CoaguChek XS PT Test

Place the meter on a flat surface (like a table or countertops) and hold it roughly horizontal so that it will warm up during testing. Vibrations or other movement can result in an error message.

Step 1: Getting a good drop of blood

Increasing the blood flow in the finger will help you get a good drop of blood. To increase flow, try the following technique until you see that the finger tip has good color:
- Warm the hand by having the patient hold it under his or her arm, use a hand warmer, and/or wash the hand with warm water.
- Have the patient hold his or her arm down to the side, so that the hand is below the waist.
- Massage the finger from its base.

If needed, immediately after lanceting, gently squeeze the finger from its base to encourage blood flow.

Step 3: Performing the test

1. Wash the patient’s hands with warm, soap-free water or wipe the finger with alcohol, if allowed by the patient to dry completely before performing the fingerstick.
2. Take a test strip out of the container. Close the container tightly.
3. Insert the test strip firmly as far as you can. The meter powers ON.
4. Confirm that the number displayed matches the number on the test strip container, then press M if the numbers are different, make sure you are using the code chip that came with the test strips you are using.
5. An hourglass flashes as the meter warms the test strip, which takes up to 30 seconds.
6. When the test strip is warm, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 180 seconds to apply blood to the test strip.
7. Use the lancet to perform a fingerstick.
8. Apply 1 drop of blood to the top or side of the target area. You must apply blood to the test strip within 15 seconds of lancering the finger and within 30 seconds of applying blood drop to the target area, or the meter may produce an inaccurate result as the coagulatoin process will have begun.
9. Do not add more blood. Do not touch or remove the test strip when a test is in progress. The flash icon on the CoaguChek XS System screen is a blood drop changer symbol indicates the meter detects sufficient sample. If the meter’s beeper is turned on, a beep sounds as the test strip warms.
10. The result appears in about 1 minute. Record the result.
11. Properly dispose of the used lancet and test strip.
12. Power the meter OFF. If you need to repeat a test, use a new lancet, a new test strip, and a different finger.

Technical information

How the test works

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation by patient’s recombinant thromboplastin. In simple test, blood works with the chemicals in the test strip to produce a small electric current in the test strip that measures blood clotting time.

Contents of the test strip

The test strip contains reagent (human recombinant thromboplastin), as well as?.

Limitations of procedure

- The CoaguChek XS System should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
- The CoaguChek XS PT Test uses only fresh capillary or non-anticoagulated venous whole blood. Plasma or serum cannot be used.
- Use only plastic tubes without anticoagulants or additives. Glass tubes or syringes are not suitable.
- The blood drop must be a minimum of 8 µL in volume. Low sample volume will cause an error message.
- Never add more blood to the test strip after the test has begun or perform another test using the same fingerstick.
- When a patient is on an intravenous infusion therapy, do not obstacle sample from the arm receiving the infusion line.
- Hematocrit range between 25-55 % do not significantly affect test results.

- Testing performed with the following in vitro spiked samples or native blood samples is expected to yield a result with no significant effect on test results:
  - Bilirubin up to 30 mg/dL.
  - Lipemic samples containing up to 500 mg/dL of triglycerides
  - Hemolysis up to 1000 mg/dL.
  - Hematocrit up to 0.8 L/mL.
  - Low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.
  - Diclofenac up to 20 mg/mL.
  - Fondaparinux up to 5 mg/mL.

- Note: Samples of patients treated with protease cannot be used with this system.

- The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. If this is suspected, another INR method should be used.

- The meter display “ERROR 6” sporadically occurring “ERROR 6” is generally due to an activation of the system’s fail safe mechanisms that are designed to prevent the release of wrong measurement results. However, in rare cases, “ERROR 6” may be received by patients under clinical conditions leading to extremely high coagulation times > 10 min, < 0.1 s), et al., e.g., treatment with warfarin (vitamin K antagonists) in combination with antibiotics and other drugs (e.g., clopidogrel). The result must be checked immediately using another method.

- In rare cases, patients with long clotting times (> 8 min) may receive an “ERROR 6” message. This is only the case when the test is repeated, the result must be checked using another method.

- The results obtained cannot be used for the determination or the assessment of a therapy with factor II or factor X antagonists.

Expected results

The CoaguChek XS Meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in the International Normalized Ratio (INR). The INR is the most commonly used unit to express prothrombin time, mainly by healthcare professionals in Europe.

Each lot of test strips is calibrated to a reference lot that is traceable to the WHO International Reference Preparations. Normal INR levels vary from person to person. When the CoaguChek XS PT Test was performed using the CoaguChek XS Meter on 121 normal, healthy, volunteer-free individuals using venous and capillary samples, 97% of the INRs ranged from 0.9 to 1.1. For the purpose of preparing universal reference INR levels, the Mean Prothrombin Time (MPT) has been established as 12 seconds for healthy volunteers and the International Sensitivity Index (ISI) for the system has been established as 1.02.

The physician must determine the INR level depending on the reason for anticoagulant treatment and how each individual responds to treatment (based on Prothrombin Time). Each physician should establish expected value ranges for his/her patient population or individual patients.

Inferences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing different prothrombin time test methods. Experience comparing results obtained using CoaguChek XS System to those obtained using common clinical laboratory reagents shows that the CoaguChek XS System correlates well with those following clinical laboratory reagents from Dade Behring. Other clinical laboratory reagents may not consistently correlate with the CoaguChek XS System.

Unexpected results

If the meter displays an error message, refer to the Error Messages section of the CoaguChek XS System User Manual. If the meter displays an unusual test result (other than an error message), check the following items:
- Is the correct code chip in the meter? The 3-number code on the test strip container must match the 3-number code on the code chip.
- Is the meter set up with the correct date and time?
- Certain drugs may affect test results affecting warfarin pharmacology. The potential effect of a drug interaction with warfarin or the effect of underlying diseases (e.g., liver disease, congestive heart failure) must be considered when interpreting a result.

Also, changes in the patient’s diet can cause unusually low or high results. Any unusual result should be followed up with appropriate coagulation studies and inquiries to define the cause of the unusual result. If the result does not match the clinical symptoms, repeat the patient test to rule out procedural error.

Performance characteristics

Measuring range: The CoaguChek XS System has a reportable range of 0.8 to 8.0 INR.

Sensitivity: The CoaguChek XS PT Test is sensitive to various clotting factors as determined by in vitro tests. Single factor depleted plasma was combined with a normal plasma pool to produce a series of diluted plasma samples. These plasma samples were then tested using three representative lots of the

Expected validity performance

Accuracy: 710 venous samples were collected from 355 outpatients at three external sites. The INR of each sample was compared to the INR of a venous plasma sample measured on a Dade Sysmex 6000 Analyser using Dade Inrinn (ISI = 1.02). The patient clinical conditions included (number of patients) normal - non on warfarin (823), atrial fibrillation (174), valve replacement (35), other heart-related disorders (4), other clotting disorders (6), other (30).
Built-in controls and diagnostics
The CoaguChek XS System has quality control functions integrated into the meter and test strips, so you do not have to run quality control tests with liquid quality controls. The meter automatically runs its own quality control test as part of every blood test. For more information about the built-in quality control functions, see the CoaguChek XS System User Manual.

Additional information
The CoaguChek XS System User Manual contains more information. If you still have questions, call Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to FDA’s MedWatch Adverse Event Reporting program online (at www.fda.gov/MedWatch/report.htm), by phone 1-800-FDA-1088, or by returning the postage-paid FDA form 3500 (which may be downloaded from www.fda.gov/MedWatch/forms.htm) by mail to MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787, or fax (1-800-FDA-0178).

Return policy
If there is a problem with the CoaguChek XS PT Test Strips, you may be asked to return them, along with the test strip code chip, to Roche Diagnostics. Before returning, call Roche Diagnostics Technical Service Center at 1-800-428-4674. You will be mailed a return authorization label which must be placed on the shipping carton.

References

Symbols
Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

SYSTEM

Analyzers/Instruments on which reagents can be used.

DIB

Global Trade Item Number

FOR US CUSTOMERS ONLY: LIMITED WARRANTY
Roche Diagnostics warrants that this product will meet the specifications stated in the labeling when used in accordance with such labeling and will be free from defects in material and workmanship until the expiration date printed on the label. THIS LIMITED WARRANTY IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE FOR INCIDENTAL, INDIRECT, SPECIAL OR CONSEQUENTIAL DAMAGES.