

OREGON HEALTH & SCIENCE UNIVERSITY  
Hospitals and Clinics  
Point of Care

**Whole Blood INR  
by CoaguChek XS Plus**

Principle

The INR is a screening test used to assess the activity of factors VII, X, V, II (prothrombin) and I (fibrinogen). The INR is performed by applying a drop of fresh whole blood directly to a test strip containing dried thromboplastin reagent and tiny iron particles. The sample, dried reagent, and iron particles move through alternating magnetic fields causing the iron particles to move. The endpoint is reached when a clot forms and stops the iron particles from moving. The analyzer then displays the PT results.

The INR (International Normalized Ratio) test is used primarily to monitor oral anticoagulant therapy. The lack of uniformity for the reporting of INR results along with variations in thromboplastin sensitivities, instrumentation, and methodologies have led to interlaboratory variations in patient's INR results.

In order to provide international standardization for reporting INR results, the World Health Organization (WHO) developed a protocol that compares all thromboplastins to the WHO reference thromboplastin. The WHO reference thromboplastin and standardized laboratory methods are used as the reference system to which all other INR reagents and methodologies are compared.

The ISI (International Sensitivity Index) is a number derived from comparison of the manufacturer's reagent to the WHO reference reagent. The ISI is then used by the laboratory or caregiver to calculate the INR. As a result, a patient on oral anticoagulant therapy could be accurately monitored anywhere in the world providing the INR is calculated and reported.

Specimen Requirements

1. Whole blood collected using the finger stick method.
2. The blood drop must be a minimum of 10  $\mu$ L in volume. Low sample volume will cause an error message.
3. Never perform a second INR test using the same finger stick.
4. The blood sample must be applied to the test strip within ten (10) minutes of removing the test strip from its container.
5. Additional blood sample CANNOT be added to the test strip once testing has begun.

6. USE THE FIRST DROP OF BLOOD collected by finger stick method. Apply the drop of blood directly from the finger to the test strip. You can also use the CoaguChek Capillary Tubes/Bulbs to collect blood from a finger stick and dose the strip.
7. Sample must be tested immediately after collection.

#### Limitations:

1. Test results may be affected by hematocrit values outside the range 25%-55%.
2. DO NOT use plasma or serum as a testing sample.
3. DO NOT collect blood in a vacutainer or syringe containing anticoagulant.
4. DO NOT use glass tubes or syringes.
5. DO NOT test clotted samples. If the sample clots before testing, recollect the sample.
6. Testing performed with the following samples indicated no significant effect on results:
  - Bilirubin up to 30 mg/dL
  - Lipemic samples containing up to 500 mg/dL of triglycerides
  - Hemolysis up to 1000 mg/dL
  - The results are unaffected by heparin concentrations up to 0.8 U/mL
  - The CoaguChek XS INR test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL
  - Clopidogrel up to 20 mg/dL
  - Fondaparinux up to 5 mg/L
7. The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies can potentially lead to elevated INR values. A comparison to an APA-insensitive laboratory method is recommended if the presence of APAs is suspected.
8. In rare cases, patients with long clotting times (>8 INR) may receive an "ERROR 7" message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

#### Linearity

1. 0.8-8.0

## Reference Range

<b>Normal Patient (INR)</b>	0.9 – 1.2
<b>Anticoagulant Therapy (INR)</b>	2.0– 3.0
<b>High Intensity Anticoagulant Therapy (patient's w/ mechanical valves) (INR)</b>	2.5– 3.5

## Action Values

Any result  $<0.8$  or  $>4.0$  that is not consistent with patient status must be reported immediately to the provider. It is recommended to collect a sample (from the opposite arm) in a citrate tube and send to Core Lab for confirmation. Do not bill for the POC test when a confirmation sample is sent to the Core Lab.

## Critical Values

Critical values are those results demonstrating such variance from normal as to represent a pathophysiological state with potential of being life threatening unless action is taken quickly. These results must be immediately reported to the care provider following current nursing policies and procedures. This notification must be documented in the test record.

1.  $INR \geq 5.1$  must be reported to the care provider immediately.

## Quality Control (QC)

1. The CoaguChek XS Plus system performs a self-check of the electronic components and functions every time the meter is turned on.
2. Run CoaguChek Liquid Controls, Level 1 and Level 2:
  - a. **Once per week.**
  - b. When a box of test strips with a new lot number is opened.
  - c. If improper storage or handling of the test strips is suspected.
  - d. If patient's INR result demonstrates a trend or is an unexpected result.
  - e. If the monitor is dropped or mishandled.
3. The CoaguChek XS Plus system automatically performs a two (2) level, on-board Quality Control test on the test strip before it displays the test result.

## Liquid QC Procedure

1. Allow test strips to sit at room temperature for 30 minutes before performing test.
2. Place the analyzer on a flat surface, free of vibrations. **Verify that the Quality Control Code Chip is in place.** This tells the machine the acceptable ranges of the QC.
3. Turn the monitor ON. **Make sure the code number on the display matches the code number on the test strip pouch.** If not, turn the monitor OFF and insert the correct Code Chip. Turn the monitor ON.
4. Make up controls:
  - a. Remove the screw-cap and rubber stopper from the quality control bottle.
  - b. Using scissors, cut off the tip of the dropper at the end of the stem. **To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.**
  - c. Invert the dropper and place the tip into the bottle.
  - d. Gently squeeze the bulb to dispense all of the contents of the dropper over the dried material. Do not allow the dropper to touch the dried material.
  - e. Remove the dropper from the bottle. **DO NOT** discard the dropper. Replace the cap first and gently swirl the bottle to dissolve the quality control. Do not shake or invert the quality control. Make sure that all control material is completely dissolved before you test it.
  - f. Use the reconstituted quality control within **30 minutes** from the time the diluent is added.
5. Remove one test strip from the container and immediately close the container. Use the test strip within **10 minutes** after removing it from container.
6. Hold the test strip so the lettering "CoaguChek XS INR" is facing upward.
7. Slide the test strip into the test strip guide in the direction indicated by the arrow. Slide the strip as far as you can into the meter. A beep tone indicates that the meter has detected a test strip.
8. Touch QC TEST
9. Select the code already stored for your current control solution. When you 1<sup>st</sup> run your control, the QC TEST screen will not display. The screen will display the next time you use the control.
10. Select level (L1 or L2) of control being run

11. The hourglass symbol shows that the test strip is warming up.
12. The dropper symbol flashes to indicate that the meter is ready to perform the test and is waiting for the control solution to be applied. A 120 second countdown begins. **YOU MUST APPLY THE CONTROL SAMPLE WITHIN THIS TIME.**
13. When the meter is ready for the sample, gently swirl the control bottle once to mix the solution. **DO NOT** mix the solution with the dropper.
14. Draw control solution into the dropper and put one drop of the liquid on the top of the target area. **DO NOT** add more control. **DO NOT** touch test strip while the test is in progress.
15. The flashing dropper symbol changes to an hourglass symbol when the meter detects a sufficient sample. A beep tone indicates that you have applied enough control solution. The dropper symbol disappears and the test starts.
16. The result and acceptable range will appear in one (1) minute. The result will be saved to memory.
17. If the quality control test fails, an up arrow (too high) or down arrow (too low) flashes on the display. Repeat test with a new test strip.
18. Remove the quality control code chip and store it with the opened box of controls.
19. Turn the meter OFF.

### Patient Testing Procedure

1. Allow test strips to sit at room temperature 30 minutes before testing.
2. Turn meter on.
3. Place the analyzer on a flat surface, free of vibrations. **Do not** move the monitor during testing.
4. Take a test strip out of the container. Close the container tightly.
5. Hold the test strip so the lettering "CoaguChek XS INR" is facing upward.
6. Slide the test strip into the test strip guide in the direction indicated by the arrows. Slide it in as far as it will go. A beep tone indicates that the meter has detected the test strip.
7. Enter your operator ID

8. Touch √ (OK) to log on and move to the main menu.
9. Touch 'PATIENT TEST'.
10. Enter patient ID
11. Touch √ (OK). An hourglass symbol indicates the test is warming up.
12. Confirm that the code number displayed on the meter matches the number on the test strip container.
13. The blood drop symbol flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied. The 120-second countdown begins.  
**DO NOT obtain sample until the flashing drop of blood appears on the display.** Strip must be used within **ten (10) minutes** of removing it from the container.
14. Identify the sample target area on the test strip and collect the finger stick or venous blood sample, applying it directly to the semicircular, transparent sample application area of the test strip.

**Finger stick:** Use the **1<sup>st</sup> drop of blood**. Apply it to the target area within **15 seconds of lancing the fingertip**. If you must repeat the test, use new finger stick from the opposite hand a new test strip. **Do Not** add more blood to the **1<sup>st</sup>** test strip.

**Capillary Tube:** Touch the capillary tube to the first blood drop. Keep tube level and allow it to fill halfway by capillary action. Put finger over hole in the capillary bulb. Hold capillary tube directly over the sample target area and expel sample within **15 seconds of lancing the fingertip**.

You will hear a beep tone when you have applied enough blood. The blood drop symbol disappears and the test starts. **DO NOT** add more sample. **DO NOT** touch the strip until the results are displayed.

15. Following the automatic quality control test on the test strip, a √ (check mark) appears after "QC".
16. Results will appear in about one (1) minute and are saved in memory.
17. Read and record results.
18. After the test results are displayed, a strip and arrow symbol appears on the screen, prompting you to remove the strip.
19. Remove test strip and turn the meter OFF.

20. After use or prior to the next patient, clean the outside of the meter.
  - a. Gloves are to be changed and hand hygiene performed between patients.
  - b. Clean meter surface when visible blood or bloody fluids are present by wiping with a disposable disinfectant wipe (e.g. PDI Sani-Cloth AF or PDI Sani-Cloth HB) to remove any visible organic material. Cleaning should be followed by disinfection (see #3).
  - c. When no visible organic material is present, after each use disinfect the exterior surface following manufacturer's directions using a disposable bleach wipe (e.g. Clorox Germicidal Wipe or PDI Bleach Wipes).
  - d. Ensure that the device remains "wet" for the duration of the contact time listed on the label of the bleach wipe.
  - e. Alcohol should never be used because it can damage the light emitting diodes (LED) readout, causing "fogging" of the plastic screens.

### Calculation

1. The INR is a mathematical formula that compensates for variations in Thromboplastin reagents, therefore, automatically standardizing PT results.
2. The CoaguChek XS calculates the INR automatically on each patient or QC using the following formula:

$$\text{INR} = (\text{PT Ratio})^{\text{ISI}}$$

Where the:

$$\text{PT ratio} = \frac{\text{Patient PT in seconds}}{\text{Normal PT mean in seconds}}$$

ISI = International Sensitivity Index

INR = International Normalized Ratio

3. The ISI of the PT reagent used in the CoaguChek XS Plus System is 1.0.

### Results Reporting

1. Report the patient INR result in the patient's chart and/or enter results into Epic.
2. If patient result is displayed as >8.0 INR, the test result is higher than the measuring range of the system. Record result as >8.0 and collect a sample in a citrate tube and send it to the Core Laboratory for confirmation.

## Storage of Meter and Reagents

1. CoaguChek XS Plus Test Strips:
  - a. Test strips are stable at 2-30°C until the expiration date on the box.
  - b. Store test strips in their original sealed foil pouch until ready to use.
  - c. The test strip must be used within **10 minutes** after removing it from container.
2. CoaguChek XS Liquid Quality Control:
  - a. QC vials are stable at 2-8°C until the expiration date on the box.
  - b. Controls are stable for **30 minutes** after adding the diluents.
  - c. **DO NOT** freeze QC vials.
3. The meter should be operated at temperatures between 65°F and 90°F (18°C-32°C).
4. Use meter on a flat, level surface, free of vibrations, in artificial light or indirect sunlight.

## Meter Cleaning

Cleaning/ Disinfecting the Meter Housing (Outside of Meter) after every patient.

- a. **Use only 70% isopropyl alcohol or 10% Sodium hypochlorite (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours.)**
- b. Use a soft lint-free moistened cloth or cotton swab with to clean the meter whenever it looks dirty with one of the solutions mentioned above.
- c. Do not use sprays of any sort.
- d. Ensure that the blue meter test strip guide cover remains tightly closed while cleaning the housing.
- e. Let the disinfectant/cleaning solution sit for at least one minute.
- f. Make sure that no liquid enters the meter or accumulates near any opening.
- g. Wipe away residual moisture and fluids after cleaning the housing.
- h. Allow wiped areas to dry for at least 15 minutes before performing a test.

Cleaning/Disinfecting the Meter Test Strip Guide- recommended once per week.

1. **Use only 70% isopropyl alcohol to clean the strip guide.**
2. If the test strip guide has become soiled with blood, you must clean this area. Do not spray any solutions on the meter.
3. Wear disposable gloves when cleaning and performing preventive maintenance. With the meter turned OFF, open the cover of the test strip by pressing upwards from the front (using your thumbnail).
4. Hold the meter upright with the test strip guide facing down. This will help prevent fluid from entering the meter.
5. Ensure that the swab is only damp, not wet.

6. Wipe the test guide area. Clean the easily accessible white areas of the test strip guide with a lint-free cloth or moistened cotton-topped swab.
7. Let the cleaning solutions sit for at least one minute.
8. Wipe away any residual moisture and fluids.
9. Let the inside of the test strip guide air dry for at least 10 minutes before re-attaching the test strip guide cover and start testing again.

## References

1. CoaguChek S Policies and Procedures Manual. Roche Diagnostics, 2007.
2. Roche Urgent Medical Device Correction Update. Roche Diagnostics, 12/15/09.

Revised 3/16/12

Month/Year \_\_\_\_\_

# Oregon Health & Science University

Log Sheet for Weekly Liquid Quality Control  
Roche Precision XSPlus Meter Serial # \_\_\_\_\_

Date _____ Initials _____	
Liquid QC Lot # _____	Exp Date _____ Code Chip # _____
<b>Level 1</b>	<b>Level 2</b>
Test Strip Lot # _____	Test Strip Lot # _____
Exp Date _____	Exp Date _____
Strip Code # _____	Strip Code # _____
INR Results _____	INR Results _____
INR Reference Range _____	INR Reference Range _____
Date _____ Initials _____	
Liquid QC Lot # _____	Exp Date _____ Code Chip # _____
<b>Level 1</b>	<b>Level 2</b>
Test Strip Lot # _____	Test Strip Lot # _____
Exp Date _____	Exp Date _____
Strip Code # _____	Strip Code # _____
INR Results _____	INR Results _____
INR Reference Range _____	INR Reference Range _____
Date _____ Initials _____	
Liquid QC Lot # _____	Exp Date _____ Code Chip # _____
<b>Level 1</b>	<b>Level 2</b>
Test Strip Lot # _____	Test Strip Lot # _____
Exp Date _____	Exp Date _____
Strip Code # _____	Strip Code # _____
INR Results _____	INR Results _____
INR Reference Range _____	INR Reference Range _____
Date _____ Initials _____	
Liquid QC Lot # _____	Exp Date _____ Code Chip # _____
<b>Level 1</b>	<b>Level 2</b>
Test Strip Lot # _____	Test Strip Lot # _____
Exp Date _____	Exp Date _____
Strip Code # _____	Strip Code # _____
INR Results _____	INR Results _____
INR Reference Range _____	INR Reference Range _____
Date _____ Initials _____	
Liquid QC Lot # _____	Exp Date _____ Code Chip # _____
<b>Level 1</b>	<b>Level 2</b>
Test Strip Lot # _____	Test Strip Lot # _____
Exp Date _____	Exp Date _____
Strip Code # _____	Strip Code # _____
INR Results _____	INR Results _____
INR Reference Range _____	INR Reference Range _____