

Office of Origin: UCSF Medical Center Clinical Laboratories (415) 353-1630

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 at UCSF.

II. REFERENCES

California Administrative Code, Title 17, Chapter 2, Subchapter 1, Group 2, Sections 1030 to 1057.

California Administrative Code, Title 22, Chapter 1, Section 70243 to 70249.

California Business and Professions Code, Division 2, Chapter 3, Section 1200 to 1322.

Clinical Laboratory Improvement Amendments of 1988, Public Law 100-578 (CLIA 88).

Joint Commission on Accreditation of Healthcare Organizations. Accreditation Manual for Pathology and Clinical Laboratory Services, 2005. Oakbrook Terrace, Illinois.

[UCSF Medical Center Point of Care Testing Manual](#)

(<http://labmed.ucsf.edu/labmanual/mftlng-mtzn/provider/index-poc.html>)

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.

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 Nursing, Quality Improvement, Purchasing, Risk Management and Medical Center Administration. Representatives from Infection Control, Hospital Information Services, 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 UCSF 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) Regulatory compliance
 - 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 application for a CLIA registration or certificate 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 UCSF 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 or disinterest in these standards will be recognized as contrary to the best interest of patient care and result in termination of the testing opportunity.

VI. APPENDICES

- A. Request for Approval Form

VII. HISTORY OF POLICY

Approved October 2001 by Mark R. Laret, CEO

Approved October 2001 by Executive Medical Board

Reviewed March 2003 by T. R. Hamill, MD (only changes include locations, quality control products)

Reviewed March 2005 by T. R. Hamill, MD (changes include locations, test lists, waived and non-waived definitions, and QC/competency updates)

Reviewed July 2005 by Policy Steering Committee; lists of POCT testing locations, waived tests, non-waived tests and Provider Performed Microscopy tests moved to [POCT website](#)

Reviewed August 2005 by Enrique Terrazas and Clifton Louie, Executive Director of Clinical Services

Reviewed September 2005 by Strategic Leadership Council

Reviewed September 2005 by Mark R. Laret, CEO

Approved October 2005 by Executive Medical Board and Chancellor J. Michael Bishop

Revised August 2007 by Tim Hamill, MD

Reviewed September 2007 by Policy Steering Committee

Approved September 2007 by Executive Medical Board, Governance Advisory Council and Chancellor J. Michael Bishop

This document is intended for use by UCSF Medical Center and personnel and no representations or warranties are made for outside use. Not for outside production or publication without permission.

Direct inquiries to the Office of Origin, or:

Administration: (415) 353-2733

Policy Office: (415) 353-2839

Appendix A: Request for Approval Form (2 pages)**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: Sandra Tye, UCSF Clinical Lab Box 0100.

Date request submitted:

1. Test requested:

2. Name(s) of device(s):

3. How did 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):