

MEDDAC Memorandum 40-29

Medical Services

Point-of-Care Testing Laboratories

**Headquarters
U.S. Army Medical Department Activity
Fort George G. Meade
2480 Llewellyn Avenue
Fort George G. Meade, MD 20755-5800
1 August 2002**

Unclassified

SUMMARY of CHANGE

MEDDAC MEMO 40-29
Point-of-Care Testing Laboratories

Specifically, this revision—

- o Has been published in a new format that includes a cover and this “Summary of Change” page.
- o Reformats the title page. The Contents section now includes the page numbers that the various chapters and paragraphs begin on.
- o Moves the list of references from paragraph 1-2 to a new appendix A, References.
- o Eliminates the ~~striketrough~~ text that was in the previous edition, which indicated deleted text, and removed the highlighting from added text, which, again, was in the previous edition. This was necessary due to some of the highlighted text inexplicably disappearing in paragraph 3-1b of the electronic (PDF file) on the internet.
- o Changes “KACC Performance Improvement (PI)/Utilization Management (UM) Committee” to read “MEDDAC Performance Improvement and Utilization Management Committee,” as the committee is currently designated in MEDDAC Reg 15-1 (paras 1-4e and 3-4).
- o Removes the unexplained acronym “PPM,” which is not repeated within the memorandum, and replaces it with “provider performed microscopy.” (para 3-1(b)(1)).
- o Replaces the passive words “are” and “must” from the text in paragraph 3-2b with the directive word “will”.

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Headquarters
United States Army Medical Department Activity
2480 Llewellyn Avenue
Fort George G. Meade, Maryland 20755-5800
1 August 2002

* MEDDAC
Memorandum 40-29

Medical Services

Point-of-Care Testing Laboratories

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History. This update publishes the third revision of this publication. It

was originally published on 3 July 1998.

Summary. This memorandum establishes responsibilities, policies and procedures for point of care laboratory testing within Kimbrough Ambulatory Care Center (KACC).

Applicability. This memorandum applies to Headquarters, U.S. Army Medical Department Activity, Fort George G. Meade (MEDDAC); that is, KACC.

Proponent. The proponent of this memorandum is the Chief, Laboratory Service (LS).

Suggested improvements. Users of this publication are invited to send comments and suggested improvements, by memorandum, directly to the Commander, U.S. Army Medical Department Activity, ATTN: MCXR-LS, Fort George G. Meade, MD 20755-5800, or to the MEDDAC's Command Editor by fax to (301) 677-8088 or e-mail to john.schneider@na.amedd.army.mil.

Distribution. Distribution of this publication is by electronic medium only.

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* This publication supersedes MEDDAC Memo 40-29, dated 21 May 2001.

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Glossary

Chapter 1 Introduction

1-1. Purpose

This memorandum prescribes responsibilities, policies and procedures for point of care laboratory testing within the MEDDAC.

1-2. References

Related publications are listed in appendix A.

1-3. Explanation of abbreviations and terms

Abbreviations and special terms used in this memorandum are explained in the glossary.

1-4. Responsibilities

a. The Deputy Commander for Clinical Services (DCCS). The DCCS will sign requests for approval of point-of-care testing laboratories (POCTL) within KACC.

b. The on-site laboratory director. The on-site laboratory director is the POCTL's department chief. (The term "department" is explained in the glossary.) The on-site laboratory director will—

- (1) Regularly review the quality control data of all POCTLs within the department.
- (2) Regularly review the proficiency testing and competency assessment data.
- (3) Take appropriate action when tolerance limits are exceeded.
- (4) Review POCTL standing operating procedures (SOPs) annually.

(5) Ensure that each individual actively involved in point-of-care testing has had a competency assessment performed prior to assumption of duties, six months later and annually thereafter. Competency assessments shall be performed more frequently for individuals who perform point-of-care testing on an irregular or infrequent basis.

c. The Chief, LS. The Chief, LS will—

(1) Provide guidance and assistance for the certification process including a recommendation to the DCCS.

(2) Provide advice and guidance on any question or problem relating to POCTL personnel standards and establishment and maintenance of POCTL quality control systems.

(3) Provide recommendations for log sheets used to document instrument maintenance and function checks on equipment used for point-of-care testing.

(4) Provide advice regarding the interpretation of statistical analysis of POCTL quality control data.

(5) Provide training to supervisory personnel working in POCTLs concerning interpretation, documentation and corrective actions required for implementation of an acceptable POCTL quality control program.

(6) Send Clinical Laboratory Improvement Program (CLIP) registration applications to the CLIP Office (CLIPO). On receipt of a certification certificate from the CLIPO, forward a copy to the named POCTL director.

d. Chiefs of clinics having POCTLs. Chiefs of clinics having POCTLs will—

(1) Establish a comprehensive quality control program and a written SOP for each procedure performed; review each SOP at least annually.

(2) Use quality control materials appropriate to each procedure performed; document

satisfactory reactivity, sensitivity and specificity of test reagents and materials at the frequency specified for that procedure.

(3) Document inspection, maintenance and performance data for each piece of equipment used in performing test procedures.

(4) Document the training and experience of the individuals performing laboratory tests and provide in-service education opportunities consistent with the size and the needs of the POCTL.

(5) Participate in an external quality assurance program (proficiency testing) appropriate to the size and needs of the POCTL. If conducting moderate and high complexity testing, participation will entail testing “unknown” specimens provided through the CAP or other recognized external proficiency testing survey. LS participates in the CAP proficiency testing program and will assist labs in determining their needs. For waived (minimal complexity) testing, competency assessment is required by either performing testing of “unknown” specimens, observation from a supervisor or delegate, or monitoring users quality control performance.

(6) Maintain results of patient testing, quality control records and proficiency testing results for two years.

e. The Point-of-Care Review Group (POCRG). The POCRG will coordinate POCTLs at KACC and provide a conduit in to the MEDDAC Performance Improvement and Utilization Management Committee.

Chapter 2

What is a POCTL, Goal of the Command Regarding Point-of-Care Testing (POCT), Authorization to Perform POCT, POCTL Standards, Accreditation, and Workload Recording

2-1. What is a POCTL?

A POCTL is any non-LS organization element within KACC within which outpatient laboratory testing is performed by a health care provider as part of a professional examination.

2-2. Goal of the command regarding point-of-care testing (POCT)

The goal of this command with regard to POCT is to ensure patients receive high quality clinical laboratory testing whenever, wherever, and by whomever performed; and to comply with the standards of the CLIP and Joint Commission on Accreditation of Healthcare Organizations (JCAHO) as they apply to point-of-care laboratory testing. The four elements necessary to achieve this goal are discussed below in paragraphs 2-3 through 2-6.

2-3. Authorization to perform POCT

a. Any element of KACC desiring to operate a POCTL must receive specific authorization. Evidence of this authorization is certification by the CLIPO. To obtain certification, an activity must route a request through the Chief, LS to the DCCS. Requests approved by the DCCS will be returned to the Chief, LS who will send the request to the CLIPO. A POCTL may not function as such until it's certificate has been received from the CLIPO.

b. Contract laboratories must comply with CLIA 88. (See paragraph 1-2f above.)

c. Health care providers are specifically authorized to perform POCT provided they comply with the provisions of this memorandum and have the appropriate certificate issued by the CLIPO.

2-4. Standards

All POCT will be performed in accordance with CLIP and JCAHO standards and CAP standards, as applicable.

2-5. Accreditation

All POCTLs performing moderately complex and/or highly complex laboratory testing will seek and gain CAP accreditation.

2-6. Workload recording

Not later than the 15th of each month, all POCTLs performing moderately complex and/or highly complex POCT will provide the Chief, LS a report of the previous month's total number of patient and quality control tests performed.

Chapter 3

Provider Performed Microscopy, Minimally Complex Tests, POCTL Oversight, and the POCRG

3-1. Provider performed microscopy

a. Health care providers may perform certain tests as a part of their professional examination. Specimen logs and specific quality control logs are not required. The results are entered directly into the patient's chart. Each lab must have the appropriate registration certificate. Provider performed microscopy tests include--

- (1) Wet mounts.
- (2) Potassium hydroxide (KOH).
- (3) Fern tests.
- (4) Pinworm examination.
- (5) Urine sediment examinations.
- (6) Post-coital direct examinations of cervical and vaginal mucous.
- (7) Nasal smears for granulocytes.
- (8) Fecal leukocyte examinations.
- (9) Qualitative semen analysis (limited to the presence or absence of sperm and detection of motility).

b. Policy. Sites that perform one or more of the tests listed in paragraph *a* must comply with the following standards:

(1) Each laboratory performing tests of moderate (including the subcategory - provider performed microscopy) must successfully participate in a proficiency testing program through CAP or other recognized external proficiency testing survey.

(2) If a procedure does not have an approved proficiency test available, the site must perform semiannual validations of method.

3-2. Minimally complex tests

Laboratories performing only minimally complex testing have requirements that vary somewhat from the above.

a. *Minimally complex tests.* As defined by CLIP, only the following are considered to be

minimally complex tests:

- (1) Dipstick or tablet urinalysis (non-automated) for the following analyses:
 - (a) Bilirubin.
 - (b) Glucose.
 - (c) Hemoglobin.
 - (d) Ketone.
 - (e) Leucocyte esterase.
 - (f) Nitrite.
 - (g) pH.
 - (h) Specific gravity.
 - (i) Urobilinogen.
 - (j) Protein.
 - (2) Fecal occult blood.
 - (3) Ovulation tests - visual color comparison tests for luteinizing hormone.
 - (4) Urine pregnancy test - visual color comparison tests.
 - (5) Erythrocyte sedimentation rate - nonautomated.
 - (6) Hemoglobin - copper sulfate - nonautomated or single analyte instrument.
 - (7) Blood glucose by monitoring devices cleared specifically by the Federal Drug Administration for home use.
 - (8) Spun hematocrit.
 - (9) Chemtrac single analyte cholesterol acoumeter.
 - (10) Serum Pyloritek Test Kit for H. pylori.
 - (11) Quidel Quick Vue In-Line One-Step Strep A Test.
 - (12) Cholestech LDX System (total cholesterol, HDL, triglyceride and glucose).
- b. *Policy.* Point-of-Care testing laboratories that perform one or more of the tests listed in paragraph *a* must comply with the following standards:
- (1) Waived testing results (that is, minimal complexity testing results) will be used for screening purposes only.
 - (2) An on-site laboratory director and those authorized to perform testing will be designated in writing.
 - (3) Individuals performing tests will have adequate and specific training and documented orientation. Individual competency assessment will be documented at specified intervals.
 - (4) Each test performed will have an SOP that addresses each of the following elements when applicable:
 - (a) Specimen collection.
 - (b) Specimen preservation.
 - (c) Instrument calibration.
 - (d) Quality control and remedial action.
 - (e) Equipment performance and evaluation.
 - (f) Test performance.
 - (5) Quality control checks will be conducted on each procedure as specified in the SOP. At a minimum, manufacturers' instructions will be followed, appropriate quality control and test records will be maintained for at least two years, and administrative paperwork will be submitted as necessary to maintain accreditation and registration.

3-3. POCTL oversight

a. The Chief, LS has oversight responsibility for all clinical laboratory testing performed with KACC. The chief will—

(1) Inspect each POCTL and provide a report with recommendations to the appropriate department chief and the Performance Improvement Coordinator at least once each calendar quarter.

(2) Provide each POCTL an inspection checklist appropriate for the type(s) and volume of testing performed.

(3) Appoint inspectors appropriate for the type of testing performed. Inspectors may be pathologists, laboratory officers, military medical laboratory technicians (in military occupational specialty 91K and in the grade of staff sergeant or higher), and civilian medical technologists.

(4) Maintain records of inspection, recommendations and reports of corrective action.

b. The chief of each clinic having a POCTL will—

(1) Maintain an inspection binder or notebook containing the following:

(a) The CLIP certificate.

(b) The current issue of this memorandum.

(c) A separate SOP for each test performed.

(d) The name of the on-site POCTL director (the department chief) and list of authorized testing personnel.

(e) In-service training records.

(f) The most recent inspection report from LS.

(g) The current month's quality control records.

(h) Results of CAP proficiency test results for the current year. (This requirement applies only to sites performing moderate and/or high complexity testing.)

(i) Patient log sheet.

(2) Within 30 working days of receipt of an inspection report, provide documentation to Chief, LS to correct any deficiencies.

(3) Report any change in personnel or testing methodology to the Chief, LS that may require an amendment of the POCTL's CLIP certificate as soon as the change occurs. Submit this information in the form of a request to amend the held certificate.

3-4. The POCRG

a. Composition.

(1) The KACC Point-of-Care Site Director (the Chief, LS) (Chairperson)

(2) The on-site laboratory director (the department chief) for each POCTL. (Member)

b. The POCRG will identify issues of concern and forward them through the Laboratory Performance Improvement Meeting to the MEDDAC Performance Improvement and Utilization Management Committee as needed.

c. The POCRG will meet at least quarterly at the direction of the chairperson. Minutes will be kept and attached to the minutes of the KACC Laboratory Performance Improvement Meeting.

Appendix A References

Section I Required Publications

This section contains no entries.

Section II Related Publications

A related publication is merely a source of additional information. The user does not have to read it in order to understand this publication.

AFIP Pam 40-24

Department of Defense Clinical Laboratory Improvement Program (DoD CLIP)

AR 40-24

Medical Laboratory Activities

College of American Pathologists (CAP)
Laboratory Accreditation Program

Joint Commission on Accreditation of Health Care Organizations (JCAHO) Accreditation Manual for Pathology and Clinical Laboratory Services

Public Law 100-578, Clinical Laboratory Improvement Amendment (CLIA) of 1988 and Code of Federal Regulations (CFR) 42

Section III Prescribed Forms

This section contains no entries.

Section IV Referenced Forms

This section contains no entries.

Glossary

Section I

Abbreviations

CAP

College of American Pathologists

CFR

Code of Federal Regulations

CLIA

Clinical Laboratory Improvement Amendment

CLIA 88

Public Law 100-578, Clinical Laboratory Improvement Amendment (CLIA) of 1988

CLIP

Clinical Laboratory Improvement Program

CLIPO

Clinical Laboratory Improvement Program Office

DCCS

Deputy Commander for Clinical Services

JCAHO

Joint Commission on Accreditation of Healthcare Organizations

KACC

Kimbrough Ambulatory Care Center

LS

Laboratory Service

MEDDAC

U.S. Army Medical Department Activity, Fort George G. Meade

POCTL

point-of-care testing laboratory

POCRG

Point-of-Care Review Group

POCT

point-of-care testing

SOP

standing operating procedure

Section II Terms

Analyte

A substance or constituent for which the laboratory conducts testing.

Categories of tests by complexity

Laboratory tests are categorized as minimally, moderately or highly complex. Testing systems are evaluated by the Centers for Disease Control and Prevention and the determination of the complexity of each test system is published in the Federal Register. Each level of complexity has differing requirements for the training and experience of supervisory and testing personnel. A test system

that is not classified by complexity listed in the Federal Register is considered to be highly complex. An additional category term, provider performed microscopy, is explained below.

Clinical Laboratory Improvement Program (CLIP)

A Department of Defense (DoD) program established to comply with the provisions of CLIA 88 as a result of a memorandum of agreement between the DoD and the Department of Health and Human Services. The CLIPO is the office established by DoD at the Armed Forces Institute of Pathology to administer the CLIP.

Competency testing

Evaluating a person's ability to perform a test and to use a testing device. This includes all aspects of testing, from specimen collection to result reporting.

Department

Clinical departments and services whose chiefs are directly subordinate to the DCCS.

Laboratory

A facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological or

other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention or treatment of any disease or impairment of or the assessment of the health of human beings. These examinations also include procedures to determine, measure or otherwise describe the presence or absence of various substances or organisms in the body. Facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.

Minimally complex tests

A term used in CLIP that is synonymous with waived testing.

On-site laboratory director

The individual who provides overall management and direction for the POCTL. The director is responsible for ensuring that testing personnel are competent to perform test procedures, test results are reported accurately, promptly, proficiently, and assuring

compliance with all applicable regulation. Department chiefs will be on-site laboratory directors for all POCTLs within their departments.

Point-of-care testing (POCT)

Testing performed outside a central laboratory environment, generally nearer to or at the site of the patient.

Provider performed microscopy

Microscopic examination performed by medical and dental health care providers as a part of their professional examination. Such testing is performed with the use of a microscope and during the patient's visit.

Quality control

The set of procedures designed to monitor the test method and the results to assure test system performance. Quality control includes testing control materials, charting the results and analyzing them to identify sources of error, and evaluating any remedial action taken as a result of this analysis.

Special function laboratories

A JCAHO term for medical treatment facility laboratories not under the supervision of the main laboratory director where in vitro laboratory procedures are performed, the results of which become a part of the medical record. The services are performed within a designated unit, the results are used for patient diagnosis and care and the laboratory employs one or more full or part-time personnel who primarily perform analytical procedures.

Waived testing

A term used by the U.S. Department of Health and Human Services as a part of the complexity model to describe those test systems that are simple laboratory examinations and procedures which are cleared by the Food and Drug Administration for home use, employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible or pose minimal risk of harm to the patient if the test is performed incorrectly.