

**BY ORDER OF THE COMMANDER
59TH MEDICAL WING**

**59TH MEDICAL WING INSTRUCTION
44-103**



24 MARCH 2016

Medical

**QUALITY ASSESSMENT FOR
POINT OF CARE TESTING**

COMPLIANCE WITH THIS PUBLICATION IS MANDATORY

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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 POCT instruction applies to all personnel assigned or on contract to the 59th Medical Wing (MDW) and 559 Medical Group (MDG). The 359 MDG and 959 MDG do not currently have any Point of Care Testing activities. This instruction does not apply to the Air National Guard or Air Force Reserve.

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SUMMARY OF CHANGES

This publication has been revised. This rewrite of 59 MDWI 44-103 includes: Added 359 MDG and 959 not performing POCT; added 559 MDG as performing POCT; updated tests authorized in the 59 MDW and 559 MDG; updated tests authorized as Physician Performed Testing; removed fecal occult blood; added Roche Inform II whole blood glucose testing meter; updated minimum requirement for individuals who are trained to perform POCT; removed Joint Commission references; updated 59 LSQ Operating Instructions (OI) references; added waived tests urine hCG and Rapid Strep and Flu; removed references to automated Clinitek 50 urine dipsticks instrumentation; changed 59 LSQ to 59 MDTS Laboratory Flight, changed office symbology from SGVLL to SGSLP

1. Responsibilities.

1.1. In consultation with the 59 MDW Chief of the Medical Staff, the 59 MDW Chief Nurse, 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, automated urine dipsticks, Prothrombin Time/International Normalized Ratio (PT/INR), urine hCG and Rapid Strep and Flu.

1.1.1.2. Tests performed as Provider Performed Testing: wet prep by potassium hydroxide (KOH), ferning, vaginal wet prep, and nitrazine swabs.

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 Senior Nurse, 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, flight commander, and 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 in order to comply with College of American Pathologists requirements.

1.4. Squadron Commanders, Flight Commanders, Department Chairpersons, Group Chief Nurses, and Risk Management as needed will:

1.4.1. Ensure only whole blood glucose, automated urinalysis using the Clinitek Status; PT/INR, urine hCG, Rapid Strep and flu waived tests formally authorized by the 59 MDTS Laboratory Flight's Medical Director are performed.

1.4.2. Ensure equipment and reagent quality control are performed and documented per approved operating instructions. 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 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 SGSLP, a Senior Nurse, and a Program Manager as the individuals accountable for ensuring compliance with all requirements of the POCT program.

1.4.5. Identify by letter to SGSLP a Medical Director for a POCT site when requested by SGSLP.

1.5. Senior Nurse or designee and Program Managers will:

1.5.1. Identify by letter to 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 SGSLP.

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 in the individual's Competency Assessment Folder or Career Field Education and Training Plan.

1.5.6. Forward a copy of all competency verification forms/tests to 59 MDTS Laboratory Flight SGSLP 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 list of individuals who are trained to perform POCT. 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.
 - 1.5.9.2. A list of all tests performed by the POCT site.
 - 1.5.9.3. All in-use quality control, corrective action, and maintenance log sheets.
 - 1.5.9.4. Procedure manual for all procedures performed in the POCT site, including safety and infection control guidelines. (See list of required OI's, Attachment 2.)
 - 1.5.9.5. Letter from 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 site. This will allow the POCT Coordinator to delete members' names from laboratory's Remote Automated Laboratory's Central Data System.
- 1.5.11. Comply with accreditation requirements for POCT from required accrediting agencies.
- 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 OI. On all reagent strip vials identify the "open date" along with user initials. A new expiration date must be recorded if opening the container changes the expiration date, storage requirement, etc., along with the initials of the user. 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 Accreditation Association for Ambulatory Health Care.

3. POCT Patient Results. Record POCT results on patients as part of the nursing functions in either ALHTA or Essentris. This will ensure testing documentation will be placed in the patient electronic health record along with any scanned POCT instrumentation documents. 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, 959 MDG and 559 MDG 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 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 Chief, Support Services, Chief of the Medical Staff, Logistics Squadron Commander and Chief Nurse. 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. Physician Performed Testing. Patient management facilitated by immediate and direct physician 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 within 59 MDW, 959 MDG, and 559 MDG that provides testing, individually performed by a physician in conjunction with the physical examination or treatment of a patient, must be registered with the Center for Laboratory Medicine Services and inspected for accreditation by the College of American Pathologists. 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 provider performed testing, the Department Chairs/Medical Directors will be responsible for identifying which waived or Physician Performed tests will be performed in their areas. Based on those decisions, all 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 Provider Activity Files, not in the notebook in the clinic. Flight commanders are not involved in the process for providers unless dual-hatted as the service chief.

5.2. Provider performed tests which require competency assessment include: amniotic fluid pH, vaginal pool fluid smears for ferning, fecal leukocytes, gastric biopsy urease, fecal and gastric occult blood, pinworm examination, post-coital mucus examination, potassium hydroxide preparations, semen analysis (qualitative), urine dipstick, urine sediment microscopy and vaginal wet mount. Additionally, each service will be responsible to perform education testing of unknown samples or electronically viewed kodachromes with patient histories twice per year.

5.3. Physician Performed Testing results should consist of the following components in the patient file: Patient identifier, test ordered/performed and physician 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 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.

6.1.1. Verify the patient is the correct patient for whom the treatment is intended for by comparing the patient's name and date of birth before taking any samples.

6.2. 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 AHLTA or Essentris (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.

6.3. 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 OIs.

NICOLA A. CHOATE, Colonel, MC
Chief of the Medical Staff

Attachment 1

GLOSSARY OF REFERENCES AND SUPPORTING INFORMATION

References

AFI 33-332, *Air Force Privacy Act and Civil Liberties Program*, 12 January 2015

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

AFPD 44-1, *Medical Operations*, 1 September 1999

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*

Abbreviations and Acronyms

IAW—In Accordance With

MDG—Medical Group

MDW—Medical Wing

OI—Operating Instruction

POCT—Point of Care Testing

PT/INR—Prothrombin Time/International Normalized Ratio

QC—Quality Control

Attachment 2

POINT OF CARE TESTING PROGRAM REQUIRED DOCUMENTS

Figure A2.1. Point of Care Testing Program Required Documents.

All Test Sites59 MDWI 44-103 *Quality Assessment for Point of Care Testing*59 MDTS/SGSLP 44Q-101 *QA Procedures for the Point of Care Testing Program*59 MDTS/SGSLP 44Q-102 *General Safety and Infection Control Policies*

List of Operators with ID number and colorblind status

59 MDTS/SGSLP 44Q-103 *QC/QM for Professional Services***Accu-Chek InformII/Performa Glucose Sites**59 MDTS/SGSLP 44Q-001 *Accu-Chek Inform II Blood Glucose Determinations*59 MDTS/SGSLP 44Q-003 *Whole Blood Glucose Determinations Using the Accu-Chek Performa Patient Monitor***Roche CoaguChek XS Plusmeter PT/INR**59 MDTS/SGSLP 44Q-30 *Roche CoaguChek XS Plusmeter for PT/INR***Urine Dipstick**59 MDTS/SGSLP 44Q-023 *Urinalysis Clinitek Status**Urinalysis Clinitek Status Daily Control Log***Physician performed Microscopy (PPM)**59 MDTS/SGSLP 44Q-025 *Wet Prep by KOH*59 MDTS/SGSLP 44Q-055 *Fern Test*59 MDTS/SGSLP 44Q-063 *Vaginal Wet Prep*59 MDTS/SGSLP 44Q-68 *Nitrazine Swabs (Amnio Test™)***Rapid Waived Tests**59 MDTS/SGSLP 44Q-100 *Sofia Rapid Strep*59 MDTS/SGSLP 44Q-101 *Sofia Rapid Flu*