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POC 5 113 COAGUCHEK XS PLUS PTINR POC TESTING

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Alert INR value

Inserted Alert INR Non-life threatening value in section 11. Change punctuation. concur Reviewed by A. Hankerson

Comments for version 4.2 (this revision)

review for upload to med training poc users reviewed Concurl Concurr revised for quality control //kabqc revision qc Reviewed by A. Hankerson

Approval and Periodic Review Signatures

Type	Description	Date	Version	Performed By	Notes
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Version History

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COAGUCHEK XS PLUS PT/INR POC TESTING

POC 5 113

Memphis VA Medical Center
Memphis, TN 38104

Service Line(s):
Pathology and Laboratory Medicine
Service- Ancillary Testing Department

Signatory Authority:
Chief, Pathology and Laboratory
Medicine Service

Effective Date:
February 8, 2021

Responsible Owner:
Kimberly Ballard, MHA, MLS (ASCP)
Ancillary Testing Coordinator

Recertification Date:
February 28, 2026

1. PURPOSE AND AUTHORITY

- a. The purpose of this standard operating procedure (SOP) contains the policies and procedure to be followed when performing PT/INR tests with the CoaguChek XS Plus point of care instrument. The CoaguChek XS Plus System measures blood-clotting time (prothrombin time) for people who are taking anticoagulation medications, such as Coumadin or Warfarin. This SOP must be followed by users who utilized the Coagu-Chek XS Plus instrument.
- b. The prothrombin time is used to monitor warfarin and Coumadin therapy because of its sensitivity to variations in the concentration of the Vitamin-K dependent factors II, VII, and X. Because of the variations in the prothrombin time results, different thromboplastins and instruments, it is recommended that the prothrombin results be converted to an INR. The INR corresponds to the value of the ratio of the patient's PT and the geometric mean PT of the normal reference population raised to the ISI (International Sensitivity Index) power.
- c. The ISI value of a given thromboplastin is determined by performing PT's on normal plasmas and coumadin-treated patient plasmas with the given thromboplastin and the WHO reference thromboplastin. The slope of this regression curve of the matched pairs is the ISI for the thromboplastin. The ISI of the WHO reference thromboplastin is 1.0.
- d. A low INR can increase risk of blood clots, while a high INR can increase risk for internal bleeding. The patient's physician will determine the best INR range for that patient, depending on why the patient is taking anticoagulants and the patient reacts to them.
- e. The CoaguChek XS Plus coagulation system will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. It allows convenient handling and precise measurement within 1 minute, using a single drop (10 µL) of blood from the fingertip. The CoaguChek XS Plus System uses fresh whole blood to provide PT



results in % Quick Seconds or INR (International Normalized Ratio). Because the test is performed at the patient’s side on fresh whole blood, the result is not affected by collection, container, or temperature conditions during transportation of the specimen.

- f. This SOP sets forth mandatory procedures and processes to ensure compliance with VA/VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, Joint Commission, the Food and Drug Administration (FDA), and College of American Pathology.

2. ASSIGNMENT OF RESPONSIBILITIES

- a. **Laboratory Director.** Has the overall responsibility for ensuring that the provisions of this SOP are followed by all personnel involved in the use of the CoaguChek instruments in the Memphis VA Medical Center’s Community Based Outpatient Clinics (CBOC).
- b. **Ancillary Testing Coordinator.** Responsible for all quality management and technical oversight functions regarding the instrument, as described in detail in Memphis VAMC Ancillary Testing POC 14 113. These responsibilities also include initial setup and validation of the instruments.
- c. **Ancillary Testing Program Specialist.** Will provide technical assistance to testing personnel as needed, perform all required proficiency testing, provide feedback to testing personnel on any specimen quality issues as well as any issues regarding unclear test orders, and assist the Ancillary Testing Coordinator in the performance of his/her duties.
- d. **Testing Personnel.** Will be responsible for the proper performance and documentation of all procedures as described in the “Procedures” of this Standard Operating Procedure (SOP). Testing personnel includes Licensed Practical Nurses (LPN), Registered Nurses (RN), Respiratory Therapists, and Medical Technologists assigned to locations that perform ancillary testing.

3. DEFINITIONS

NONE

4. SPECIMEN INFORMATION

- a. Fingertstick blood sample is the preferred primary acceptable sample type.

5. SPECIAL SAFETY PRECAUTIONS

- a. CoaguChek PT test strips. These may be stored at room temperature provided that room temperature is monitored and its daily maximum is recorded on a worksheet. They may also be stored at 4 to 8°C in a similarly monitored refrigerator. Each container of test strips contains a “code chip” which stores



essential information about the test strips. The code chip must be inserted into a slot in the instrument at the start of testing. The test strip container is labeled with a 3-character identifying number; the code chip is labeled with the same number preceded by an "S".

(1) Staff under nursing supervision must record, on a log sheet, on each working day, the maximum and minimum temperatures of the storage locations over the previous 24 hours (or longer for weekends/holidays) as shown on the electronic monitor display.

(2) This log sheet must be reviewed and initiated by the nursing supervisor monthly.

b. If the measured temperatures fall outside of the acceptable range on the log sheet, nursing staff must:

(1) Record the out-of-range temperature(s)

(2) Quarantine the strips

(3) Notify the ATC immediately

(4) NOT use the strips

6. EQUIPMENT/FORMS

a. CoaguChek XS PT/PLUS meter- Fully charged and coded to the test strip lot you intent to use.

b. RALS Data management System

c. Base/Downloader (including all ethernet cables and power cords)

7. REAGENTS

a. CoaguCheck PT Test strip vial

b. Single-use, disposable lancets

c. Alcohol swab

d. Cotton Ball, tissue or gauze for wiping finger after alcohol and after stick

e. Personal Protection equipment as required by infection control and isolation policies and procedures

f. Disposable transfer pipette or syringe as needed if testing a venous, arterial or line draw sample

g. Biohazard sharps container



h. Control reagents (if required)

8. QUALITY CONTROL

- a. Performed on new lot of control reagent or test strips.
- b. Regularly performed during the first full week of each month unless otherwise communicated in ancillary testing area under direct observation of coordinator or specialist except at CBOCs.
- c. Quality controls are indicated by either “PASS” or “FAIL”. Instruments where quality controls have “PASSED” are satisfactory for patient use.
- d. Instruments where quality controls have “FAILED” should be repeated using a new test strip/ cartridge and control solutions. Failed results could be an indicator of sampling air bubbles, expired reagents/ supplies, or underfilling test strips/ cartridges.
- e. Cease patient testing if failed quality controls persist by the third trial. Contact ATC for further troubleshooting instructions, to gain a replacement meter, or other testing supplies.
- f. If ATC is unavailable, cease patient testing, remove meter from service (attach a ‘Do Not Use’ label or give to charge nurse on duty to arrange return to ATC) collect appropriate patient sample for analysis by the main lab.
- g.
- h. Failed/ unacceptable quality controls should be repeated using new test strips and/ or control solution.
- i. Notify Ancillary Testing of unacceptable quality control results which will prohibit the meter from further use. A replacement meter may be issued until further troubleshooting actions are successful.

9. EQUIPMENT CALIBRATION AND MAINTENANCE

- a. Calibration/correlation is performed semi-annually using combination of quality control and proficiency sample results.
- b. There is not an available calibration reagent therefore correlation studies are done.
- c. Historical data is permitted while reviewing semi-annual meter checks.
- d. Maintenance includes daily cleaning, recharging on downloader, replacing batteries, and notating under the quality control menu that “Monitor Cleaning Performed”.



- e. Correlation study is performed on every new lot of test strips or quality controls.
- f. Refer to the “Method Validation” procedure for more information.

10. PROCEDURES

a. Background.

- (1) Pre-requisites for testing: CoaguChek Tests may only be performed if:
 - (a) Testing personnel have been appropriately trained and, if necessary, have been appropriately trained and, if necessary, have undergone competency assessments at required intervals (part B, below).
 - (b) Quality control procedures appropriate for the test(s) to be performed have been followed and have produced acceptable results (part E, below).
 - (c) Appropriate blood specimens have been obtained (part C, below).

b. Qualifications, Training, and competency assessment.

- (1) Qualifications and training: Because the CoaguChek INR is a “waived” test, no specific personnel qualifications are defined other than documentation of training and periodic competency assessments.
- (2) Training is done by the Ancillary Testing Specialist (ATS) or Ancillary Testing Coordinator (ATC). Training must cover the essential elements of how to use the instrument as well as common testing errors. It concludes with a written exam. After an individual is trained, the ancillary testing staff will enter that individual’s identifying information into the online database. This database is then accessed by the instrument when any testing is performed, i.e. the user is identified when testing is performed.
- (3) Competency assessments are performed by the ATS or ATC 6 months after initial training, and annually thereafter. Competency assessments must include items selected from the six elements stipulated by accrediting agency.
- (4) Documentation of training and of competency assessment is maintained by the ATS or ATC.

c. General procedure.

- (1) Assemble the necessary materials for the instrument and for obtaining a blood specimen.
- (2) If a “code chip” is inserted into the instrument, compare the number on the code chip matches the number on the test strip container. If it does not match with the test strip to be used, the instrument is designed to not allow testing.



- (3) If the correct code chip is not in the instrument, remove the code chip form the container of test strips to be used and insert it into the instrument.
- (4) Obtain proper patient identification by using the two forms of full patient identification per facility policy.
- (5) Place meter on a flat surface, free of vibrations. Or hold it in your hand so the meter is roughly horizontal. Do not move the meter during testing.
- (6) Take a test strip out of the container. Close the container tightly.
- (7) Hold the test strip so the lettering “CoaguChek XS PT” is facing upward.
- (8) Slide the test strip into the test strip guide in the direction indicated by the arrows.
- (9) Slide the test strip into the test strip guide in the direction indicated by the arrows.
- (10) Slide the test strip in as far as it will go. This turns the meter ON. A beep tone indicates that the meter has detected the test strip (provided the beeper is turned on in the settings).
- (11) Check the battery level. If there are no bars left in the battery symbol, you cannot perform any more tests without changing the batteries.
- (12) Enter your operator ID.
- (13) Touch [OK] to log on and move to the main menu.
- (14) Touch Patient Test or Quality Control.
- (15) Select or enter Patient ID or quality control level.
- (16) Touch [OK]. An hourglass symbol indicates the test is warming up.
- (17) Confirm that the code number displayed on the meter matches the number on the test strip container. If the numbers are different, make sure you are using the code chip that came with the test strips you are using (see above).
- (18) The blood drop symbol flashes to indicate that the meter is ready to perform the test and is waiting for sample to be applied. The 180-second count down begins.
- (19) Identify the sample target area on the test strip.
- (20) Collect the fingerstick blood samples as outlined below.
 - (a) Have the patient let the arm hand down by his/her side before lancing a finger. Prepare the patient’s finger by massaging the finger from its base. Clean the selected finger with alcohol wipe and allow to air dry completely. Puncture the



finger and immediately massage along the side of the finger to obtain a good drop of blood without pressing or squeezing too hard.

- (b) Do NOT wipe away the first drop of blood. Apply the first drop of blood to the top or side of the target area within 15 seconds of puncture. Hold the blood drop to the test strip until you hear a beep (provided the beeper is set to ON).
- (c) Apply the blood directly to the semicircular, transparent sample application area of the test strip.
- (d) You hear a beep tone when you have applied enough blood (provider the beeper is turned on). The blood drop symbol disappears, and the test starts. NOTE: DO NOT add more sample. DO NOT touch the test strip or move the meter until the result is displayed.
- (e) The meter automatically performs a two-level, on-board quality control test on the test strip before it displays the test result. "QC" appears in the display.
- (f) Following a successful outcome of the quality control test, a check mark appears after "QC".
- (g) You must WAIT for results- this takes about one minute. The result is displayed in the unit of measure you chose when setting up the meter. It is automatically saved to memory.
- (h) After the test results are displayed, a strip and arrow symbols appear on the screen, prompting you to remove the strip.
- (i) Remove the test strip from the measurement chamber.
- (j) Turn meter OFF.
- (k) Dispose of all biohazardous material in the appropriate designated biohazard or sharps container.

d. **Interferences.** An interferent is a substance which, if present at significant levels in the blood specimen being analyzed, will produce an error in the result of the analyte being measured. Refer to the table below for known and suspected interferents for this test.

Table 1

Interferant	Effect on INR
Direct Thrombin inhibitors (such as dabigatran or hirudin)	Increases INR
Factor X Inhibitors (such as	



apixoban or rivaroxaban)	Increased INR
Low/High Hematocrit	Low/High INR
Glass syringe	Increased INR
Lupus Anticoagulants	Increased INR
Daptomycin (cubucin)	Increased INR
Chlorhexidine gluconate	Increased INR
Anticoagulant found in Blood collection tubes (citrate, heparin, EDTA, oxalate)	Increased INR

11. ENTRY OF RESULTS

- a. CoaguChek results are displayed on the unit and are then automatically entered into the patient’s medical record when the unit is placed in the downloader. Below is guidance on the normal range, what range of abnormal results constitute critical values, and what interfering substances (chiefly medications) might generate an abnormal result.
- b. Reference Range & Reportable Range: the range of test values expected from 95% of fasting individuals presumed to be healthy is an INR of 0.9 to 1.2 units. Report range (the range of test values throughout which the measurement system’s results have been shown to be valid) is 0.8 to 8.0 units.
- c. **Critical Results:** Critical results are those that fall above a defined value such that they pose an immediate risk to the patient. These results will be automatically flagged as critical on the instrument’s display. Per hospital policy, these results must be reported to the patient’s health care provider within 30 minutes. The results must be reported to the patient’s health care provider within 30 minutes. These results reported, and the time at which they were communicated to the provider, must subsequently be documented in the patient’s medical record using the critical value template.

(1) The current critical result threshold for the CoaguChek INR is **5.5**.

d. INR Non-threatening Alert

- (1) In accordance with VHA Directive 1108.16 Anticoagulation Therapy Management, P&LMS will identify the non-life-threatening international normalized ratio (INR) value of **4.5 or greater** as a value requiring notification to the provider.
- (2) Nursing and Medical staff performing INR tests utilizing point of care meters will send samples to the main lab for confirmation of result. Orders will be placed for either ward or routine collection and the appropriate staff will collect and transport to the lab for confirmatory testing.



- (3) Medical Technologists competent in coagulation studies will provide notification to the ordering provider via phone for PT/INR results **4.5 or greater**. Note: PT/INR values in the range of **4.5 to 5.49** are considered non-life-threatening and may be batched if necessary.
- (4) The following comment will be used in VISTA to indicate Alert value: AC (Alert value called to and was read back by:) by medical technologist after confirmation of result.
- (5) If workload demands, inability to reach an ordering provider, or limited staffing situations affect ability of medical technologist(s) to provide notification. Management recommends that the send-out specialist be utilized to provide next day notification.
- (6) PT/INR values **greater than or equal to 5.5** are considered (potentially life threatening) critical values. Immediate notification is required. Batching in these cases is not permissible.
- (7) Lab supervisors will review a daily report to ensure notification and documentation of non-life-threatening PT/INR values of 4.5-5.49

12. NOTIFICATION

- a. The provider will be notified if the CoaguChek INR is 4.5 after verification by the operator.
- b. The nurse must document reporting of critical values in CPRS using the Critical Lab Value Template.

13. REFERENCES

- a. VHA Directive 1106.01, Pathology and Laboratory Medicine Service (P&LMS) Procedures, January 29, 2016, http://vaww.lab.med.va.gov/References_Directives_and_Regulations_P.asp
- b. VHA Directive 1108.16, Anticoagulation Therapy Management, January 29,2021
- c. Rivera Z, Finch Cruz CN (2017). Method Validation Program POC 12 113
- d. P&LMS SOP QA 37 113
- e. Guyatt et al (2012). Chest 141:7S-47S
- f. Heneghan et al(2012). Lancet 379:292-293
- g. Heneghan C, Alonso-Coello P, Garcia-Alamino JM, Perera R, Meats E, Glasziou P. Slef-monitoring of oral anticoagulation: a systematic review and meta-analysis. Lancet 2006; 367:404-411



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14. APPENDICES

None

15. REVIEW

This SOP will be reviewed at least every 2 years, when there are changes to the government document that need to be made and any regulatory requirement for frequent review.

16. RECERTIFICATION

This SOP is scheduled for recertification on or before the last working day of February 2026. In the event of contradiction with national policy, the national policy supersedes and controls.

17. SIGNATORY AUTHORITY

Dr. Eugene Pearlman
Pathology and Laboratory Medicine Service, Chief

NOTE: *The signature remains valid until rescinded by an appropriate administrative action.*

DISTRIBUTION: This SOP is available in Media Lab at:

https://www.medialab.com/lms/admin/ad_tab_doc_frameset.aspx?oid=46207142&o=7a58da35c5a10f062a5552272e5afcc4