) Training Documented
   d) Ongoing Competency Assessment Plan
3) Instrumentation
   a) Standard Instrumentation as approved by the POCT Committee
4) Reagents (493.1407 E 2 Standard)
   a) Supply Log
   b) Storage requirements must be determined, including adequately assuring proper environmental conditions for testing
5) Policy and Procedure Manual (493.1202 C 1 Standard)
   a) Must follow manufacturers instructions for operations, preventive maintenance calibration, etc.
   b) Written in Standard CLSI format
   c) Signed by director with documentation of review by each person performing testing.
6) Patient Record System
   a) The record system must include the identity of the personnel who performed the test (493.1107D Standard)
   b) A test report must indicate the name and address of the laboratory location where the test was performed, the test performed, the test result and, if applicable, the units of measurement. (493.1109B Standard)
7) Controls
   a) The Laboratory must establish and follow written quality control procedures for monitoring and evaluating the quality of the analytical testing process of each method to assure the accuracy and reliability of the patient test results and reports. (493.1201-493-1221 Standards)
   i) Quality controls must be run every eight hours of patient testing. These may be internal or external electronic controls, internal or external liquid controls, and must, at a minimum, meet manufacturer’s recommendations for quality control testing. Liquid controls must also be run with each new lot number, shipment or package of reagents. Individuals performing patient testing must be involved in performance of quality control.
8) Maintenance (493.1407 E 2 Standard)
   a) Temperature Verification, as required by regulations and manufacturer’s recommendations.
   b) Daily and Weekly Maintenance is documented.
9) Proficiency Testing (493.1709 B Standard)
   a) The Laboratory must have a system for verifying the accuracy of its test results at least twice a year. Individuals performing patient testing must be involved in performance of proficiency testing.
10) Verification procedures to determine accuracy, precision and other pertinent performance characteristics of the method. (493.1407 D Standard)
11) Ensure that the quality control program and quality assurance programs are established and maintained to assure the quality of laboratory services. (493.1407 D Standard)

All of the above must be documented and the documentation is maintained in the department and also in the Clinical Laboratory QA/POCT & Regulatory Compliance Section.

Procedures pertaining to non-waived testing are found in the following location:
"Type your file access information here"

1) Lab X POCT – Non-Waived (Moderately Complex) Test Procedures manual:

- ACT testing with Medtronic ACT PLUS™ and HEMOCHRON® Elite
- Blood Gas, Lactate and Glucose analysis with GEM® Premier 3000
- Electrolyte and Blood Gas analysis with i-STAT 1
- Hematocrit by Conductance
- Co-oximetry with AVOXimeter
APPENDIX D: PROVIDER PERFORMED MICROSCOPY

Physician competence is verified annually by an online competency program. The following PPM are currently performed in the hospital and clinics:

- All potassium hydroxide (KOH) preparations (QOI 2)
- Wet mounts, including preparation of vaginal, cervical or skin specimens (QO111)
- Pinworm examinations (QOI 13)
- Ferntest (Q0114)
- Urinalysis, microscopic only (CPT 81015)
APPENDIX E: POCT REQUEST FORM

POCT REQUEST FORM

REQUEST FOR APPROVAL OF NEW POINT OF CARE TEST OR DEVICE

All point of care in-vitro laboratory testing must be evaluated and approved by the POCT Committee to ensure that it meets institutional goals as well as state and federal regulations. To expedite your request, please complete all information below. Please attach all pertinent documents to this form and submit to: POCT Committee, Attn: “Staff name and contact information”

1. Test requested: __________________________

2. Name(s) of device(s):
   I you learn about this test?
   [ ] Contacted by vendor(s) (Company & name): __________________________
   [ ] Journal article (Citation): ____________________________________________
   [ ] Conference (name of conference and date): ____________________________
   [ ] Recommended by colleague (name, institution and phone #): ____________

   [ ] Physician request (name, pager #):

4. Purpose for introducing test
   [ ] Patient care goals. Explain: _________________________________________
   [ ] Provides greater benefit than current system. Explain: ________________
   [ ] Rapid result (< 30-60 min) improves patient care or reduces cost. Explain:

   _________________________________________________________________
   _________________________________________________________________

   [ ] Test not currently provided by this institution.
   [ ] New technology
   [ ] Replacement for (test) , or (instrument) Describe:

   _________________________________________________________________

5. Where will this test be used? (List patient population, nursing units and/or departments):
   _________________________________________________________________
   _________________________________________________________________

6. Estimate annual test volume: __________________________

7. Estimate of annual cost: __________________________
8. Personnel
   Estimate of number of potential users: __________
   Job categories of potential users: __________________________

9. Name of requestor: (Title, Department, Phone #, Pager #, e-mail):
   __________________________
   __________________________

10. Name of contact person (Title, Department, Phone #, Pager #, e-mail):
    __________________________
    __________________________