

Director Approval \_\_\_\_\_ Date \_\_\_\_\_

<b>UCSF</b> Medical Center <b>Clinical Laboratories</b>	<b>Point of Care Testing</b>
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## CoaguChek S Prothrombin Time INR

### I. PURPOSE

Patients on the anticoagulant warfarin are monitored with the blood test Prothrombin Time to ensure that their anticoagulant level is maintained within the appropriate therapeutic range. The CoaguChek S monitor is a Point-of-Care instrument that measures Prothrombin Time. The monitor requires only a drop of blood from a fingerstick to produce a result in 1 minute. This allows the clinician to adjust the dosage if necessary during the same patient visit.

### II. PRINCIPLE

The CoaguChek S system consists of the portable Prothrombin Time monitor, disposable test strips containing prothrombin time reagents, a two level daily electronic control cartridge, aqueous controls, and a code chip. A drop of blood from a fingerstick is applied to a test strip inserted into the monitor. The blood travels via capillary action to the reaction chamber where it is mixed with thromboplastin that contains iron particles. The monitor starts the timer and the oscillating magnetic field causing the iron particles in the reagent to move back and forth. When blood begins to clot, the iron particles stop moving and the monitor stops the timer. CoaguChek S displays Prothrombin Time in seconds and calculates the INR.

### III. EQUIPMENT AND REAGENTS

#### A. COAGUCHEK S MONITOR

Monitor measures 6.8 x 4.9 x 1.75 inches and weighs 1.0 lbs.

An onboard computer stores 60 patient or QC test results. Results are identified by only date and time. The CoaguChek does not have the ability to store patient ID's.

Monitor:

- Front:
1. Display screen
  2. On / Off Button
  3. Mem Button
  4. Test Strip Guide
  5. Door

Back:

1. Set Button
2. A/C Power Port
3. Data Port
4. Code Chip Slot

Bottom:

1. Battery Compartment
2. Battery Door Release
3. Code Chip Slot

CoaguChek S Operating Conditions:

1. Roche recommends an ambient temperature of 18 to 32 °C (65 to 90 °F). If the room temperature is outside of these limits, allow the monitor to equilibrate to the recommended temperature before using.
2. Relative humidity of 10 to 85% (without condensation).
3. Monitor should be placed on a flat surface free from vibrations.
4. Perform testing only under artificial or indirect sunlight. Bright direct sunlight interferes with the testing process.

B. TEST STRIP KIT

1. Test strips in foil pouches
2. Code Chip
3. Package insert

C. TEST STRIP

1. Printed surface with round clear target area and directional arrows.
2. CoaguChek S test strip contains rabbit thromboplastin, stabilizer, preservatives, and iron particles.
3. Roche calibrates each lot of strips to a reference reagent and programs the information into a Code Chip included with each box of 48 individually sealed foil pouches. Insert a new Code Chip into the monitor each time a new box of strips is opened. The three numbers on the Code Chip must match the last three numbers on the pouch of the test strip.
4. The operator is required to test two levels of liquid controls before using a new box of test strips for patient care.
5. Test strip must be used within 4 minutes of opening the sealed pouch.
6. Storage:
  - a. Store in the refrigerator at 2 to 8 °C until the expiration date. Equilibrate a refrigerated test strip at room temperature for five minutes or a box for 30 minutes before using.

- b. Test strips may be stored at room temperature 18 to 32 °C for 60 days. Mark the box with the date when removed from refrigeration. All expired test strips must be discarded.

#### D. POWER

1. CoaguChek S is powered by four 1.5V AA alkaline batteries that provide sufficient power for 60 Prothrombin Time tests. The batteries also maintain CoaguChek S memory and all four must be replaced as soon as the monitor displays the low battery message. Under “low battery” conditions, the clinician cannot perform a test but can access the monitor’s memory.
2. The AC adapter must be used in conjunction with the four AA batteries.
3. The monitor saves power by automatically turning off after 3 minutes if no button is pressed or no test strip is inserted.
4. Battery icon is divided into five segments, which correspond to the level of the battery power.

#### E. CONTROLS

There are two types of controls, the Electronic Quality Control (EQC) and the liquid quality controls. Both have assigned quality control values that represent acceptable performance. EQC monitors CoaguChek S performance whereas the liquid controls test the integrity of the Prothrombin Time testing process, user’s technique, as well as the performance of the monitor and strips together.

##### 1. ELECTRONIC QUALITY CONTROL (EQC)

Electronic QC cartridge  
EQC Code Chip  
Carrying Case

- a. EQC kit includes a carrying case, EQC code chips, user’s manual and the EQC device.
- b. The code chip provides specific information about the EQC device. Insert the EQC code chip into the CoaguChek S with each new EQC device with the monitor off. The EQC code chip must be also reinserted if the CoaguChek S loses power for more than 10 minutes. Store the code chip in the original storage case at room temperature.
- c. Test two levels of the Electronic Quality Control (EQC) daily to verify proper CoaguChek S performance.
- d. Press the appropriate button to test level 1 and level 2 controls. The CoaguChek S appends stored results with “C” and display shows control results followed by a “C”.
- e. The acceptable control range for each level is printed on top of the EQC device.
- f. Store the EQC device in its carrying case at room temperature and avoid exposure to moisture.
- g. EQC must be performed each day of patient testing.

## 2. LIQUID CONTROLS

- a. Liquid controls contain non-human plasma with varying coagulation levels, stabilizers and preservative.
- b. A glass capsule within the plastic control vial separates the control reagents into compartments. To mix the reagents, break the glass separator by squeezing the lower half of the vial. Protect self from injury by wrapping vial in gauze before squeezing.
- c. Each box of controls contains 4 vials of level 1 and 4 vials of level 2 controls.
- d. Acceptance range for each control level is listed on the package insert.
- e. Storage conditions:
  1. Store controls at 2 to 8 °C until the listed expiration date. Controls must equilibrate at room temperature for 30 minutes before testing.
  2. Controls may also be stored at room temperature for 30 days. Mark the control and / or box with the new 30-day expiration date if removed from refrigeration.
- h. Two levels of liquid controls must be performed weekly, and when a new box of test strips is opened.

F. Bulb and plastic capillary tubes for collecting and dispensing blood samples.

G. Safety lancets for finger stick

H. Alcohol Swabs.

I. Refrigerator

J. Sharps container

K. Gauze

L. QC log sheets

M. Patient Test Log Sheet

M. Gloves

N. Band-aids

O. Towelettes

P. Thermometer

## IV. SPECIMENS

### A. ACCEPTABLE SPECIMENS

1. Fresh whole blood sample from a fingerstick. Collect only the **first** hanging drop of blood in a plastic capillary tube.
2. Fresh venous blood sample collected with a plastic syringe without an anticoagulant.
3. Minimal volume: greater than 10 uL of blood.

### B. UNACCEPTABLE SPECIMENS

1. Plasma or serum.
2. Venous sample collected in a syringe containing an anticoagulant.
3. Sample collected in a glass syringe or glass capillary tube.
4. The second drop of blood from a fingerstick. If you did not collect at least 10 uL of blood, you must repeat the fingerstick with new equipment. Do not test with the second drop of blood.
5. Blood from a finger still damp with alcohol.

6. Air bubbles in the capillary collection tube.
7. Patients on heparin therapy.

## V. QUALITY CONTROL

### A. POLICY

The CoaguChek system is classified by CLIA as a waived instrument provided that the following conditions are met:

1. Daily: Run 2 levels of EQC controls on the CoaguChek S monitor. The results must be within stated ranges before the user may use the monitor to test patients.
2. Weekly: Run 2 levels of Liquid controls weekly. The results must be within stated ranges before the user may use the monitor to test patients.
3. In addition, each time a new box of test strips is opened, you must test 2 levels of liquid controls. The results must be within the manufacturer's acceptance range before you may use it to test patients. If you do not have sufficient controls to test the new box, you may not use the instrument to test patients.
4. Document the following in the QC log: Date of test, CoaguChek S number, QC lot number and expiration date, QC acceptance range (both electronic and liquid), test strip lot number and expiration date, QC result and initials of operator.

### B. ELECTRONIC QUALITY CONTROL

1. Turn the monitor on by pressing the button with the switch symbol. The display shows either "EC" or test strip code number presently in the monitor.
2. The display prompts the user through all the steps.

PROMPT	ACTION
Test strip icon flashes	Insert EQC device and push in.
Test strip icon stops flashing; clock icon appears and then flashing blood drop icon appears	Press level 1 button on EQC device before the counter reaches zero.

3. Do not touch or move the device while testing. Result appears in 30 seconds.
4. Compare result with range printed on the EQC device.
5. Repeat above procedure for level 2 control.
6. If the monitor is dropped or mishandled, user must always test two levels of EQC before using it for patient care. Document in the EQC control log.
7. When testing is completed, turn the monitor OFF.
8. Corrective action for out of range or error messages:
  - a. Repeat EQC test.
  - b. If the repeat gives error message or is out of range, run 2 levels of liquid quality controls to assess the CoaguChek S performance.
  - c. If liquid QC are outside of the acceptable range, do not use the instrument.
  - d. Call the Roche Technical Services at 1-800-428-4674.

### C LIQUID CONTROLS

1. Remove test strips and controls from refrigerator and allow controls and test strips to come to room temperature (strips: for individual strip wait 5 minutes, for the entire box wait 30 minutes, for controls wait 30 minutes).
2. Insure that the test strip code matches the monitor's code.

3. Remove the seal from the control vial.
4. Tap vial to settle glass capsule to the bottom.
5. Wrap vial in gauze before squeezing the lower half of vial hard enough to break the glass capsule inside. Do not bend the vial. Control must be used within 4 minutes.
6. Start a timer for two and a half minutes.
7. Immediately tap the vial hard on the table ten times.
8. Allow the vial to sit undisturbed for the remainder of the two and a half minutes.
9. At the end of the two and a half minutes, turn the monitor on.
10. When the test strip icon flashes, open the test strip pouch and remove the strip. Test strip must be used within 4 minutes.
11. Insert test strip with the printed side up. Push it in until it stops; this action causes the strip icon to stop flashing and a clock icon appears and flashes.
12. Once the blood drop icon appears and flashes, turn the control vial upside down and shake hard to force the contents into the dropper end.
13. Squeeze the vial and discard the first drop of control into the cap.
14. Apply the second drop to the sample application area of the test strip, which is highlighted from below by a flashing yellow light. The monitor beeps as it detects the drop. Completely cover the sample area with control.
15. Do not disturb the strip during testing.
16. Result appears followed by a "C" to indicate control.
17. Compare displayed result with listed acceptable limits. If results are within range, the system is working properly. Discard strip.
18. Document results on the QC log.
19. Repeat procedure for Level 2 control.
20. Corrective action for out of range result.
  - a. Review the following before repeating the control: control and test strip lot numbers and expiration dates, and the acceptance range from the package insert.
  - b. If control fails again, do not use that box of test strips. Mark "Do Not Use" on the box. Document on the QC Log.
  - c. Warm another box of strips and controls. Repeat control procedure.

## **VI. PATIENT TESTING**

### **A. PATIENT PREPARATION**

1. Explain test and procedure to patient.
2. Verify patient's first name, last name, and date of birth.
3. Ask patient to wash hands in warm soapy water.
4. Ask patient to dry hands thoroughly.

### **B. PATIENT TEST**

1. Place CoaguChek S on a flat surface.
2. Turn monitor on and confirm code displayed matches code number of test strip.
3. Testing is ready when the test strip icon flashes on the display.
4. Open test strip foil pouch. Remove strip and gently insert the test strip in the direction of the arrows with the printed side facing up.
5. Clean finger with alcohol swab and allow to air dry.
6. Position the patient's hand so that the fingers are hanging down.

7. When the flashing drop of blood icon appears, use a safety lancet to prick the bottom side of the middle or ring finger away from the thumb.
8. CoaguChek S allows you 3 minutes to collect the first hanging drop of blood and apply it to the test strip.
9. Do not wipe the first drop of blood.
10. Gently massage the finger to form a large hanging drop.
11. Keep the capillary tube level and touch it to the hanging drop of blood.
12. Fill capillary tube at least half way. Avoid getting air bubbles into the capillary tube.
13. Place your finger over hole in the capillary bulb.
14. Hold capillary tube directly over yellow target on the test strip.
15. Push down gently on the bulb to expel the sample. Cover the yellow target completely with blood. When the blood drop is detected, the monitor beeps as testing begins.
16. During the testing process, do not disturb the monitor.
17. INR = X.X Result appears in one minute.
18. Record Patient Name, Med. Rec. #, INR, prothrombin time in seconds, time and date of test, monitor ID, and initials of the operator in the Patient Test Log.

## VII. REPORTABLE RANGE

- A. INR Range for Normals not on Coumadin therapy: 0.9 – 1.2.
- B. Reportable INR range: 0.6 – 8.0.
- C. An INR greater than 4.0 must be confirmed with a Prothrombin Time performed by the Clinical Laboratory.

## VIII. REPORTING RESULTS

- A. Document results on the Patient Test Log and on the patient's chart.
- B. At the end of each day, connect the CoaguChek S to the printer and print patient data.
- C. Verify INR results recorded on the Patient Test Log by comparing them with the CoaguChek S printout. Make corrections if necessary. File the printout. Report any discrepancies to the patient's MD and document this on the Patient Test Log.
- D. Send a copy of Patient Test Log for data entry into the Hospital electronic record
- E. Verify electronic record with the department Patient Test Log.
- F. Take corrective action if necessary.

## IX. MAINTENANCE

- A. Clean the monitor once a week or whenever it becomes contaminated with 10% bleach 70% isopropyl alcohol or pre-packaged bleach towelettes.
- B. Clean the strip guide with a cotton swab moistened with 10% bleach or 70% isopropyl alcohol.
  1. Lift the monitor door.
  2. Clean strip guide.
  3. Clean underside of the door.
  4. Allow to dry for 10 minutes.

5. Close the monitor door.

## **X. PROCEDURE NOTES**

### **A. RECALLING RESULTS**

1. Turn on Monitor.
2. Wait for flashing test strip icon to appear.
3. Press MEM button.
4. Memory stores up to 60 tests.
5. The most recent result will appear with date and time of test. A "C" identifies each control result. Use the MEM button to scroll through the monitor's memory.

### **B. EQC CODE CHIP PROCEDURE**

1. Turn off monitor. Flip over unit.
2. Hold the Code Chip with the code number facing up.
3. Insert Code Chip into the monitor.
4. Snap Code Chip into place.
5. Press ON to activate the monitor. CoaguChek will download EQC information and enter it into the monitor memory.
6. Follow the prompts displayed.
7. Insert the EQC when the flashing blood drop icon appears.
8. Remove the EQC cartridge when testing is completed. Press OFF to turn off the monitor.
9. Remove the EQC Code Chip and store in the carrying case.
10. Do not expose Code Chip to moisture or devices that produce magnetic fields.
11. If the batteries are not replaced when the low power message is displayed, you must reprogram the monitor following the above procedure.
12. Use this procedure for all new EQC cartridges.

### **C. INSERTION OF NEW CODE CHIP**

1. A new Code Chip is included with each Test Kit. Use the Code Chip only with tests using that kit.
2. The numbers on the Code Chip should match the last three numbers on the test strip pouches in each kit.
3. Turn off monitor before inserting a new Code Chip or removing an old one.
4. Remove old Code Chip and discard.
5. Insert new Code Chip with the label up.
6. Push until it snaps in place.
7. Code Chip remains in the CoaguChek until the last strip in the box is used.

## D. ERROR MESSAGES

These messages represent possible errors that may occur.

1. The display reads: ERROR CODE, word “code” flashes means a corrupt or incorrect code chip is in monitor or not readable. Action: Turn monitor off. Then, insert a new / correct code chip into monitor. Turn monitor back on.
2. The display reads ERROR CODE and contains test strip icon, word “code” flashes means Test Strip Code Chip does not match the strip in the monitor. Action: Turn monitor off. Then, insert correct Test Strip Code Chip. Turn monitor back on.
3. Display reads CODE, word “code” flashes means code chip is missing. Action: Turn monitor off. Then insert a Code Chip. Turn monitor back on.
4. Display reads ERROR and displays test strip icon, which is flashing. Cause may be either Heparin interference, test was interrupted by strip motion or removal, the ON or MEM button was pushed during testing, the INR of sample is outside measuring range of system. Action: Recollect a sample that does not contain heparin. Repeat test with new strip and new fingerstick without moving strip; repeat test without pushing buttons, once testing has begun. Repeat test using new test strip and new fingerstick. Have lab sample drawn and processed.
5. Display reads ERROR, displays test strip icon and the “no” blood drop icon flashes means either insufficient sample was applied to strip, the Hematocrit of the blood sample is outside the acceptable range (high or low) or excessive strip movement. Action: Repeat the test with larger size sample (using new fingerstick and new test strip). Have lab sample drawn and processed. Repeat testing using either blood or control sample.

## XI. PRECAUTIONS

- A. The patient’s finger must be free of alcohol before incising the finger with the lancet.
- B. Milking the finger will result in a false reading due to dilution with tissue thromboplastin. Massage gently to increase blood flow.
- C. Use only the first hanging drop of blood.
- D. Always use the capillary tubes for collecting blood. To minimize cross contamination, do not have the patient touch the test strip to apply the sample.
- E. Do not test a sample that contains gas bubbles in the blood in the capillary tube.
- F. Do not use glass capillary tubes. Contact with glass will shorten Prothrombin Time.
- G. Standard precautions are observed for collection and testing of patient blood samples. Disposable gloves must be worn when collecting specimens, performing test procedures and cleaning test equipment. Hands must be thoroughly washed with soap and water after removing gloves.

## XII. LIMITATIONS

- A. The CoaguChek should not be used with patients having the following conditions:
  - a. Lupus anticoagulant
  - b. Triglyceride >500
  - c. Bilirubin >20
  - d. On heparin therapy within the last 24 hours.
  - e. Hematocrit < 30 or >52.
- B. Collect only the first drop of blood from a fingerstick. The second drop of blood may have begun the clotting process.

- C. Plasma and serum are not acceptable
- D. Venipuncture samples may be collected using only plastic syringes. Glass tubes or syringes may not be used.
- E. The minimum volume is 10 uL. Low sample volume will cause ERROR display.
- F. Do not attempt to add more blood to the test strip after testing has begun. Repeat test with a new fingerstick and equipment.
- G. If the patient is on intravenous infusion therapy, do not collect the sample from the same arm.
- H. The CoaguChek S monitor, test strips, and Code Chip operate on magnetic principles. It is important to keep these items away from magnetic materials and magnetic fields. Magnetic fields will erase the calibration information on the Code Chip.

### **XIII. REFERENCES**

CoaguChek S System User's Manual, Roche Diagnostics Corporation, 9115 Hague Road, Indianapolis, IN 46256 2002

CoaguChek S System Package Insert, Roche Diagnostics Corporation, 9115 Hague Road, Indianapolis, IN 46256 2002

CoaguChek S System Controls, Roche Diagnostics, 9115 Hague Road, Indianapolis, IN, 46246 2006

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