BY ORDER OF THE COMMANDER
59TH MEDICAL WING

59TH MEDICAL WING INSTRUCTION
44-103

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Medical

QUALITY ASSESSMENT FOR POINT OF CARE TESTING

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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(Colonel Marie P. Colasanti)

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This instruction implements Air Force Policy Directive 44-1, *Medical Operations.* This instruction applies to any clinical service, or outpatient, involved with procedures pertinent to the Point of Care Testing (POCT) program. This instruction establishes policies and procedures to ensure POCT is performed with the same high standards as tests performed within the 59 MDTS Laboratory Flight's (59 MDTS Laboratory Flight) main laboratory. These policies and procedures provide a means to ensure that POCT results accurately reflect the patient's state of health. Patient health information must be handled in accordance with AFI 41-210, *TRICARE Operations and Patient Administration Functions*. This instruction applies to all personnel assigned or on contract to the 59th Medical Wing (MDW). This instruction does not apply to the Air National Guard or Air Force Reserve. **Note:** This publication requires the collection and maintenance of information protected by the Privacy Act of 1974. Privacy Act System Notices F044 AF SG D, *Automated Medical/Dental Record System* and F044 AF SG E, *Medical Record System,* apply. Collected information is "For Official Use Only." Request to release Privacy Act information to persons or agencies outside the DoD must be IAW AFI 33-332, *Air Force Privacy Act Program*, DoD 5400.7 *Freedom of Information Act and Health Insurance Portability and Accountability Act* (HIPAA) of 1996 Pub. L. 104-191. Refer recommended changes and questions about this publication to the Office of Primary Responsibility using the AF Form 847, *Recommendation for Change of Publication*. Ensure that all records created as a result of processes prescribed in this publication are maintained in accordance with (IAW) Air Force Manual (AFMAN) 33-363, *Management of Records*, and disposed of IAW Air Force Records Information Management System (AFRIMS) Records Disposition Schedule (RDS).The use of

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SUMMARY OF CHANGES

This publication has been revised. This rewrite of 59 MDWI 44-103 includes: updated tests authorized in the 59 MDW; updated tests authorized as Privileged Provider Performed Testing; removed nitrazine swabs, removed waived Prothrombin Time/International Normalized Ratio (PT/INR); added Roche PCR (polymerase chain reaction) LIAT (Laboratory In A Tube) for Flu A/B and Strep A ; updated minimum requirement for individuals who are trained to perform POCT; added The Joint Commission references; updated 59 MDTS/SGSLP instruction references; removed and added Rapid Sofia Strep and Flu (GBC only); removed Roche Performa personal meter from test menu; removed references to automated Clinitek 50 urine dipsticks instrumentation; changed 59 LSQ to 59 MDTS Laboratory Flight and changed squadron symbology from SGVLL and SGVLS.

1. Responsibilities.

1.1. In consultation with the Chief of the Medical Staff, the Chief Nurse Executive, and the 59 MDTS Laboratory Flight Chief, Support Services, the 59 MDTS's Laboratory Flight Medical Director will:

1.1.1. Specify tests authorized to be performed in the facility.

1.1.1.1. Tests that are authorized: waived whole blood glucose, waived semi-automated urine dipsticks, waived Rapid Strep and Flu (GBC Only), PCR waived Strep A and Flu A/B.

1.1.1.2. Tests performed as Privileged Provider Performed Testing: vaginal wet prep by potassium hydroxide (KOH), ferning, vaginal wet prep, KOH skin/nail scrapings and scabies.

1.1.2. Ensure a viable process exists to implement and maintain a quality program for each test performed.

1.2. The 59 MDTS Laboratory Flight Commander will appoint a POCT Program Coordinator.

1.3. The POCT Program Coordinator will:

1.3.1. Provide a POCT current procedure manual at current registered POCT site(s).

1.3.2. Provide initial training to Nurse Managers, Program Managers and alternate Program Managers of designated POCT sites.

1.3.3. Provide consultation for developing appropriate quality control (QC) procedures.

1.3.4. Inspect 59 MDW POCT sites quarterly and provide a written report of the findings to the Laboratory Quality Improvement Committee and the POCT site's program manager, main laboratory Flight Commander, and clinical laboratory Medical Director.

1.3.5. At least once per month review all Quality Control logs and proficiency testing records.

1.3.6. Provide a yearly summary report to the Laboratory Quality Improvement Committee.

1.3.7. Retain all Quality Control forms and records for two years in accordance with Air Force Records Disposition Schedule. These will be centrally filed, in 59 MDTS Laboratory Flight/SGSLP POCT QA/QI office in order to comply with College of American Pathologists requirements.

1.4. Squadron Commanders, Flight Commanders, Department Chairpersons, Group Senior Nurse Executives, and Risk Management as needed will:

1.4.1. Ensure only whole blood glucose, semi-automated urinalysis, the Clinitek Status; the Rapid Strep A and Flu A/B (GBC only) waived tests and the PCR Strep A or Flu A/B and tests formally authorized by the 59 MDTS Laboratory Flight's Medical Director are performed.

1.4.2. Ensure equipment, reagent quality control are performed and within manufacturer's required ranges and documented prior to testing any patient samples. Any deviation or change in operating instructions can only be directed from the Point of Care Testing office by official memo for record and updated operating instructions signed by the 59 MDTS/SGVLS POCT Medical Director. This cannot be accomplished verbally. To validate changes in procedures, verify with 59 MDTS Laboratory Flight Point of Care Testing office.

1.4.3. Ensure appropriate supervisory review is accomplished and documented.

1.4.4. Identify by letter to 59 MDTS/SGSLP, a Nurse Manager, and a Program Manager as the individuals accountable for ensuring compliance with all requirements of the 59 MDW POCT program.

1.4.5. Identify by letter to 59 MDTS/SGSLP a Medical Director for a Clinic's POCT site when requested by 59 MDTS/SGSLP.

1.5. Nurse Managers or designee and Program Managers will:

1.5.1. Identify by letter to 59 MDTS/SGSLP all personnel authorized to perform testing, their operator identification numbers, and colorblind status. Colorblind personnel are not authorized to perform any manual visual color changing laboratory test.

1.5.2. Serve for a period of at least six months in order to ensure continuity within the POCT program.

1.5.3. Seek guidance and initial training from 59 MDTS Laboratory Flight POCT office.

1.5.4. During the first year of an individual's duties, competency must be assessed at least semiannually. After an individual has performed his/her duties for one year, competency must be assessed annually

1.5.5. Document the training of all personnel who perform POCT on the units or outpatient clinics. Training and competency records are to be kept in the individual's two-part Competency Assessment folder or for military personnel in their electronic Career Field Education and Training Plan.

1.5.6. Forward a copy of all competency verification forms/tests to 59 MDTS Laboratory Flight POCT office for accreditation compliance files.

1.5.7. Review quality control forms at least weekly for completeness, compliance with standards, discrepancies, and documentation of corrective action. Maintain documentation of same.

1.5.8. Forward all QC documentation to 59 MDTS Laboratory Flight SGSLP at least monthly.

1.5.9. Maintain a readily available POCT program notebook at the POCT site. This notebook must contain the following current information:

1.5.9.1. A current list of individuals who are trained to perform POCT in their clinic. This list must include, at a minimum: individual's last name, first name; unique operator identification number and tests authorized to perform. **Note**: All individuals performing tests that require color comparison must be documented as having normal color vision and visual acuity by performing colorblind test in the main laboratory.

1.5.9.2. A list of all tests performed by the POCT site.

1.5.9.3. All current in-use quality control, corrective action, and maintenance log sheets.

1.5.9.4. POCT operating instruction binder for all POCT procedures performed in the POCT site, including safety and infection control guidelines. (See list of required Instructions, Attachment 2.)

1.5.9.5. Letter from 59 MDTS/SGSLP authorizing the POCT site and identifying all tests authorized for use at this site.

1.5.10. Notify the POCT Coordinator in writing, of those personnel who have left their POCT work area. This will allow the POCT Coordinator to delete members' names from laboratory's Hospital Central Data System.

1.5.11. Comply with accreditation requirements for POCT from College of American Pathologists and The Joint Commission.

1.6. Medical Directors are ultimately responsible for the overall program at their POCT site.

2. Requirements of all Personnel Performing POCT.

2.1. Be restricted to only those tests in which they have been trained, certified, and which are identified as being authorized for that work unit.

2.2. Store all reagents according to the labeling requirements or as prescribed by current Instruction. On all reagents and strips, the date "in-use", the expiration date, and the user's initials must be listed. Do not use expired reagents.

2.3. Document appropriate control log sheets in accordance with this instruction and the POCT procedure manual.

2.4. Comply with accreditation requirements for POCT from College of American Pathologists and The Joint Commission.

3. POCT Patient Results. Record POCT results on out-patients as part of the nursing functions on the patient's chart using Standard Form 558, *Medical Record-Emergency Care and Treatment*, or Standard Form 600, *Health Record-Chronological Record of Medical Care*. The date and the name of the individual who performed the test will be documented as well. This identifies the results as being performed at the POCT site.

3.1. POCT results within the 59 MDW are approved for use as a screen, or in monitoring procedures upon which clinical decisions may be made, when results are consistent with clinical/surgical expectations. When results are inconsistent with these expectations, additional confirmatory tests must be performed. The whole blood glucose procedure may be used to diagnose hypoglycemia and to guide therapy in emergent and urgent situations, but the procedure may not be used to definitively diagnose diabetes. All POCT results are recorded in a manner that identifies them as being performed at the POCT site.

4. Creation of New Point of Care Testing Sites. The creation of new Point of Care Testing sites within Wilford Hall Ambulatory and Surgical Center requires cooperation between a clinical service and an existing clinical laboratory. The clinical service contributes the financial and personnel resources needed to perform the test, while the laboratory provides a medical director, expertise on regulatory standards, and a license to perform testing granted by an approved accrediting agency.

4.1. To facilitate the creation of Point of Care sites, a committee has been established to coordinate and approve proposals. The committee is composed of the Medical Director of the Laboratory, the Laboratory's Flight Chief, Support Services, Chief of the Medical Staff, and the Logistics Squadron Commander. The committee will meet on an ad hoc basis to consider requests for new Point of Care Testing sites within the Wing.

4.2. The committee will formally review all proposals and suggest for consideration possible alternatives with the intent of standardizing test methods within the facility and minimizing costs. The laboratory will design a quality assurance program for the proposed site and determine the extent of laboratory support needed to ensure compliance with regulatory standards. After a final review, the committee will approve or reject the proposal. Committee approval is required before a Point of Care Testing site can be established.

5. Privileged Provider Performed Testing. Patient management facilitated by immediate and direct privileged provider performance of some simple laboratory test at the time of a patient encounter, must be maintained through standards to ensure the correctness of a test result. Any clinic or ward within 59 MDW that provides testing, personally performed by a privileged provider must be registered with the Center for Clinical Laboratory Management to obtain required licensing. It will also be inspected for accreditation by the College of American Pathologists biennially. The 59 MDTS Laboratory Flight Point of Care Testing office provides this service along with the listing of what tests are affected, pertinent operating instructions, educational proficiency tests and preventive maintenance logs.

5.1. For Privileged Provider Performed Testing, the Department Chairs/Service Chiefs will be responsible for identifying which waived or privileged provider performed tests will be performed in their work areas. Based on those decisions, all privileged providers will need to be trained or recertified yearly on the tests identified. Training will be done in SWANK. Department Chairs/Service Chiefs will maintain documentation of training in the privileged

provider's Provider Activity Files, not in the notebook in the clinic. Flight Commanders are not involved in the process for privileged providers unless dual-hatted as the service chief.

5.2. Privileged Provider performed tests which require competency assessment include: vaginal pool fluid smears for ferning, KOH preparations, and vaginal wet mount. Additionally, each service will be responsible to perform education testing of unknown samples or electronically viewed images with patient histories twice per year.

5.3. Privileged provider performed testing results should consist of the following components in the patient file: Patient identifier, test ordered/performed and privileged provider name/identifier, date/time of specimen collection, test result and reference interval or interpretive notes, as appropriate.

6. Patient Safety. Patient safety is the responsibility of all medical healthcare workers and patients alike. The purpose of these goals is to ensure organizations address specific areas of concern in regards to patient safety.

6.1. Outpatient Identification. Prior to any procedure, i.e. administering fluids for glucose tolerance testing, or drawing a patient's blood, the following patient information process will occur.

6.2. Verify the patient is the correct patient for whom the treatment is intended for by comparing the patient's name and date of birth. Civilian patient verification is accomplished by comparing the patient's full name and date of birth.

6.3. Read Back of Telephone Orders and verbal laboratory results. Once personnel have taken a verbal telephone order or given a verbal laboratory result, the order or verbal result must be written on a requisition form or consult sheet and/or typed into Composite Health Care System (for verbal telephone orders). Personnel receiving the verbal telephone order or laboratory result will then read back the order to the personnel giving the verbal telephone order or supplying the laboratory result. Once the correct order has been received or laboratory result given, the receiving personnel will annotate "RB" next to the order and annotate their name, in the computer or on the consult sheet etc, to signify the read back process was completed. Compliance with this process will be measured through medical records checks.

6.4. Improve the effectiveness of Alarm Systems in the laboratory: Regular preventive maintenance and monitoring alarms systems containing laboratory products, i.e., blood, reagents, etc. will be accomplished to ensure the alarms function properly and are audible. Various alarms in and outside the laboratory are for temperature controls of blood products, reagents, and temperature sensitive equipment. These tasks will be performed according to manufacturer's recommendations, applicable accrediting organizations, and current approved Instructions.

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Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

AFI 41-210, *TRICARE Operations and Patient Administration Functions*, 6 June 2012

AFPD 44-1, *Medical Operations*, 9 June 2016

AFI 44-102, *Medical Care Management,* 17 March 2015

AFI 44-119, *Medical Quality Operations,* 16 August 2011

Adopted Forms

AF Form 847, *Recommendation for Change of Publication*

SF 558, *Medical Record-Emergency Care and Treatment*

SF 600, *Health Record-Chronological Record of Medical Care*

Abbreviations and Acronyms

IAW—In Accordance With

KOH—Potassium hydroxide

MDW—Medical Wing

PCR—Polymerase Chain Reaction

POCT—Point of Care Testing

PT/INR—Prothrombin Time/International Normalized Ratio

QC—Quality Control

Attachment 2

POINT OF CARE TESTING PROGRAM REQUIRED DOCUMENTS

All Test Sites

59MDWI 44-103	*Quality Assessment for Point of Care Testing*
59 MDTS/SGSLP 44PC-.04	*QA Procedures for the Point of Care Testing Program*
59 MDTS/SGSLP 44PC-.01	*General Safety and Infection Control Policies*
	List of Operators with ID number and colorblind status
59 MDTS/ SGSLP 44PC-.02	*QC/QM for Professional Services*

Accu-Chek Inform/Advantage Glucose Sites

59 MDTS/ SGSLP 44PC-.06	*Accu-Chek Inform II Blood Glucose Determinations*

Urine Dipstick

59 MDTS/SGSLP 44PC-.10	*Urinalysis Clinitek Status*
	Urinalysis Clinitek Status Daily Control Log

Physician performed Microscopy (PPM)

59 MDTS/SGSLP 44PC-.15	*Wet Prep and KOH*
59 MDTS/SGSLP 44PC-.16	*Fern Test*

RAPID TESTS

59 MDTS/SGSLP 44PC-.11	*Sofia Flu*
59 MDTS/SGSLP 44PC-.12	*Sofia Strep A*

PCR tests

59 MDTS/SGSLP 44PC-.20	*LIAT PCR Flu/A/B*
59 MDTS/SGSLP 44PC-.21	*LIAT PCR Strep A*